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AGENDA

State Health Affairs Committee Retained Counsel Meeting

Omni Nashville
250 5th Ave S, Nashville, TN 37203

AGENDA

Wednesday, October 24

12:00-12:45 PM	**Networking Lunch** Legends Ballroom E
12:50-1:00 PM	**Welcome and Opening Remarks** Legends Ballroom F/G Lauren Rowley, PCMA
1:00-1:45 PM	**Formulary Management** Chris Stewart, Humana
1:45-2:30 PM	**Disclosure & Transparency** Pat Twohy, Prime Therapeutics
2:30-3:15 PM	**MAC** Kim Robinson, Cigna
3:15-3:30 PM	**Break**
3:30-5:00 PM	**PCMA Counsel Roundtable Discussion** Legends Ballroom F/G
5:00-5:15 PM	**Break for Cocktail Reception and Dinner**
5:30-6:00 PM	**Shuttle to Cocktail Reception**
6:00-7:00 PM	**Cocktail Reception** 424 Church Street, Suite 2700 Nashville, TN
7:00-9:00 PM	**Dinner-Hermitage Hotel** 231 6th Ave N, Nashville, TN
9:30 PM	**Shuttle Back to Omni Hotel**

State Health Affairs Committee and Retained Counsel Meeting

Omni Nashville
250 5th Ave S, Nashville, TN 37203

AGENDA

Thursday, October 25

7:00-8:50 AM	**Breakfast Available-**Legends Ballroom E
8:50-9:00 AM	**Opening Remarks-**Legends Ballroom F/G **Antitrust Statement** Lauren Rowley, PCMA Barbara Levy, PCMA
9:00-10:00 AM	**AR SB2/HB1010 Discussion** Melodie Shrader, PCMA Robbie Wills, PCMA Retained Counsel (AR)
10:00-10:20 AM	**NAIC Update and Discussion** Scott Woods, PCMA
10:20-10:35 AM	**Break**
10:35-11:00 AM	**Legal Update** Barbara Levy, PCMA
11:00-12:00 PM	**Federal Affairs Update** Kristin Bass, PCMA
12:00-1:00 PM	**Networking Lunch** Legends Ballroom E
1:00-2:00 PM	**Guided Discussion of 2018-2019 Issues** Legends Ballroom F/G • PSAO Model Legislation • Specialty Pharmacy Accreditation & Credentialing • Transparency & Disclosure • Opioids • Prior Authorization & Step Therapy • Co-Pay Accumulators
2:00-2:15 PM	**Break**
2:15-5:00 PM	**Continue Guided Discussion of 2018-2019 Issues**
5:00-5:50 PM	**Break for Dinner**
6:00-10:00 P.M.	**Tour of Country Music Hall of Fame & Dinner** Connected to Omni Hotel.

State Health Affairs Committee

Omni Nashville
250 5th Ave S, Nashville, TN 37203

AGENDA

Friday, October 26

7:00-8:30 AM	**Breakfast Available** Mockingbird 1
8:30-12:00 PM	**Wharton School Negotiation Training** Cumberland 1/2 Professor Eric Max, University of Pennsylvania
12:00-1:00 PM	**Networking Lunch** Mockingbird 1
1:00-3:30 PM	**Continue Wharton School Negotiation Training** Cumberland1/2
3:30 PM	**Adjourn**

Meeting Attendees

2018 PCMA State Health Affairs Committee (SHAC) Meeting
Member Company Attendees

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2018 PCMA State Health Affairs Committee (SHAC) Meeting
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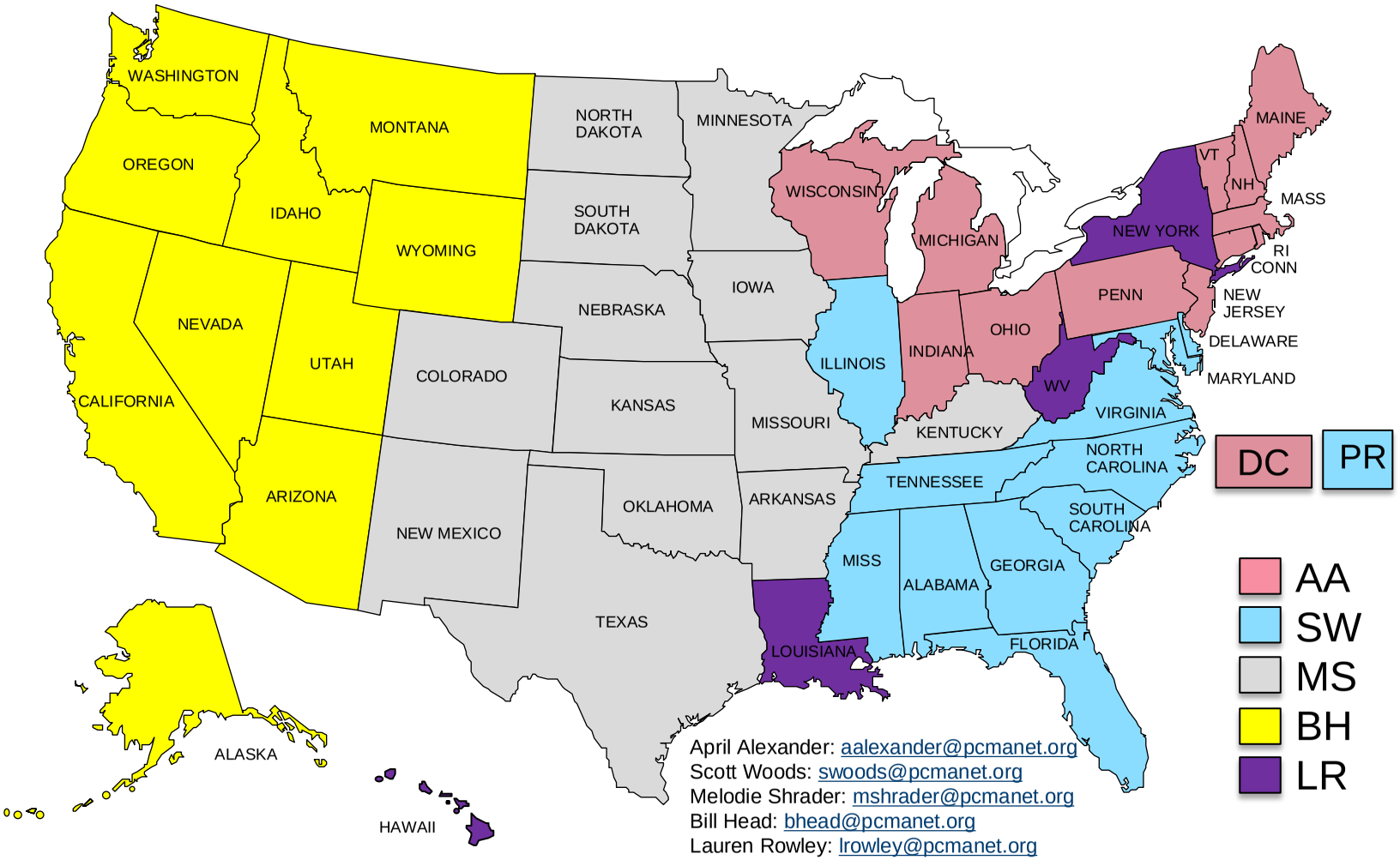
PCMA Staff & Retained Counsel Coverage

2018-2019 PCMA State Affairs Staff Coverage



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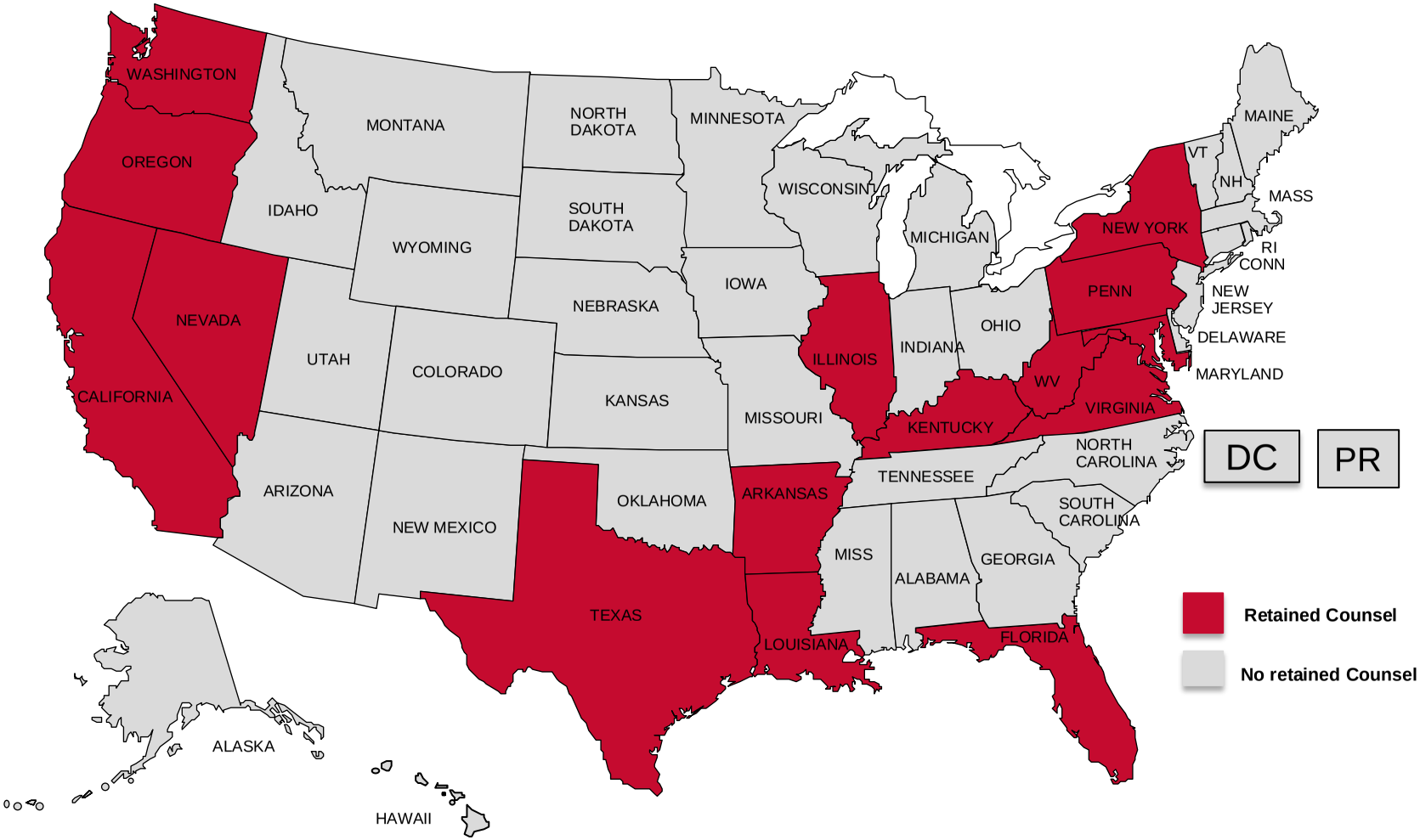
PCMA

2018-2019 PCMA Retained Counsel Map



2019 State Information

2019 STATE LEGISLATIVE SESSIONS

FiscalNote

State	Convenes	Adjourns	Carryover
Alabama	03/05/2019	06/17/2019	N
Alaska	01/15/2019	04/19/2019	N
Arizona*	01/07/2019	05/07/2019	N
Arkansas*	01/14/2019	04/26/2019	N
California*	01/02/2019	08/30/2019	N
Colorado*	01/09/2019	05/07/2019	N
Connecticut	01/09/2019	06/05/2019	N
Delaware	01/08/2019	06/30/2019	N
Florida*	01/07/2019	04/01/2019	N
Georgia*	01/07/2019	03/28/2019	N
Hawaii	01/16/2019	05/02/2019	N
Idaho*	01/07/2019	03/27/2019	N
Illinois*	01/09/2019	05/31/2019	N
Indiana	01/07/2019	04/29/2019	N
Iowa	01/14/2019	05/03/2019	N
Kansas*	01/14/2019	05/03/2019	N
Kentucky	01/08/2019	03/30/2019	N
Louisiana	04/08/2019	06/06/2019	N
Maine	12/5/2018	06/19/2019	N
Maryland	01/09/2019	04/08/2019	N
Massachusetts*	TBD	TBD	N
Michigan*	01/09/2019	TBD	N
Minnesota*	01/08/2019	05/20/2019	N
Mississippi	01/08/2019	04/07/2019	N
Missouri	01/03/2019	05/18/2019	N
Montana	01/07/2019	05/01/2019	N
Nebraska	01/09/2019	06/06/2019	N
Nevada	02/04/2019	06/03/2019	N
New Hampshire*	TBD	TBD	N
New Jersey*	01/08/2019	01/07/2020	Y
New Mexico	01/15/2019	03/16/2019	N
New York*	TBD	TBD	N
North Carolina*	01/30/2019	TBD	N
North Dakota	01/03/2019	04/26/2019	N
Ohio*	01/01/2019	12/31/2019	N
Oklahoma	02/04/2019	05/31/2019	N
Oregon	01/22/2019	06/30/2019	N
Pennsylvania*	01/01/2019	11/29/2019	N
Rhode Island*	01/01/2019	06/30/2019	N
South Carolina*	01/08/2019	05/09/2019	N
South Dakota*	01/08/2019	03/25/2019	N
Tennessee*	01/08/2019	04/26/2019	N
Texas	01/08/2019	05/27/2019	N
Utah	01/28/2019	03/14/2019	N
Vermont*	01/02/2019	05/11/2019	N
Virginia*	01/09/2019	03/09/2019	Y
Washington*	01/07/2019	03/07/2019	N
West Virginia*	01/09/2019	03/09/2019	N
Wisconsin*	01/15/2019	05/08/2019	N
Wyoming*	01/08/2019	03/14/2019	N
Wash D.C.*	01/02/2019	12/31/2019	N

*Indicates an estimated session date. All pre-file dates are currently TBD and will be updated as information becomes available.

STATE LEGISLATION EFFECTIVE DATES

FiscalNote

State	Effective Dates
Alabama	Enactment clauses specifying the effective date are included in each bill.
Alaska	Legislation becomes effective 90 days after enactment, including Saturdays and Sundays, unless specified otherwise within the bill.
Arizona	If the Governor signs the bill, the law takes effect immediately if it was emergency or Proposition 108 legislation; otherwise the law takes effect 90 days after the Legislature adjourns sine die. Proposition 108
Arkansas	Unless there is an emergency clause or an enactment clause that specifies otherwise, the legislation takes effect 90 days after sine die adjournment.
California	Most bills go into effect on the first day of January of the following year. Urgency measures take effect immediately after they are signed or after they are allowed to become law without signature. Special session bills without specific effective date clauses take effect 90 days after the adjournment of the special session.
Colorado	If a bill contains a safety clause (meaning the bill is not subject to the citizens' right to file a referendum petition against it), the bill takes effect on the date specified within it, or if no date is specified, then upon its passage (the date on which the Governor either approves the bill or allows it to become law without his signature). If a bill does not contain a safety clause, a special effective date clause explaining an alternative effective date will be added to the bill in lieu of the safety clause. Assuming that a referendum petition is not filed against a bill lacking a safety clause, the earliest the bill can take effect is the day after the expiration of the 90-day period following adjournment. If a referendum petition containing sufficient signatures is filed against a bill within the 90-day period, the bill cannot take effect until approved by the voters at an even-year statewide election.
Connecticut	The effective date is specified on the bill. Usually the date given is either July 1 or October 1.
Delaware	Bills take effect as soon as they are signed into law unless otherwise noted within an enactment clause in the bill.
District of Columbia	Most Council bills, with the exception of emergency legislation, contain clauses indicating that they take effect following approval by the Mayor, a 30-day period of Congressional review and publication in the District of Columbia Register.
Florida	Each law shall take effect on the 60th day after adjournment sine die of the session of the Legislature in which enacted or as otherwise provided within the bill.
Georgia	Legislation takes effect on July 1 unless otherwise specified within an enactment clause in the bill.
Guam	Effective dates are specified in the bill text.
Hawaii	Enactment clauses are included in each bill.
Idaho	In general, unless a bill contains an emergency clause or a clearly-indicated effective date, bills take effect 60 days following session adjournment (normally, July 1).
Illinois	If a bill has no express effective date, then the Effective Date of Laws Act, 5 ILCS 75/, supplies the date. If the bill passed prior to June 1, it takes effect the following January 1. If it passed after May 31, it takes effect June 1 of the following year. Bill passage is defined as when a bill has passed both chambers in the same form and will be sent to the governor.

State	Effective Dates
Indiana	A bill takes effect upon the date indicated at the beginning of the relevant statutory section referenced in the bill. This applies to special session bills and bills that have passed without the Governor's signature.
Iowa	Legislation becomes effective 90 days after enactment, including Saturdays and Sundays, unless specified otherwise within the bill.
Kansas	The vast majority of the time effective dates are at the end of a bill. If there is no effective date noted, however, a bill becomes effective "upon publication in the statute book." This is always July 1 of the year that the bill passed the Legislature. This rule applies to special session bills and bills that passed without the Governor's signature.
Kentucky	Effective dates are normally noted in the text of the bill. If it is not noted, however, then the bill becomes effective 90 days after the official end of the session. The official end of the session is determined by the Attorney General. The 90-day rule applies to bills that pass into law without the Governor's signature, as well as special sessions. For special sessions, a bill would become effective 90 days after the special session ends, as determined by the Attorney General.
Louisiana	If an effective date is not within the bill text, the bill will become effective on August 1 of the year that the bill passed the Legislature. This rule also applies to bills that pass into law without the Governor's signature. For special sessions, the bill would become effective 60 days after adjournment of the special session (assuming no specified effective date in the bill text).
Maine	Effective dates are normally noted in the bill, but for bills that do not have an effective date, the bill becomes effective 90 days after the session has ended. This rule also applies to special sessions and bills that pass into law without the Governor's signature.
Maryland	Bills will always have an effective date noted in the bill text. The only bills that will not have effective dates in the bill text are emergency bills. Emergency bills become effective on the day they are signed.
Massachusetts	The majority of bills will have effective dates within the bill text. If a bill does not have an specific effective date noted, then it will be effective 90 days after it was signed by the Governor. If a bill was not signed by the Governor, then it will become effective 90 days after the end of the session.
Michigan	Most bills will have an effective date noted in the text of the bill. If an effective date is not noted, however, and if the bill passed by a two-thirds vote, then the bill takes effect immediately. If the bill does not pass by a two-thirds vote, then the bill becomes effective 90 days after adjournment.
Minnesota	Most bills will have effective dates within the bill text. For bills that do not have effective dates noted in the text, the bills would become effective on August 1 of the year in which the bill passed the Legislature, except for appropriation bills. Appropriation bills become effective on
Mississippi	If a bill does not have an effective date within the bill text, then the bill becomes effective 60 days after passage. This includes bills passed during a special session and bills that have become effective without the Governor's signature.
Missouri	If a bill does not have an effective date within the bill text, then the bill will become effective on August 28 of the year with which it passed the Legislature. If the bill is an emergency bill, then it is effective immediately unless otherwise noted within the bill. For special sessions, if there is
Montana	If a bill does not have an effective date within the bill text, then the bill becomes effective on October 1 of the year that it passed the Legislature. For special sessions, bills become effective upon passage if an effective date is not within the bill text.

State	Effective Dates
Nebraska	Bills without emergency clauses or effective dates specified in bill text become law three calendar months after the legislative session ends (Article III, Sec, 27 Nebr. Const.). Bills with emergency clauses become law the day after they are signed by the Governor.
Nevada	Bills without effective dates specified in bill text become effective on October 1.
New Hampshire	Effective dates for all bills are specified in bill text.
New Jersey	Bills without effective dates specified in bill text become effective on July 4 of the year after they are approved.
New Mexico	Bills without effective dates specified in bill text or emergency clauses become effective 90 days after adjournment of the Legislature. Bills with emergency clauses become effective upon signing by the Governor.
New York	Effective dates for all bills are specified in bill text.
North Carolina	Bills without effective dates specified in bill text become effective 60 days after adjournment of the session in which they passed.
North Dakota	Bills without effective dates specified in bill text become effective on August 1, unless they are appropriations or tax bills, in which case they become effective on July 1. Tax bills include any enforced contribution for public purposes (e.g., this would include fees). Emergency measures become effective when they are filed with the Secretary of State's office, which is usually, but not always, the same day that the Governor signs the bill.
Ohio	Bills without effective dates specified in bill text become effective 90 days after signature by the Governor. If the Governor does not sign the bill, it becomes effective 90 days after the bill signing deadline passes.
Oklahoma	Bills without effective dates specified in bill text become effective 90 days after the session adjourns. Emergency measures become effective upon signing by the Governor.
Oregon	Except as otherwise provided in the Act, an Act of the Legislative Assembly takes effect on January 1 of the year after passage of the Act.
Pennsylvania	Effective dates for all bills are specified in bill text.
Puerto Rico	Effective dates are specified in the bill text.
Rhode Island	Effective dates for all bills are specified in bill text.
South Carolina	A law becomes effective 20 days after approval by the Governor, unless a date is specified. Usually it becomes effective upon approval by the Governor.
South Dakota	The state Constitution provides that no law can take effect sooner than 90 days following the legislative session. In addition, existing state law sets the effective date of bills passed during the regular session at July 1, unless the new law itself lists a later effective date. The exception to this is a law that contains an emergency clause
Tennessee	No law of a general nature shall take effect until 40 days after its passage unless the same or the caption thereof shall state that the public welfare requires that it should take effect sooner.

State	Effective Dates
Texas	No law passed by the Legislature, except the general appropriation act, shall take effect or go into force until 90 days after the adjournment of the session at which it was enacted, unless the Legislature shall, by a vote of two-thirds of all the members elected to each house, otherwise direct; said vote to be taken by yeas and nays, and entered upon the journals. The final vote is indicated on the signature page of an enacted bill.
U.S. Virgin Islands	Effective dates are specified in the bill text.
Utah	Enacted bills are effective 60 days following adjournment, unless otherwise specified in the bill.
Vermont	If a bill does not contain an enactment clause, it becomes effective on July 1 after the session has ended.
Virginia	Bills that become law at a regular session (or the reconvened session that follows) are effective July 1 following adjournment of the regular session, unless otherwise specified.
Washington	Laws go into effect 90 days after the adjournment of the session, unless specified otherwise.
West Virginia	No act of the Legislature shall take effect until the expiration of 90 days after its passage, unless the Legislature shall by a vote of two-thirds of the members elected to each house, taken by yeas and nays, otherwise direct.
Wisconsin	Unless otherwise specified, the date of enactment of a bill is one day after the date of publication.
Wyoming	Each bill contains an enactment clause that indicates when the law shall become effective.
US Congress	Effective dates are specified in the bill text.

All specified information accurate as of 10/8/18

2018 Legislation

LAWS OF ALASKA

2018

Source
CSHB 240(FIN)

Chapter No.
_____

AN ACT

Relating to prescription prices available to consumers; relating to penalties for certain pharmacy or pharmacist violations; relating to the registration and duties of pharmacy benefits managers; relating to procedures, guidelines, and enforcement mechanisms for pharmacy audits; relating to the cost of multi-source generic drugs and insurance reimbursement procedures; relating to the duties of the director of the division of insurance; and providing for an effective date.

_____

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

THE ACT FOLLOWS ON PAGE 1

AN ACT

Relating to prescription prices available to consumers; relating to penalties for certain pharmacy or pharmacist violations; relating to the registration and duties of pharmacy benefits managers; relating to procedures, guidelines, and enforcement mechanisms for pharmacy audits; relating to the cost of multi-source generic drugs and insurance reimbursement procedures; relating to the duties of the director of the division of insurance; and providing for an effective date.

*** Section 1.** AS 08.80.297 is amended by adding a new subsection to read:

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

*** Sec. 2.** AS 08.80.297 is amended by adding new subsections to read:

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;

(B) a governmental or employee welfare benefit plan under 29 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);

(C) a plan offered under AS 39.30.090 or 39.30.091;

(D) a federal governmental plan as defined under AS 21.54.500;

(E) the Medicaid or Medicare program; or

(F) a self-insured employer benefit plan;

(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

*** Sec. 3.** AS 08.80.460(a) is amended to read:

(a) **Except for a violation of AS 08.80.297, a** [A] person who violates a provision of this chapter is guilty of a class B misdemeanor.

*** Sec. 4.** AS 08.80.460(b) is amended to read:

(b) A person who violates the provisions of AS 08.80.295 **or 08.80.297 may be punished** [IS PUNISHABLE] by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

*** Sec. 5.** AS 21.27 is amended by adding new sections to read:

Article 10. Pharmacy Benefits Managers.

Sec. 21.27.901. Registration of pharmacy benefits managers; scope of business practice. (a) A person may not conduct business in the state as a pharmacy benefits manager unless the person is registered with the director as a third-party administrator under AS 21.27.630.

(b) A pharmacy benefits manager registered under AS 21.27.630 may

(1) contract with an insurer to administer or manage pharmacy benefits provided by an insurer for a covered person, including claims processing services for and audits of payments for prescription drugs and medical devices and supplies;

(2) contract with network pharmacies;

(3) set the cost of multi-source generic drugs under AS 21.27.945; and

(4) adjudicate appeals related to multi-source generic drug reimbursement.

Sec. 21.27.905. Renewal of registration. (a) A pharmacy benefits manager shall biennially renew a registration with the director.

(b) To renew a registration under this section, a pharmacy benefits manager shall pay a renewal fee established by the director. The director shall set the amount of the renewal fee to allow the renewal and oversight activities of the division to be self-supporting.

Sec. 21.27.910. Pharmacy audit procedural requirements. (a) When a pharmacy benefits manager conducts an audit of the records of a pharmacy, the period covered by the audit of a claim may not exceed two years from the date that the claim was submitted to or adjudicated by the pharmacy benefits manager, whichever is earlier. Except as required under AS 21.36.495, a claim submitted to or adjudicated by a pharmacy benefits manager does not accrue interest during the audit period.

(b) A pharmacy benefits manager conducting an on-site audit shall give the pharmacy written notice of at least 10 business days before conducting an initial audit.

(c) A pharmacy benefits manager may not conduct

(1) an audit during the first seven calendar days of any month unless agreed to by the pharmacy;

(2) more than one on-site audit of a pharmacy within a 12-month period; or

(3) on-site audits of more than 250 separate prescriptions at one pharmacy within a 12-month period unless fraud by the pharmacy or an employee of the pharmacy is alleged.

(d) If an audit involves clinical or professional judgment, the individual conducting the audit must

(1) be a pharmacist who is licensed and in good standing under AS 08.80; or

(2) conduct the audit in consultation with a pharmacist who is licensed and in good standing under AS 08.80.

(e) A pharmacy, in responding to an audit, may use

(1) verifiable statements or records, including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner, to validate the pharmacy record;

(2) a legal prescription to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, prescriptions transmitted by facsimile, electronic prescriptions, or documented telephone calls from the prescriber or the prescriber's agent.

(f) A pharmacy benefits manager shall audit each pharmacy under the same standards and parameters as other similarly situated pharmacies in a network pharmacy contract in this state.

Sec. 21.27.915. Overpayment or underpayment. (a) When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager shall base a finding of overpayment or underpayment by the pharmacy on the actual overpayment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs, except as provided in (b) of this section.

(b) A pharmacy benefits manager may resolve a finding of overpayment or underpayment by entering into a settlement agreement with the pharmacy. The settlement agreement

(1) must comply with the requirements of AS 21.36.125; and

(2) may be based on a statistically justifiable projection method.

(c) A pharmacy benefits manager may not include the dispensing fee amount in a finding of an overpayment unless

(1) a prescription was not actually dispensed;

(2) the prescriber denied authorization;

(3) the prescription dispensed was a medication error by the pharmacy; or

(4) the identified overpayment is solely based on an extra dispensing fee.

Sec. 21.27.920. Recoupment. (a) When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager shall base the recoupment of overpayments on the actual overpayment of the claim, except as provided in AS 21.27.915(b).

(b) A pharmacy benefits manager conducting an audit of a pharmacy may not

(1) use extrapolation in calculating recoupments or penalties for audits, unless required by state or federal contracts;

(2) assess a charge-back, recoupment, or other penalty against a pharmacy solely because a prescription is mailed or delivered at the request of a patient; or

(3) receive payment

(A) based on a percentage of the amount recovered; or

(B) for errors that have no actual financial harm to the patient or medical plan.

Sec. 21.27.925. Pharmacy audit reports. (a) A pharmacy benefits manager shall deliver a preliminary audit report to the pharmacy audited within 60 days after the conclusion of the audit.

(b) A pharmacy benefits manager shall allow the pharmacy at least 30 days following receipt of the preliminary audit report to provide documentation to the pharmacy benefits manager to address a discrepancy found in the audit. A pharmacy benefits manager may grant a reasonable extension upon request by the pharmacy.

(c) A pharmacy benefits manager shall deliver a final audit report to the pharmacy within 120 days after receipt of the preliminary audit report, settlement

agreement, or final appeal, whichever is latest.

Sec. 21.27.930. Pharmacy audit appeal; future repayment. (a) A pharmacy benefits manager conducting an audit shall establish a written appeals process.

(b) Recoupment of disputed funds or repayment of funds to the pharmacy benefits manager by the pharmacy, if permitted by contract, shall occur, to the extent demonstrated or documented in the pharmacy audit findings, after final internal disposition of the audit, including the appeals process. If the identified discrepancy for an individual audit exceeds $15,000, future payments to the pharmacy may be withheld pending finalization of the audit.

(c) A pharmacy benefits manager may not assess against a pharmacy a charge-back, recoupment, or other penalty until the pharmacy benefits manager's appeals process has been exhausted and the final report or settlement agreement issued.

Sec. 21.27.935. Fraudulent activity. When a pharmacy benefits manager conducts an audit of a pharmacy, the pharmacy benefits manager may not consider unintentional clerical or record-keeping errors, including typographical errors, writer's errors, or computer errors regarding a required document or record, to be fraudulent activity. In this section, "fraudulent activity" means an intentional act of theft, deception, misrepresentation, or concealment committed by the pharmacy.

Sec. 21.27.940. Pharmacy audits; restrictions. The requirements of AS 21.27.901 - 21.27.955 do not apply to an audit

(1) in which suspected fraudulent activity or other intentional or wilful misrepresentation is evidenced by a physical review, a review of claims data, a statement, or another investigative method; or

(2) of claims paid for under the medical assistance program under AS 47.07.

Sec. 21.27.945. Drug pricing list; procedural requirements. (a) A pharmacy benefits manager shall

(1) make available to each network pharmacy at the beginning of the term of the network pharmacy's contract, and upon renewal of the contract, the methodology and sources used to determine the drug pricing list;

(2) provide a telephone number at which a network pharmacy may

contact an employee of a pharmacy benefits manager to discuss the pharmacy's appeal;

(3) provide a process for a network pharmacy to have ready access to the list specific to that pharmacy;

(4) review and update applicable list information at least once every seven business days to reflect modification of list pricing;

(5) update list prices within one business day after a significant price update or modification provided by the pharmacy benefits manager's national drug database provider; and

(6) ensure that dispensing fees are not included in the calculation of the list pricing.

(b) When establishing a list, the pharmacy benefits manager shall use

(1) the most up-to-date pricing data to calculate reimbursement to a network pharmacy for drugs subject to list prices;

(2) multi-source generic drugs that are sold or marketed in the state during the list period.

Sec. 21.27.950. Multi-source generic drug appeal. (a) A pharmacy benefits manager shall establish a process by which a network pharmacy, or a network pharmacy's contracting agent, may appeal the reimbursement for a multi-source generic drug. A pharmacy benefits manager shall resolve an appeal from a network pharmacy within 10 calendar days after the network pharmacy or the contracting agent submits the appeal.

(b) A network pharmacy, or a network pharmacy's contracting agent, may appeal a reimbursement from a pharmacy benefits manager for a multi-source generic drug if the reimbursement for the drug is less than the amount that the network pharmacy can purchase from two or more of its contracted suppliers.

(c) A pharmacy benefits manager may grant a network pharmacy's appeal if an equivalent multi-source generic drug is not available at a price at or below the pharmacy benefits manager's list price for purchase from national or regional wholesalers who operate in the state. If an appeal is granted, the pharmacy benefits manager shall adjust the reimbursement of the network pharmacy to equal the network

pharmacy acquisition cost for each paid claim included in the appeal.

(d) If the pharmacy benefits manager denies a network pharmacy's appeal, the pharmacy benefits manager shall provide the network pharmacy with the

(1) reason for the denial;

(2) national drug code of an equivalent multi-source generic drug that has been purchased by another network pharmacy located in the state at a price that is equal to or less than the pharmacy benefits manager's list price within seven days after the network pharmacy appeals the claim; and

(3) name of a pharmaceutical wholesaler who operates in the state in which the drug may be acquired by the challenging network pharmacy.

(e) A network pharmacy may request a hearing under AS 21.06.170 - 21.06.240 for an adverse decision from a pharmacy benefits manager within 30 calendar days after receiving the decision. The parties may present all relevant information to the director for the director's review.

(f) The director shall enter an order that

(1) grants the network pharmacy's appeal and directs the pharmacy benefits manager to make an adjustment to the disputed claim;

(2) denies the network pharmacy's appeal; or

(3) directs other actions considered fair and equitable.

Sec. 21.27.955. Definitions. In AS 21.27.901 - 21.27.955,

(1) "audit" means an official examination and verification of accounts and records;

(2) "claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or device;

(3) "extrapolation" means the practice of inferring a frequency or dollar amount of overpayments, underpayments, invalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount of overpayments, underpayments, invalid claims, or other errors actually measured in a sample of claims;

(4) "list" means the list of multi-source generic drugs for which a

predetermined reimbursement amount has been established such as a maximum allowable cost or maximum allowable cost list or any other list of prices used by a pharmacy benefits manager;

(5) "multi-source generic drug" means any covered outpatient prescription drug that the United States Food and Drug Administration has determined is pharmaceutically equivalent or bioequivalent to the originator or name brand drug and for which there are at least two drug products that are rated as therapeutically equivalent under the United States Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations";

(6) "network pharmacy" means a pharmacy that provides covered health care services or supplies to an insured or a member under a contract with a network plan to act as a participating provider;

(7) "pharmacy" has the meaning given in AS 08.80.480;

(8) "pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler or distributor charges for a pharmaceutical product as listed on the pharmacy's invoice;

(9) "pharmacy benefits manager" means a person that contracts with a pharmacy on behalf of an insurer to process claims or pay pharmacies for prescription drugs or medical devices and supplies or provide network management for pharmacies;

(10) "recoupment" means the amount that a pharmacy must remit to a pharmacy benefits manager when the pharmacy benefits manager has determined that an overpayment to the pharmacy has occurred.

*** Sec. 6.** The uncodified law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. (a) AS 21.27.901 - 21.27.955, enacted by sec. 5 of this Act, apply to audits of pharmacies conducted by pharmacy benefits managers and contracts entered into or renewed on or after the effective date of sec. 5 of this Act.

(b) AS 08.80.297(b), enacted by sec. 1 of this Act, applies to contracts entered into or renewed on or after the effective date of sec. 1 of this Act.

(c) In this section, "pharmacy" and "pharmacy benefits manager" have the meanings

given in AS 21.27.955, enacted by sec. 5 of this Act.

*** Sec. 7.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITIONAL PROVISIONS: REGULATIONS. The division of insurance may adopt regulations necessary to implement the changes made by this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the law implemented by the regulation.

*** Sec. 8.** The uncodified law of the State of Alaska is amended by adding a new section to read:

REVISOR'S INSTRUCTIONS. The revisor of statutes is requested to renumber AS 21.27.900 as AS 21.27.990. The revisor of statutes is requested to change "AS 21.27.900" to "AS 21.27.990" in AS 21.36.475(c)(2) and (4) and AS 21.97.900(27).

*** Sec. 9.** Sections 1, 3, 6(b), and 7 of this Act take effect immediately under AS 01.10.070(c).

*** Sec. 10.** Except as provided in sec. 9 of this Act, this Act takes effect July 1, 2019.

State of Arkansas Call Item 5
91st General Assembly **A Bill**
Second Extraordinary Session, 2018 SENATE BILL 2

By: Senators Caldwell, Rapert, Bledsoe, Bond, E. Cheatham, L. Chesterfield, A. Clark, Collins-Smith, J. Cooper, L. Eads, Elliott, J. English, Flippo, T. Garner, J. Hendren, Hickey, J. Hutchinson, K. Ingram, Irvin, B. Johnson, B. King, U. Lindsey, Maloch, Rice, B. Sample, D. Sanders, G. Stubblefield, Teague, D. Wallace
By: Representatives M. Gray, Wardlaw, Murdock, Gazaway, F. Allen, Baltz, Barker, Bentley, Blake, Boyd, Bragg, Brown, Capp, Cavenaugh, Coleman, Cozart, Dalby, Davis, Deffenbaugh, C. Douglas, D. Douglas, Drown, Eaves, Farrer, D. Ferguson, K. Ferguson, Fielding, C. Fite, L. Fite, V. Flowers, Fortner, Gates, Gillam, M.J. Gray, Hammer, Henderson, K. Hendren, Hillman, G. Hodges, M. Hodges, Holcomb, Hollowell, Jean, Jett, Leding, Lemons, Lowery, Lundstrum, Lynch, Maddox, Magie, A. Mayberry, McElroy, McNair, D. Meeks, S. Meeks, Miller, Nicks, Payton, Penzo, Petty, Pilkington, Richey, Richmond, Rushing, Rye, Sabin, B. Smith, Sorvillo, Speaks, Sturch, Sullivan, Tosh, Tucker, Vaught, Walker, Warren, Watson, D. Whitaker, Wing

For An Act To Be Entitled

AN ACT TO CREATE THE ARKANSAS PHARMACY BENEFITS MANAGER LICENSURE ACT; TO REGULATE AND LICENSE PHARMACY BENEFITS MANAGERS; TO AUTHORIZE PENALTIES AND FINES REGARDING THE REGULATION AND LICENSURE OF PHARMACY BENEFITS MANAGERS; TO DECLARE AN EMERGENCY; AND FOR OTHER PURPOSES.

Subtitle

TO CREATE THE ARKANSAS PHARMACY BENEFITS MANAGER LICENSURE ACT; AND TO DECLARE AN EMERGENCY.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 23, Chapter 92, is amended to add an additional subchapter to read as follows:

Subchapter 5 — Arkansas Pharmacy Benefits Manager Licensure Act

23-92-501. Title.

This subchapter shall be known and may be cited as the "Arkansas Pharmacy Benefits Manager Licensure Act".

23-92-502. Purpose.

(a) This subchapter establishes the standards and criteria for the regulation and licensure of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans.

(b) The purpose of this subchapter is to:

(1) Promote, preserve, and protect the public health, safety, and welfare through effective regulation and licensure of pharmacy benefits managers;

(2) Provide for powers and duties of the Insurance Commissioner, the State Insurance Department, and other state agencies and officers; and

(3) Prescribe penalties and fines for violations of this subchapter.

23-92-503. Definitions.

As used in this subchapter:

(1) "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

(A) Receiving payments for pharmacist services;

(B) Making payments to pharmacists or pharmacies for pharmacist services; or

(C) Both subdivisions (1)(A) and (B) of this section;

(2)(A) "Health benefit plan" means any individual, blanket, or group plan, policy, or contract for healthcare services issued or delivered by a healthcare insurer in this state.

(B) “Health benefit plan” does not include:

(i) Accidental-only plans;

(ii) Specified disease plans;

(iii) Disability income plans;

(iv) Plans that provide only for indemnity for hospital confinement;

(v) Long-term care only plans that do not include pharmacy benefits;

(vi) Other limited-benefit health insurance policies or plans; or

(vii) Health benefit plans provided under Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

(3) "Healthcare insurer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation;

(4) "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including without limitation:

(A) Negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(B) Disbursing or distributing rebates;

(C) Managing or participating in incentive programs or arrangements for pharmacist services;

(D) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(E) Developing formularies;

(F) Designing prescription benefit programs; or

(G) Advertising or promoting services;

(5) "Pharmacist" means an individual licensed as a pharmacist by the Arkansas State Board of Pharmacy;

(6) "Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy as defined in § 17-92-101;

(7) "Pharmacy" means the same as defined in § 17-92-101;

(8)(A) "Pharmacy benefits manager" means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans.

(B) "Pharmacy benefits manager" does not include any:

(i) Healthcare facility licensed in Arkansas;

(ii) Healthcare professional licensed in Arkansas;

(iii) Consultant who only provides advice as to the selection or performance of a pharmacy benefits manager; or

(iv) Entity that provides claims processing services or other prescription drug or device services for the fee-for-service Arkansas Medicaid Program only in that capacity;

(9) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager;

(10) “Pharmacy benefits manager network” means a network of pharmacists or pharmacies that are offered by an agreement or insurance contract to provide pharmacist services for health benefit plans;

(11) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services under a health benefit plan;

(12) "Pharmacy services administrative organization" means an organization that helps community pharmacies and pharmacy benefits managers or third party payers achieve administrative efficiencies, including contracting and payment efficiencies;

(13)(A) "Rebate" means a discount or other price concession based on utilization of a prescription drug that is paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

(B) "Rebate" includes without limitation incentives, disbursements, and reasonable estimates of a volume-based discount; and

(14) "Third party" means a person, business, or entity other than a pharmacy benefits manager that is not an enrollee or insured in a health benefit plan.

23-92-504. License to do business — Annual statement — Assessment.

(a)(1) A person or organization shall not establish or operate as a pharmacy benefits manager in Arkansas for health benefit plans without obtaining a license from the Insurance Commissioner under this subchapter.

(2) The commissioner shall prescribe the application for a license to operate in Arkansas as a pharmacy benefits manager and may charge application fees and renewal fees as established by rule.

(b)(1) The commissioner shall issue rules establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers under this subchapter.

(2)(A) When adopting the initial rules to implement this subchapter, the final rule shall be filed with the Secretary of State for adoption under § 25-15-204(f):

(i) On or before September 1, 2018; or

(ii) If approval under § 10-3-309 has not occurred by September 1, 2018, as soon as practicable after approval under § 10-3-309.

(B) The State Insurance Department shall file the proposed rule with the Legislative Council under § 10-3-309(c) sufficiently in advance of September 1, 2018, so that the Legislative Council may consider the rule for approval before September 1, 2018.

23-92-505. Pharmacy benefits manager network adequacy.

A pharmacy benefits manager shall provide:

(1)(A) A reasonably adequate and accessible pharmacy benefits manager network for the provision of prescription drugs for a health benefit plan that shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence.

(B) A mail-order pharmacy shall not be included in the calculations determining pharmacy benefits manager network adequacy; and

(2) A pharmacy benefits manager network adequacy report describing the pharmacy benefits manager network and the pharmacy benefits manager network's accessibility in this state in the time and manner required by rule issued by the State Insurance Department.

23-92-506. Compensation — Prohibited practices.

(a)(1) The Insurance Commissioner may review and approve the compensation program of a pharmacy benefits manager with a health benefit plan to ensure that the reimbursement for pharmacist services paid to a pharmacist or pharmacy is fair and reasonable to provide an adequate pharmacy benefits manager network for a health benefit plan under the standards issued

by rule of the State Insurance Department.

(2) All information and data acquired during the review under subdivision (a)(1) of this section is:

(A) Considered proprietary and confidential under § 23-61-107(a)(4) and § 23-61-207; and

(B) Not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq.

(b) A pharmacy benefits manager or representative of a pharmacy benefits manager shall not:

(1) Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;

(2) Unless reviewed and approved by the commissioner, charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including without limitation a fee for:

(A) The receipt and processing of a pharmacy claim;

(B) The development or management of claims processing services in a pharmacy benefits manager network; or

(C) Participation in a pharmacy benefits manager network;

(3) Unless reviewed and approved by the commissioner in coordination with the Arkansas State Board of Pharmacy, require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the board;

(4)(A) Reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(B) The amount shall be calculated on a per-unit basis using the same generic product identifier or generic code number; or

(5) Do any combination of the actions listed in subdivisions (b)(1)-(4) of this section.

(c) A claim for pharmacist services shall not be retroactively denied or reduced after adjudication of the claim, unless:

(1) The original claim was submitted fraudulently;

(2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services; or

(3) The pharmacist services were not properly rendered by the

pharmacy or pharmacist.

(d) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network shall not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered.

(e) The commissioner may issue a rule establishing prohibited practices of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans.

23-92-507. Gag clauses prohibited.

(a) The prohibitions under § 23-99-407 apply to participation contracts between pharmacy benefits managers and pharmacists or pharmacies providing prescription drug coverage for health benefit plans.

(b) A pharmacy or pharmacist may provide to an insured information regarding the insured's total cost for pharmacist services for a prescription drug.

(c) A pharmacy or pharmacist shall not be proscribed by a pharmacy benefits manager from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if a more affordable alternative is available.

(d) A pharmacy benefits manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Insurance Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements under this subchapter.

23-92-508. Enforcement.

(a) The Insurance Commissioner shall enforce this subchapter.

(b)(1) The commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine if the pharmacy benefits manager is in compliance with this subchapter.

(2) The information or data acquired during an examination under subdivision (b)(1) of this section is:

(A) Considered proprietary and confidential under § 23-61-

107(a)(4) and § 23-61-207; and

(B) Not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq.

23-92-509. Rules.

(a)(1) The Insurance Commissioner may adopt rules regulating pharmacy benefits managers that are not inconsistent with this subchapter.

(2) Rules that the commissioner may adopt under this subchapter include without limitation rules relating to:

(A) Licensing;

(B) Application fees;

(C) Financial solvency requirements;

(D) Pharmacy benefits manager network adequacy;

(E) Prohibited market conduct practices;

(F) Data reporting requirements under § 4-88-803;

(G) Compliance and enforcement requirements under § 17-92-507 concerning Maximum Allowable Cost Lists;

(H) Rebates;

(I) Compensation; and

(J) Lists of health benefit plans administered by a pharmacy benefits manager in this state.

(b) Rules adopted under this subchapter shall set penalties or fines, including without limitation monetary fines, suspension of licensure, and revocation of licensure for violations of this subchapter and rules adopted under this subchapter.

(c)(1) In addition to the filing requirements under the Arkansas Administrative Procedure Act, § 25-15-201 et seq., and under § 10-3-309, the State Insurance Department shall file a proposed rule or a proposed amendment to an existing rule under this subchapter with the Senate Committee on Insurance and Commerce and the House Committee on Insurance and Commerce at least thirty (30) days before the expiration of the period for public comment under the Arkansas Administrative Procedure Act, § 25-15-201 et seq.

(2) The Senate Committee on Insurance and Commerce and the House Committee on Insurance and Commerce shall review the proposed rule or proposed amendment to an existing rule within forty-five (45) days of the date the proposed rule or proposed amendment to an existing rule is filed

with the Senate Committee on Insurance and Commerce and the House Committee on Insurance and Commerce.

(3)(A) If the department adopts an emergency rule under this subchapter, in addition to the filing requirements under the Arkansas Administrative Procedure Act, § 25-15-201 et seq., and under § 10-3-309, the department shall notify the following individuals of the emergency rule and provide each individual with a copy of the rule within five (5) business days of adopting the rule:

(i) The Speaker of the House of Representatives;

(ii) The President Pro Tempore of the Senate;

(iii) The Chair of the Senate Committee on Insurance and Commerce; and

(iv) The Chair of the House Committee on Insurance and Commerce.

(B) The Senate Committee on Insurance and Commerce and the House Committee on Insurance and Commerce shall review the emergency rule within forty-five (45) days of the date that the emergency rule is provided to the Chair of the Senate Committee on Insurance and Commerce and the Chair of the House Committee on Insurance and Commerce.

23-92-510. Applicability.

(a) This subchapter is applicable to a contract or health benefit plan issued, renewed, recredentialed, amended, or extended on and after September 1, 2018.

(b) A contract existing on the date of licensure of the pharmacy benefits manager shall comply with the requirements of this subchapter as a condition of licensure for the pharmacy benefits manager.

SECTION 2. Arkansas Code § 4-88-803, concerning required practices under the Fair Disclosure of State Funded Payments for Pharmacists' Services Act, is amended to add a new subsection to read as follows:

(d)(1) Unless otherwise required more frequently by the Insurance Commissioner, a pharmacy benefits manager shall file an annual report with the commissioner providing the information required under subsection (a) of this section pursuant to the timing, format, and requirements issued by rule of the State Insurance Department.

(2) The annual report is:

(A) Considered proprietary and confidential under § 23-61-107(a)(4) and § 23-61-207; and

(B) Not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq.

(3) This section is not subject to § 4-88-113(f)(1)(B).

SECTION 3. Arkansas Code § 17-92-507(g), concerning the Maximum Allowable Cost Lists, is amended to read as follows:

(g)(1) A violation of this section is a deceptive and unconscionable trade practice under the Deceptive Trade Practices Act, § 4-88-101 et seq., and a prohibited practice under the Arkansas Pharmacy Benefits Manager Licensure Act, § 23-92-501 et seq., and the Trade Practices Act, § 23-66-201 et seq.

(2) This section is not subject to § 4-88-113(f)(1)(B).

SECTION 4. Effective on and after September 1, 2018, Arkansas Code § 23-92-201 is amended to read as follows:

23-92-201. ~~Definitions~~ Definition.

As used in this subchapter~~.~~, "third-party administrator":

~~(1) "Pharmacy benefits manager" means an entity that administers or manages a pharmacy benefits plan or program;~~

~~(2) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides pharmacist services to individuals who reside in or are employed in this state; and~~

~~(3)(A)~~(1) ~~"Third-party administrator" means~~ Means a person, firm, or partnership that collects or charges premiums from or adjusts or settles claims on residents of this state in connection with life or accident and health coverage provided by a self-insured plan or a multiple employer trust or multiple employer welfare arrangement~~.~~;

~~(B)~~(2) ~~"Third-party administrator" includes:~~ Includes

~~(i) An~~ an administrative-services-only contract offered by insurers and health maintenance organizations; and

~~(ii) A pharmacy benefits manager that administers or manages a pharmacy benefits plan or program that furnishes, covers the cost~~

~~of, or otherwise provides for the practice of pharmacy as defined in § 17-92-101 under any life and accident and health coverage provided in this state by a self-insured plan, a multiple-employer trust, or a multiple-employer welfare arrangement.~~

~~(C)~~(3) ~~"Third-party administrator" does~~ Does not include:

~~(i)~~(A) An employer, for its employees or for the employees of a subsidiary or affiliated corporation of the employer;

~~(ii)~~(B) A union, for its members;

~~(iii)~~(C) An insurer or health maintenance organization licensed to do business in this state;

~~(iv)~~(D) A creditor, for its debtors, regarding insurance covering a debt between the creditor and its debtors;

~~(v)~~(E) A credit-card-issuing company that advances for, or collects premiums or charges from, its credit card holders, as long as that company does not adjust or settle claims;

~~(vi)~~(F) An individual who adjusts or settles claims in the normal course of his or her practice or employment and who does not collect charges or premiums in connection with life or accident and health coverage; or

~~(vii)~~(G) An agency licensed by the Insurance Commissioner and performing duties pursuant to an agency contract with an insurer authorized to do business in this state.

SECTION 5. DO NOT CODIFY. SEVERABILITY CLAUSE. If any provision of this act or the application of this act to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this act are declared severable.

SECTION 6. EFFECTIVE DATE CLAUSE.

SECTION 4 of this act is effective on and after September 1, 2018.

SECTION 7. EMERGENCY CLAUSE. It is found and determined by the General Assembly of the State of Arkansas that the unregulated behavior of pharmacy benefits managers is threatening the sustainability of pharmacies in

Arkansas; that regulation of pharmacy benefits managers by the State Insurance Department will stabilize the pharmacy industry in this state; and that Section 1, 2, 3, and 5 of this act are immediately necessary to ensure that Arkansas residents have continued access to pharmacy services across the state. Therefore, an emergency is declared to exist, and Sections 1, 2, 3, and 5 of this act, being immediately necessary for the preservation of the public peace, health, and safety, shall become effective on:

(1) The date of the act's approval by the Governor;

(2) If the bill is neither approved nor vetoed by the Governor, the expiration of the period of time during which the Governor may veto the bill; or

(3) If the bill is vetoed by the Governor and the veto is overridden, the date the last house overrides the veto.

Assembly Bill No. 315

CHAPTER 905

An act to add Sections 4079.5 and 4441 to the Business and Professions Code, and to add Article 6.1 (commencing with Section 1385.001) to Chapter 2.2 of Division 2 of, to add and repeal Section 1368.6 of, and to repeal Section 1385.007 of, the Health and Safety Code, relating to pharmacy benefit management.

[Approved by Governor September 29, 2018. Filed with Secretary of State September 29, 2018.]

LEGISLATIVE COUNSEL'S DIGEST

AB 315, Wood. Pharmacy benefit management.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. A violation of the Pharmacy Law is a crime.

This bill would require a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price. If the customer pays the retail price, the bill would require the pharmacy to submit the claim to the plan or insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy. The bill would provide that the payment rendered by an enrollee would constitute the applicable cost sharing, as specified. The bill would provide that a violation of those provisions would not be grounds for disciplinary or criminal action.

Existing law imposes specified requirements on an audit of pharmacy services provided to beneficiaries of a health benefit plan and defines a "pharmacy benefit manager" for those purposes as a person, business, or other entity that, pursuant to a contract or under an employment relationship with a carrier, health benefit plan sponsor, or other 3rd-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, plan sponsor, or other 3rd-party payer.

The bill would require pharmacy benefit managers to exercise good faith and fair dealing. Among other things, the bill would require a pharmacy benefit manager to notify a purchaser, as defined, in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the purchaser to exercise good faith and fair dealing. The bill would require a pharmacy benefit manager to disclose, on a quarterly basis, and upon the request of the purchaser, certain information with respect to prescription product benefits specific to the

purchaser, including, but not limited to, the aggregate wholesale acquisition costs from a pharmaceutical manufacturer or labeler for certain therapeutic drugs and any administrative fees received from a pharmaceutical manufacturer or labeler. The bill would exempt from those requirements proprietary information, as defined, if the purchaser fails to agree, in writing, to maintain that information as confidential. The bill would impose additional requirements on pharmacy benefit managers to disclose to pharmacy network providers or their contracting agents of any material change to a contract provision that affects, among other things, the terms of reimbursement. The bill would prohibit a pharmacy benefit manager from including in a contract with a pharmacy network provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication. The bill would exempt from the above provisions a health care service plan or health insurer, or its affiliate, subsidiary, related entity, or contracted medical group, if it offers, provides, or administers pharmacy benefit management services only to enrollees, subscribers, policyholders, or insureds, as specified, and certain contracts under the Labor Code.

On and after January 1, 2020, and until January 1, 2023, the bill would also establish a pilot project in the Counties of Riverside and Sonoma to assess the impact of health care service plan and pharmacy benefit manager prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies. In those counties, the bill would prohibit a health care service plan from prohibiting, or permitting any delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing a particular amount of a prescribed medication if the plan or pharmacy benefit manager allows that amount to be dispensed through a pharmacy owned or controlled by the plan or pharmacy benefit manager, except as specified. The bill would require plans in those counties to report annually to the Department of Managed Health Care information and data relating to the pilot project. The bill would require the department to provide a summary of that data to the Governor and health policy committees of the Legislature.

This bill would make legislative findings and declarations as to the necessity of a special statute for the Counties of Riverside and Sonoma.

Existing law provides for the regulation of health care service plans by the Department of Managed Health Care. A willful violation of those provisions is a crime. Existing law requires health care service plans that cover prescription drug benefits and that issue cards to enrollees to issue to each of its enrollees a uniform prescription drug information card that, at a minimum, contains specified information, including information required by the benefit administrator or health care service plan that is necessary to commence processing a pharmacy claim and a telephone number that pharmacy providers may call for assistance.

On and after January 1, 2020, the bill would impose additional requirements on health care service plans with regard to contracted pharmacy providers and pharmacy benefit managers. Among other things, the bill would prohibit a health care service plan from including in a contract with

a pharmacy provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication. The bill would require a health care service plan that contracts with a pharmacy benefit manager for management of any or all of its prescription drug coverage to require the pharmacy benefit manager to comply with specified provisions, register with the department pursuant to these provisions, and exercise good faith and fair dealing in the performance of its contractual duties to a health care service plan. The bill would require the registration of those pharmacy benefit managers with the department, as specified, and would authorize the department to set a fee for registration, as specified. The bill would establish enforcement provisions. The bill would also establish a Task Force on Pharmacy Benefit Management Reporting, until February 1, 2020, to determine what information related to pharmaceutical costs, if any, the department should require to be reported by health care service plans or their contracted pharmacy benefit managers. The bill would require the department to submit a report of the task force to specified persons and entities within the Legislature.

Because a willful violation of these provisions by health care service plans would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4079.5 is added to the Business and Professions Code, to read:

4079.5. (a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is entered into on or after January 1, 2019, that is inconsistent with this section is void and unenforceable.

(e) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other

provisions or applications that can be given effect without the invalid provision or application.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

SEC. 2. Section 4441 is added to the Business and Professions Code, to read:

4441. (a) For purposes of this section, the following definitions shall apply:

(1) "Labeler" means a person or entity that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Part 207 of Title 21 of the Code of Federal Regulations.

(2) "Proprietary information" means information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel that is held by a pharmacy benefit manager and used for its business purposes.

(3) "Purchaser" means a health benefit plan sponsor or other third-party payer with whom a pharmacy benefit manager contracts to provide the administration and management of prescription drug benefits, except for a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(b) This section shall apply to pharmacy benefit manager contracts that are entered into, amended, or renewed on or after January 1, 2019.

(c) A pharmacy benefit manager shall exercise good faith and fair dealing.

(d) A pharmacy benefit manager shall notify a purchaser in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the purchaser to exercise good faith and fair dealing pursuant to subdivision (c).

(e) The pharmacy benefit manager shall, on a quarterly basis, disclose, upon the request of the purchaser, the following information with respect to prescription product benefits specific to the purchaser:

(1) The aggregate wholesale acquisition costs from a pharmaceutical manufacturer or labeler for each therapeutic category of drugs containing three or more drugs, as outlined in the state's essential health benefits benchmark plan pursuant to Section 1367.005 of the Health and Safety Code.

(2) The aggregate amount of rebates received by the pharmacy benefit manager by therapeutic category of drugs containing three or more drugs, as outlined in the state's essential health benefits benchmark plan pursuant to Section 1367.005 of the Health and Safety Code. The aggregate amount of rebates shall include any utilization discounts the pharmacy benefit manager receives from a pharmaceutical manufacturer or labeler.

(3) Any administrative fees received from the pharmaceutical manufacturer or labeler.

(4) Whether the pharmacy benefit manager has a contract, agreement, or other arrangement with a pharmaceutical manufacturer to exclusively

dispense or provide a drug to a purchaser's employees, insureds, or enrollees, and the application of all consideration or economic benefits collected or received pursuant to that arrangement.

(5) Prescription drug utilization information for the purchaser's enrollees or insureds that is not specific to any individual enrollee or insured.

(6) The aggregate of payments, or the equivalent economic benefit, made by the pharmacy benefit manager to pharmacies owned or controlled by the pharmacy benefit manager.

(7) The aggregate of payments made by the pharmacy benefit manager to pharmacies not owned or collected by the pharmacy benefit manager.

(8) The aggregate amount of the fees imposed on, or collected from, network pharmacies or other assessments against network pharmacies, and the application of those amounts collected pursuant to the contract with the purchaser.

(f) The information disclosed pursuant to subdivision (e) shall apply to all retail, mail order, specialty, and compounded prescription products.

(g) Except for utilization information specified in paragraph (5) of subdivision (e), a pharmacy benefit manager is not required to make the disclosures required by subdivision (e) unless and until the purchaser agrees, in writing, to maintain as confidential any proprietary information.

(h) A pharmacy benefit manager shall not impose a penalty or offer an inducement to a purchaser for the purpose of deterring the purchaser from requesting the information set forth in subdivision (e).

(i) A pharmacy benefit manager shall disclose to a pharmacy network provider or its contracting agent any material change to a contract provision that affects the terms of reimbursement, the process for verifying benefits and eligibility, dispute resolution, procedures for verifying drugs included on the formulary, and contract termination at least 30 days before the date of the change to the provision.

(j) A pharmacy benefit manager shall not notify an individual receiving benefits through the pharmacy benefit manager that a pharmacy has been terminated from the pharmacy benefit manager's network until the notification of termination has been provided to that pharmacy pursuant to subdivision (i).

(k) A pharmacy benefit manager shall not include in a contract with a pharmacy network provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

(*l*) This section shall not apply to the following:

(1) A health care service plan or health insurer, if the health care service plan or health insurer offers, provides, or administers pharmacy benefit management services and if those services are offered, provided, or administered only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered, provided, or administered by that health care service plan or health insurer.

(2) An affiliate, subsidiary, related entity, or contracted medical group of a health care service plan or health insurer that would otherwise qualify

as a pharmacy benefit manager, but offers, provides, or administers services only to enrollees, subscribers, policyholders, or insureds who are also covered by health benefits offered, provided, or administered by the health care service plan or health insurer.

(3) A contract authorized by Section 4600.2 of the Labor Code.

(m) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

SEC. 3. Section 1368.6 is added to the Health and Safety Code, to read:

1368.6. (a) Effective January 1, 2020, there is established a pilot project to assess the impact of health care service plan and pharmacy benefit manager prohibitions on the dispensing of certain amounts of prescription drugs by network retail pharmacies. The provisions of subdivision (b) shall apply to pharmacy providers located in the Counties of Riverside and Sonoma.

(b) Pursuant to the pilot project, a health care service plan shall not prohibit, or permit any delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing a particular amount of a prescribed medication if the plan or pharmacy benefit manager allows that amount to be dispensed through a pharmacy owned or controlled by the plan or pharmacy benefit manager, unless the prescription drug is subject to restricted distribution by the federal Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(c) This section shall not be construed to prohibit a health care service plan or pharmacy benefit manager from requiring the same reimbursement and terms and conditions for a pharmacy network provider as for a pharmacy owned or controlled by the health care service plan or pharmacy benefit manager.

(d) This section shall not be construed to prohibit differential cost sharing designed to encourage or discourage the use of mail-order pharmacy services or preferred pharmacies.

(e) On or before July 1, 2020, health care service plans subject to this section shall report annually to the Department of Managed Health Care information and data relating to changes, if any, to costs and utilization of prescription drugs attributable to the prohibition of contract terms in subdivision (b). The department shall solicit and receive any additional information relevant to changes in costs or utilization attributable to the pilot project from other interested stakeholders. The department shall summarize data received pursuant to this subdivision and provide the summary to the Governor and health policy committees of the Legislature on or before December 31, 2022.

(f) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 4. Article 6.1 (commencing with Section 1385.001) is added to Chapter 2.2 of Division 2 of the Health and Safety Code, to read:

Article 6.1. Pharmacy Benefit Management Services

1385.001. For the purposes of this article, “pharmacy benefit manager” means a person, business, or other entity that, pursuant to a contract with a health care service plan, manages the prescription drug coverage provided by the health care service plan, including, but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs. This definition shall not include a health care service plan licensed under this chapter or any individual employee of a health care service plan or its contracted provider, as defined in subdivision (i) of Section 1345, performing the services described in this section.

1385.002. (a) Except as specified in Section 1385.007, the requirements of this article shall become operative on January 1, 2020.

(b) Notwithstanding subdivision (a), the department has the authority to enforce the provisions of this article, including the authority to adopt, amend, or repeal any rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public and to implement this article, including, but not limited to, the director’s enforcement authority under this chapter.

(c) Notwithstanding subdivision (a) and Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this article by means of all-plan letters or similar instructions to plans and pharmacy benefit managers, without taking regulatory action, until such time as regulations are adopted.

(d) The department may contract with a consultant or consultants with expertise in this subject area to assist the department in developing guidance or instructions described in subdivision (c), or the report required pursuant to Section 1385.007. The department’s contract with a consultant shall include conflict-of-interest provisions to prohibit a person from participating in any report in which the person knows or has reason to know he or she has a material financial interest, including, but not limited to, a person who has a consulting or other agreement with a person or organization that would be affected by the results of the report.

(e) Contracts entered into pursuant to the authority in this article shall be exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, Section 19130 of the Government Code, and Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, and shall be exempt from the review or approval of any division of the Department of General Services.

1385.003. (a) A health care service plan shall disclose to a contracted pharmacy provider or its contracting agent the prescription drug information contained in subdivision (a) of Section 1363.03, including, but not limited

to, the telephone number pharmacy providers may call for assistance and information necessary to process a pharmacy claim.

(b) A health care service plan shall not include in a contract with a pharmacy provider or its contracting agent a provision that prohibits the provider from informing a patient of a less costly alternative to a prescribed medication.

1385.004. (a) A health care service plan that contracts with a pharmacy benefit manager for management of any or all of its prescription drug coverage shall require the pharmacy benefit manager to do all of the following:

(1) Comply with the provisions of Section 1385.003.

(2) Register with the department pursuant to the requirements of this article.

(3) Exercise good faith and fair dealing in the performance of its contractual duties to a health care service plan.

(4) Comply with the requirements of Chapter 9.5 (commencing with Section 4430) of Division 2 of the Business and Professions Code, as applicable.

(5) Inform all pharmacists under contract with or subject to contracts with the pharmacy benefit manager of the pharmacist's rights to submit complaints to the department under Section 1371.39 and of the pharmacist's rights as a provider under Section 1375.7.

(b) A pharmacy benefit manager shall notify a health care service plan in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents a conflict of interest that interferes with the discharge of the pharmacy benefit manager's duty to the health care service plan to exercise good faith and fair dealing in the performance of its contractual duties pursuant to subdivision (a).

1385.005. (a) A pharmacy benefit manager required to register with the department pursuant to Section 1385.004 shall complete an application for registration with the department that shall include, but not be limited to, all of the information required by subdivision (c).

(b) A pharmacy benefit manager registration obtained pursuant to this section is not transferable.

(c) The department shall develop an application form for pharmacy benefit manager registration. The application form for a pharmacy benefit manager registration shall require the pharmacy benefit manager to submit the following information to the department:

(1) The name of the pharmacy benefit manager.

(2) The address and contact telephone number for the pharmacy benefit manager.

(3) The name and address of the pharmacy benefit manager's agent for service of process in the state.

(4) The name and address of each person beneficially interested in the pharmacy benefit manager.

(5) The name and address of each person with management or control over the pharmacy benefit manager.

(d) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the name, address, usual occupation, and professional qualifications of each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the department, the applicant shall furnish the department with the name, address, usual occupation, and professional qualifications of partners, members, or stockholders not named in the application, or shall refer the department to an appropriate source for that information.

(e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this article. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or shall describe the reasons that prevent the applicant from being able to comply with the requirements with respect to the statement.

(f) The department may set a fee for a registration required by this article. The application fee shall not exceed the reasonable costs of the department in carrying out its duties under this article.

(g) Within 30 days of a change in any of the information disclosed to the department on an application for a registration, the pharmacy benefit manager shall notify the department of that change in writing.

(h) For purposes of this section, "person beneficially interested" with respect to a pharmacy benefit manager means and includes the following:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

1385.006. The failure by a health care service plan to comply with the contractual requirements pursuant to this article shall constitute grounds for disciplinary action. The director shall, as appropriate, investigate and take enforcement action against a health care service plan that fails to comply with these requirements and shall periodically evaluate contracts between health care service plans and pharmacy benefit managers to determine if any audit, evaluation, or enforcement actions should be undertaken by the department.

1385.007. (a) By July 1, 2019, the department, in collaboration with other agencies, departments, advocates, experts, health care service plan representatives, and other entities and stakeholders that it deems appropriate, shall convene a Task Force on Pharmacy Benefit Management Reporting to determine what information related to pharmaceutical costs, if any, the department should require to be reported by health care service plans or their contracted pharmacy benefit managers, in addition to reporting required

by Section 1367.243. The task force shall consider inclusion of information including, but not limited to, the following:

(1) Wholesale acquisition costs of pharmaceuticals.

(2) Rebates obtained by the health care service plan or the pharmacy benefit manager from pharmaceutical manufacturers.

(3) Payments to network pharmacies.

(4) Exclusivity arrangements between health care service plans or contracted pharmacy benefit managers with pharmaceutical manufacturers.

(b) The task force shall consider the results of information reporting pursuant to Section 1367.243 and Chapter 9 (commencing with Section 127675) of Part 2 of Division 107 in determining what information should be reported pursuant to subdivision (a).

(c) The department shall submit a report of the Task Force on Pharmacy Benefit Management Reporting to the President pro Tempore of the Senate, the Speaker of the Assembly, and the Senate and Assembly Committees on Health, with the recommendations of the task force no later than February 1, 2020, on which date the task force shall cease to exist.

(d) This section shall become inoperative on February 1, 2020, and, as of January 1, 2021, is repealed.

SEC. 5. The Legislature finds and declares that a special statute is necessary and that a general statute cannot be made applicable within the meaning of Section 16 of Article IV of the California Constitution for purposes of implementing Section 3 in different geographic regions for data comparison purposes.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Title of Rule: Revision to the Executive Director of the Department of Health Care Policy and Financing Rule Concerning All-Payers Claims Database. 10 CCR 2505-5, Sections 1.200.1, 1.200.2 A
Rule Number: ED 18-04-28-A
Division / Contact / Phone: / Alejandro Vera, 303.866.6435 / CIVHC- John Mathieu, 720.4840.4111

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   This rule changes makes multiple amendments.

   1: Update the DSG with a new version for housekeeping changes to align with the upcoming Medicare Beneficiary Identifier (MBI) requirements from the Centers for Medicare & Medicaid Services.

   2: Adds alternate payment model files and prescription drug rebate files to the Reporting Requirements.

   Problem:

   Health care costs continue to increase for all stakeholders that engage with the system, whether as a consumer, payer, or provider. Currently, in Colorado, there is no data regarding either the amount of alternative payments or the volume of prescription drug rebates. Both are important and growing components of overall health care spending and costs.

   Purpose:

   One of the charges of the CO APCD in the enabling statute was to report on health care costs in Colorado in order to increase transparency and move toward containing these costs. The proposed changes support health care programs' drive toward the Triple Aim with more data surrounding the total level of spending and cost of health care in Colorado. The proposed additions to the Reporting Requirements will provide a more complete picture of how health care is paid for in Colorado and will better represent the ultimate cost of prescription drugs across payer types in the state.

   Value:

   One of the characteristics of an efficient market is access to comprehensive and objective cost information by those who purchase, sell and provide health care goods and services. Transparent cost information enables consumers and employer purchasers to better identify high-value care to help improve quality of care and reduce costs.

Title of Rule: Revision to the Executive Director of the Department of Health Care Policy and Financing Rule Concerning All-Payers Claims Database. 10 CCR 2505-5, Sections 1.200.1, 1.200.2 A
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2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☐ for the preservation of public health, safety and welfare.

   Explain:

3. Federal authority for the Rule, if any:

4. State Authority for the Rule:

   Section 25.5-1-108, C.R.S. (2017);
   Section 25.5-1-204(9), C.R.S. (2017)

Title of Rule: Revision to the Executive Director of the Department of Health Care Policy and Financing Rule Concerning All-Payers Claims Database. 10 CCR 2505-5, Sections 1.200.1, 1.200.2 A
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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   Private and public payers who submit data to the CO APCD using Data Submission guide Version 9 2017 (DSG V9) will need to modify their current file format to accommodate the proposed changes. CIVHC and stakeholders requesting data from the CO APCD will benefit from more comprehensive data that supports the Triple Aim: better health, better care, lower costs.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   CIVHC will work collaboratively with all private health payers to meet the requirements of the revised submission guide, including using the established waiver process to provide a short term relaxed data standard or an extended timeline to submit conforming data.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   The APCD is not state funded; this amendment will have no impact on state appropriations

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The state will not incur any costs due to action or inaction. The state would benefit from this rule change because the additional information would add to the collaborative understanding of health system performance now underway such as the State Innovation Model (SIM) project and other state based projects.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There are no less costly of intrusive strategies to achieve the purpose of the proposed rule.

Title of Rule: Revision to the Executive Director of the Department of Health Care Policy and Financing Rule Concerning All-Payers Claims Database. 10 CCR 2505-5, Sections 1.200.1, 1.200.2 A
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6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   None

1.200 ALL-PAYERS CLAIMS DATABASE

1.200.1 Definitions

"administrator" means the administrator of the APCD appointed by the director of the department.

"APCD" means the Colorado All-Payer Claims Database.

"Alternative Payment Model (APM)" means payments made to providers outside of the traditional fee-for-service model. This includes: Pay for Performance Payment/Penalty, Shared Savings/Shared Risk, Global Budget, Limited Budget, Capitation – Unspecified, Bundled/Episode-Based, Integrated Delivery System, Patient-Centered Medical Home, and Other Non-FFS payments.

"dental claims data file" means a file that includes data about dental claims and other encounter information, according to the requirements contained in the submission guide.

"department" means the Colorado Department of Health Care Policy and Financing.

"director" means the Executive Director of the department.

"eligibility data file" means a file that includes data about a person who receives health care coverage from a payer, according to the requirements contained in the submission guide.

"ERISA" means the Employee Retirement Income Security Act of 1974, as codified at 29 U.S.C. ch. 18.

"HIPAA" means the Health Insurance Portability and Accountability Act, U.S.C. § 1320d – 1320d-8, and its implementing regulations, 45 C.F.R. Parts 160, 162 and 164, as may be amended.

"historic data" means eligibility data file(s), medical claims data file(s), pharmacy file(s) and provider file(s) for the period commencing January 1, 2009 through December 31, 2014 (except in the case of a self-insured employer-sponsored health plan, in which case, "historic data" shall mean, at minimum, such data file(s) for the period commencing January 1, 2015 through December 31, 2015).

"medical claims data file" means a file that includes data about medical claims and other encounter information, according to the requirements contained in the submission guide.

"payer" means a private health care payer and a public health care payer.

"pharmacy file" means a file that includes data about prescription medications and claims filed by pharmacies, according to the requirements contained in the submission guide.

"Prescription Drug Rebate" means aggregated information regarding the total amount of any prescription drug rebates and other pharmaceutical manufacturer price concessions paid by pharmaceutical manufacturers to a payer or their pharmacy benefit manager(s).

-"private health care payer" means an insurance carrier as defined in C.R.S. § 10-16-102(8) covering an aggregate of 1,000 or more enrolled lives in health coverage plans as defined in C.R.S. § 10-16-102(34). For purposes, of this regulation, "private health care payer" includes carriers offering health benefits plans under C.R.S. § 10-16-102(32)(a) and dental, vision, limited benefit health insurance, and short-term limited-duration health insurance. For the purposes of this regulation, a "private health care payer" also means a self-insured employer-sponsored health plan covering an aggregate of 100 or more enrolled lives in Colorado. It does not include a self-insured employer-sponsored health plan, if such health plan is administered by a third-party administrator or administrative services only organization ("TPA/ASO") that services less than an aggregate of 1,000 enrolled lives in Colorado; carriers offering accident only; credit; benefits for long term care, home health care, community-based care, or any combination thereof under Article 19 of Title 10; disability income insurance; liability insurance including general liability insurance and automobile liability insurance; coverage issued as a supplement to liability insurance; worker's compensation or similar insurance; or automobile medical payment insurance, specified disease, or hospital indemnity and other fixed indemnity insurance.

"protected health information" shall have the same meaning as in the HIPAA Privacy Rule in 45 C.F.R. § 160.103.

"provider file" means a file that includes additional information about the individuals and entities that submitted claims that are included in the medical claims file; and is submitted according to the requirements contained in the submission guide.

"public health care payer" means the Colorado Medicaid program established under articles 4, 5 and 6 of title 25.5, C.R.S., the children's basic health plan established under article 8 of title 25.5, C.R.S. and Cover Colorado established under part 5 article 8 of title 10, C.R.S.

"submission guide" means the document entitled "Colorado All-Payer Claims Database Data Submission Guide" developed by the administrator that sets forth the required schedules, data file format, record specifications, data elements, definitions, code tables and edit specifications for payer submission of eligibility data files, medical, dental and pharmacy claims data files and provider data files to the APCD dated Version ~~9 2017~~ 10 2018, which document is hereby incorporated by reference.

1.200.2 Reporting Requirements

1.200.2.A Payers shall submit complete and accurate eligibility data files, medical claims data files, pharmacy claims data files, dental claims data files, alternative payment model data files, prescription drug rebate data files and provider files to the APCD pursuant to the submission guide. The administrator may amend the submission guide and shall provide notice of the revisions to payers. Any revision to the submission guide will be effective only when incorporated into this rule and issued in compliance with the requirements of C.R.S. § 24-4-103 (12.5). Reports submitted 120 days following the

effective date of the revision of this rule and the submission guide shall follow the revised submission guide.

1.200.2.B. A private health care payer subject to the provisions of ERISA is not required under this rule to submit claims data to the APCD but may continue to submit claims data or elect to submit claims data at any time in accordance with the procedures described in Sections 1.200.2.A and 1.200.3.

1.200.3 Schedule for Mandatory Data Reporting

1.200.3.A. Payers shall submit a test file of its eligibility data, medical and pharmacy claims data and provider files for a consecutive twelve month period to the administrator by no later than March 31, 2012 or no later than 160 calendar days after the effective date of this rule, whichever is later.

1.200.3.B. Payers shall submit complete and accurate historic data to the administrator that conforms to submission guide requirements by no later than June 30, 2012, or no later than 250 calendar days after the effective date of this rule, whichever is later.

1.200.3.C. Payers will transmit complete and accurate eligibility data, medical claims data, pharmacy claims data, dental claims data and provider files covering the period from January 1, 2012 and ending June 30, 2012 to the administrator by no later than August 15, 2012, or for the period as specified by the administrator no later than 305 days after the effective date of this rule, whichever is later.

1.200.3.D. On a monthly basis thereafter, payers will transmit complete and accurate monthly eligibility data, medical claims data, pharmacy claims data, dental claims data and provider files to the administrator. These data files for the period ending July 31, 2012, shall be submitted no later than September 15, 2012, or for the period as specified by the administrator, no later than 305 days after the effective date of this rule, whichever is later. For each month thereafter, files shall be submitted no later than 30 days after the end of the reporting month. Any time extension shall be provided to payers in writing by administrator at least 30 days prior to established deadlines.

1.200.4 APCD Reports

1.200.4.A. The administrator shall, at a minimum, issue reports from the APCD data at an aggregate level to describe patterns of incidence and variation of targeted medical conditions, state and regional cost patterns and utilization of services.

1.200.4.B. The APCD reports shall be available to the public on consumer facing websites and shall provide aggregate and summary reports to achieve the purposes of the APCD. Any such reports shall protect patient identity in accordance with HIPAA's standard for the de-identification of protected health information.

1.200.5 Requests for Data and Reports

1.200.5.A. A state agency or private entity engaged in efforts to improve health care quality, value or public health outcomes for Colorado residents may request a specialized report or data set from the APCD by submitting to the administrator a written request detailing the purpose of the project, the methodology, the qualifications of the research entity, and by executing a data use agreement, to comply with the requirements of HIPAA.

1.200.5.B. A data release review committee shall review those requests for reports or data sets containing protected health information and shall advise the administrator on whether release of the data is consistent with the statutory purpose of the APCD, will contribute to efforts to improve health care quality, value or public health outcomes for Colorado residents and complies with the requirements of HIPAA. The administrator shall include a representative of a physician organization, hospital organization, non-physician provider organization and a payer organization on the data release review committee.

1.200.5.C. The administrator may charge a reasonable fee to provide the requested data.

1.200.6 Penalties

1.200.6.A. If any payer fails to submit required data to the APCD in a timely basis, or fails to correct submissions rejected because of errors, the administrator shall provide written notice to the payer. The administrator may grant an extension of time for just cause. If the payer fails to provide the required information within thirty days following receipt of said written notice, the administrator shall provide the payer with notice of the failure to report and will notify the director of the payer's failure to report. The director shall assess a penalty of up to $1,000 per week for each week that a payer fails to provide the required data to the APCD up to a maximum penalty of $50,000. In determining whether to impose a penalty, the director may consider mitigating factors such as the size and sophistication of a payer, the reasons for the failure to report and the detrimental impact upon the public purpose served by the APCD.

1.200.6.B The penalties specified in Section 1.200.6.A shall not apply to a private health care payer that is subject to the provisions of ERISA, since those payers are not required under this rule to submit claims data to the APCD.

1.200.7 Interagency Agreement

1.200.7.A. The director may enter into an Interagency Agreement on behalf of the APCD and the administrator with the Division of Insurance in the Colorado Department of Regulatory Agencies to assist in the enforcement of these regulations and under the Divisions' authority in Title 10 of the Colorado Revised Statues.

1.200.8 Privacy and Confidentiality

1.200.8.A. Pursuant to C.R.S. § 24-72-204(3)(a)(I) medical and other health care data on individual persons is not an open record and the department shall deny any open records request for such information.

1.200.8.B. Certain aggregate and de-identified data reports from the APCD shall be available to the public pursuant to C.R.S. § 25.5-1-204(7) when disclosed in a form and manner that ensures the privacy and security of protected health information in compliance with HIPAA.

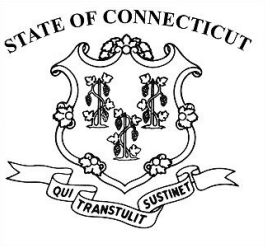
1.200.8.C. The administrator shall institute appropriate administrative, physical and technical safeguards to ensure that the APCD, its operations, data collection and storage, and reporting disclosures are in compliance with the requirements of HIPAA. All eligibility claims data, medical, dental, and pharmacy claims data shall be transmitted to the APCD and stored by the APCD in a secure manner compliant with HIPAA.

1.200.9 Incorporation by Reference

1.200.9A The rules incorporate by reference (as indicated within) material originally published elsewhere. Such incorporation, however, excludes later amendments to or editions of the referenced material. Pursuant to C.R.S. § 24-4-103(12.5), the Department of Health Care Policy and Financing maintains copies of the incorporated texts in their entirety which shall be available for public inspection during regular business hours at:

Colorado Department of Health Care Policy and Financing
Medical Services Board Coordinator
1570 Grant Street
Denver, CO 80203

Copies of material shall be provided by the department, at cost, upon request.



Substitute House Bill No. 5384

Public Act No. 18-41

AN ACT CONCERNING PRESCRIPTION DRUG COSTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective January 1, 2020*) For the purposes of this section and sections 2 to 6, inclusive, of this act:

(1) "Commissioner" means the Insurance Commissioner.

(2) "Department" means the Insurance Department.

(3) "Drug" has the same meaning as provided in section 21a-92 of the general statutes.

(4) "Health care plan" means an individual or a group health insurance policy that provides coverage of the types specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes and includes coverage for outpatient prescription drugs.

(5) "Health carrier" means an insurance company, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues a health care plan in this state.

(6) "Person" has the same meaning as provided in section 38a-1 of

the general statutes.

(7) "Pharmacist" has the same meaning as provided in section 38a-479aaa of the general statutes.

(8) "Pharmacist services" has the same meaning as provided in section 38a-479aaa of the general statutes.

(9) "Pharmacy" has the same meaning as provided in section 38a-479aaa of the general statutes.

(10) "Pharmacy benefits manager" or "manager" means any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health care plan on behalf of a health carrier.

(11) (A) "Rebate" means a discount or concession, which affects the price of an outpatient prescription drug, that a pharmaceutical manufacturer directly provides to a (i) health carrier for an outpatient prescription drug manufactured by the pharmaceutical manufacturer, or (ii) pharmacy benefits manager after the manager processes a claim from a pharmacy or a pharmacist for an outpatient prescription drug manufactured by the pharmaceutical manufacturer.

(B) "Rebate" does not mean a bona fide service fee, as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, as amended from time to time.

(12) "Specialty drug" means a prescription outpatient specialty drug covered under the Medicare Part D program established pursuant to Public Law 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended from time to time, that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

Sec. 2. (NEW) (*Effective January 1, 2020*) (a) Not later than March 1, 2021, and annually thereafter, each pharmacy benefits manager shall file a report with the commissioner for the immediately preceding calendar year. The report shall contain the following information for health carriers that delivered, issued for delivery, renewed, amended or continued health care plans that included a pharmacy benefit managed by the pharmacy benefits manager during such calendar year:

(1) The aggregate dollar amount of all rebates concerning drug formularies used by such health carriers that such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that (A) were covered by such health carriers during such calendar year, and (B) are attributable to patient utilization of such drugs during such calendar year; and

(2) The aggregate dollar amount of all rebates, excluding any portion of the rebates received by such health carriers, concerning drug formularies that such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that (A) were covered by such health carriers during such calendar year, and (B) are attributable to patient utilization of such drugs by covered persons under such health care plans during such calendar year.

(b) The commissioner shall establish a standardized form for reporting information pursuant to subsection (a) of this section after consultation with pharmacy benefits managers. The form shall be designed to minimize the administrative burden and cost of reporting on the department and pharmacy benefits managers.

(c) All information submitted to the commissioner pursuant to subsection (a) of this section shall be exempt from disclosure under the Freedom of Information Act, as defined in section 1-200 of the general statutes, except to the extent such information is included on an

aggregated basis in the report required by subsection (d) of this section. The commissioner shall not disclose information submitted pursuant to subdivision (1) of subsection (a) of this section, or information submitted pursuant to subdivision (2) of said subsection in a manner that (1) is likely to compromise the financial, competitive or proprietary nature of such information, or (2) would enable a third party to identify a health care plan, health carrier, pharmacy benefits manager, pharmaceutical manufacturer, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

(d) Not later than March 1, 2022, and annually thereafter, the commissioner shall submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to insurance. The report shall contain (1) an aggregation of the information submitted to the commissioner pursuant to subsection (a) of this section for the immediately preceding calendar year, and (2) such other information as the commissioner, in the commissioner's discretion, deems relevant for the purposes of this section. Not later than February 1, 2022, and annually thereafter, the commissioner shall provide each pharmacy benefits manager and any third party affected by submission of a report required by this subsection with a written notice describing the content of the report.

(e) The commissioner may impose a penalty of not more than seven thousand five hundred dollars on a pharmacy benefits manager for each violation of this section.

(f) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 3. (NEW) (*Effective January 1, 2020*) (a) Each health carrier that

delivers, issues for delivery, renews, amends or continues a health care plan on or after January 1, 2021, shall submit the following information and data to the commissioner, for such health care plan for the immediately preceding calendar year, at the time that such health carrier submits a rate filing for such health care plan pursuant to sections 38a-183 of the general statutes, as amended by this act, 38a-481 of the general statutes, as amended by this act, or 38a-513 of the general statutes, as amended by this act, as applicable:

(1) For covered outpatient prescription drugs that were prescribed to insureds under such health care plan during such calendar year, the names of:

(A) The twenty-five most frequently prescribed outpatient prescription drugs;

(B) The twenty-five outpatient prescription drugs that the health care plan covered at the greatest cost, calculated by using the total annual plan spending by such health care plan for each outpatient prescription drug; and

(C) The twenty-five outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated by using the total annual plan spending by such health care plan for each outpatient prescription drug.

(2) The portion of the premium for such health care plan that is attributable to each of the following categories of covered outpatient prescription drugs that were prescribed to insureds under such health care plan during such calendar year:

(A) Brand name drugs;

(B) Generic drugs; and

(C) Specialty drugs.

(3) The year-over-year increase, calculated on a per member, per month basis and expressed as a percentage, in the total annual cost of each category of covered outpatient prescription drugs set forth in subdivision (2) of this subsection.

(4) A comparison, calculated on a per member, per month basis, of the year-over-year increase in the cost of covered outpatient prescription drugs to the year-over-year increase in the costs of other contributors to the premium cost of such health care plan.

(5) The name of each specialty drug covered during such calendar year.

(6) The names of the twenty-five most frequently prescribed outpatient prescription drugs for which the health carrier received rebates from pharmaceutical manufacturers during such calendar year.

(b) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 4. (NEW) (*Effective January 1, 2020*) Beginning on March 1, 2022, and annually thereafter, each health carrier shall submit to the commissioner, in a form and manner prescribed by the commissioner, a written certification for the immediately preceding calendar year, certifying that the health carrier accounted for all rebates in calculating the premium for health care plans that such health carrier delivered, issued for delivery, renewed, amended or continued during such calendar year.

Sec. 5. (NEW) (*Effective January 1, 2020*) Not later than March 1, 2022, and annually thereafter, the commissioner shall submit a report, in accordance with section 11-4a of the general statutes, to the joint

standing committee of the General Assembly having cognizance of matters relating to insurance. The report shall contain (1) an aggregation of the information and data submitted to the commissioner pursuant to section 3 of this act for the immediately preceding calendar year, (2) a description of the impact of the cost of outpatient prescription drugs on health insurance premiums in this state, and (3) such other information as the commissioner, in the commissioner's discretion, deems relevant to the cost of outpatient prescription drugs in this state.

Sec. 6. (NEW) (*Effective January 1, 2020*) Not later than March 1, 2021, and annually thereafter, the commissioner shall prepare a report, for the immediately preceding calendar year, describing the rebate practices of health carriers. The report shall contain (1) an explanation of the manner in which health carriers accounted for rebates in calculating premiums for health care plans delivered, issued for delivery, renewed, amended or continued during such year, (2) a statement disclosing whether, and describing the manner in which, health carriers made rebates available to insureds at the point of purchase during such year, (3) any other manner in which health carriers applied rebates during such year, and (4) such other information as the commissioner, in the commissioner's discretion, deems relevant for the purposes of this section. The commissioner shall publish a copy of the report on the department's Internet web site.

Sec. 7. Section 38a-183 of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(a) (1) A health care center governed by sections 38a-175 to 38a-194, inclusive, shall not enter into any agreement with subscribers unless and until it has filed with the commissioner a full schedule of the amounts to be paid by the subscribers and has obtained the

commissioner's approval thereof. Such filing shall include the information and data required under section 3 of this act if the contract or policy is subject to said section, and an actuarial memorandum that includes, but is not limited to, pricing assumptions and claims experience, and premium rates and loss ratios from the inception of the contract or policy. The commissioner may refuse such approval if the commissioner finds such amounts to be excessive, inadequate or discriminatory. As used in this subsection, "loss ratio" means the ratio of incurred claims to earned premiums by the number of years of policy duration for all combined durations.

(2) Premium rates offered to individuals shall be consistent with the requirements set forth in section 38a-481, as amended by this act.

(3) Premium rates offered to small employers, as defined in section 38a-564, shall be consistent with the requirements set forth in section 38a-567.

(4) No such health care center shall enter into any agreement with subscribers unless and until it has filed with the commissioner a copy of such agreement or agreements, including all riders and endorsements thereon, and until the commissioner's approval thereof has been obtained. The commissioner shall, within a reasonable time after the filing of any request for an approval of the amounts to be paid, any agreement or any form, notify the health care center of the commissioner's approval or disapproval thereof.

(b) A health care center may establish rates of payment by any method permitted by the Federal Health Maintenance Organization Act and the regulations adopted thereunder from time to time unless otherwise determined by the commissioner by regulation.

(c) Each such health care center may include as a component of its rate a sum up to ten per cent of such rate to be used for the objects and

purposes set forth in section 38a-184. An amount not exceeding ten per cent of the annual net premium income of such center may be set aside annually as a capital reserve fund and may be accumulated from year to year by such health care center, to be expended for the objects and purposes as set forth and in accordance with said section.

(d) Each such health care center shall, if such health care center intends to account for rebates, as defined in section 1 of this act in the manner specified in section 4 of this act, account for such rebates in calculating premium rates offered on or after January 1, 2021, if such health care center is subject to section 4 of this act.

Sec. 8. Subsection (a) of section 38a-481 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(a) No individual health insurance policy shall be delivered or issued for delivery to any person in this state, nor shall any application, rider or endorsement be used in connection with such policy, until a copy of the form thereof and of the classification of risks and the premium rates have been filed with the commissioner. Rate filings shall include the information and data required under section 3 of this act if the policy is subject to said section, and an actuarial memorandum that includes, but is not limited to, pricing assumptions and claims experience, and premium rates and loss ratios from the inception of the policy. Each premium rate filed on or after January 1, 2021, shall, if the insurer intends to account for rebates, as defined in section 1 of this act in the manner specified in section 4 of this act, account for such rebates in such manner, if the policy is subject to section 4 of this act. The commissioner **[**shall**]** may adopt regulations, in accordance with the provisions of chapter 54, to establish a procedure for reviewing such policies. The commissioner shall disapprove the use of such form at any time if it does not comply with the requirements of law, or if it contains a provision or provisions that

are unfair or deceptive or that encourage misrepresentation of the policy. The commissioner shall notify, in writing, the insurer that has filed any such form of the commissioner's disapproval, specifying the reasons for disapproval, and ordering that no such insurer shall deliver or issue for delivery to any person in this state a policy on or containing such form. The provisions of section 38a-19 shall apply to such orders. As used in this subsection, "loss ratio" means the ratio of incurred claims to earned premiums by the number of years of policy duration for all combined durations.

Sec. 9. Subdivision (2) of subsection (a) of section 38a-513 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(2) No group health insurance policy or certificate for a small employer, as defined in section 38a-564, shall be delivered or issued for delivery in this state unless the premium rates have been submitted to and approved by the commissioner. Premium rate filings shall include the information and data required under section 3 of this act if the policy is subject to said section, and an actuarial memorandum that includes, but is not limited to, pricing assumptions and claims experience, and premium rates and loss ratios from the inception of the policy. Each premium rate filed on or after January 1, 2021, shall, if the insurer intends to account for rebates, as defined in section 1 of this act in the manner specified in section 4 of this act, account for such rebates in such manner, if the policy is subject to section 4 of this act. As used in this subdivision, "loss ratio" means the ratio of incurred claims to earned premiums by the number of years of policy duration for all combined durations.

Sec. 10. (NEW) (*Effective January 1, 2020*) (a) For the purposes of this section:

(1) "Accelerated approval" has the same meaning as provided in 21

USC 356, as amended from time to time;

(2) "Biologics license application" means an application filed pursuant to Section 601.2 of Title 21 of the Code of Federal Regulations, as amended from time to time;

(3) "Breakthrough therapy" has the same meaning as provided in 21 USC 356, as amended from time to time;

(4) "Drug" has the same meaning as provided in section 21a-92 of the general statutes;

(5) "Fast track product" has the same meaning as provided in 21 USC 356, as amended from time to time;

(6) "New drug application" has the same meaning as provided in Section 314.3 of Title 21 of the Code of Federal Regulations, as amended from time to time;

(7) "New molecular entity" has the same meaning as such term is used in 21 USC 355-1, as amended from time to time;

(8) "Orphan drug" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations, as amended from time to time;

(9) "Pipeline drug" means a drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration;

(10) "Prescription drug" means a drug prescribed by a health care provider to an individual in this state;

(11) "Priority review" has the same meaning as such term is used in 21 USC 356, as amended from time to time;

(12) "Rebate" has the same meaning as provided in section 1 of this act;

(13) "Research and development cost" means a cost that a pharmaceutical manufacturer incurs in researching and developing a new product, process or service, including, but not limited to, a cost that a pharmaceutical manufacturer incurs in researching and developing a product, process or service that the pharmaceutical manufacturer has acquired from another person by license;

(14) "Sponsor" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations, as amended from time to time; and

(15) "Wholesale acquisition cost" has the same meaning as provided in 42 USC 1395w-3a, as amended from time to time.

(b) Beginning on January 1, 2020, each sponsor shall submit to the Office of Health Strategy, established in section 19a-754a of the general statutes, in a form and manner specified by the office, written notice informing the office that such sponsor has filed with the federal Food and Drug Administration:

(1) A new drug application or biologics license application for a pipeline drug, not later than sixty days after such sponsor receives an action date from the federal Food and Drug Administration regarding such application; or

(2) A biologics license application for a biosimilar drug, not later than sixty days after such sponsor's receipt of an action date from the federal Food and Drug Administration regarding such application.

(c) (1) Beginning on January 1, 2020, the executive director of the Office of Health Strategy may conduct a study, with the assistance of the Comptroller and not more frequently than once annually, of each

pharmaceutical manufacturer of a pipeline drug that, in the opinion of the executive director in consultation with the Comptroller and the Commissioner of Social Services, may have a significant impact on state expenditures for outpatient prescription drugs. The office may work with the Comptroller to utilize existing state resources and contracts, or contract with a third party, including, but not limited to, an accounting firm, to conduct such study.

(2) Each pharmaceutical manufacturer that is the subject of a study conducted pursuant to subdivision (1) of this subsection shall submit to the office, or any contractor engaged by the office or the Comptroller to perform such study, the following information for the pipeline drug that is the subject of such study:

(A) The primary disease, condition or therapeutic area studied in connection with such drug, and whether such drug is therapeutically indicated for such disease, condition or therapeutic area;

(B) Each route of administration studied for such drug;

(C) Clinical trial comparators, if applicable, for such drug;

(D) The estimated year of market entry for such drug;

(E) Whether the federal Food and Drug Administration has designated such drug as an orphan drug, a fast track product or a breakthrough therapy; and

(F) Whether the federal Food and Drug Administration has designated such drug for accelerated approval and, if such drug contains a new molecular entity, for priority review.

(d) (1) On or before March 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy, in consultation with the Comptroller, Commissioner of Social Services and Commissioner

of Public Health, shall prepare a list of not more than ten outpatient prescription drugs that the executive director, in the executive director's discretion, determines are (A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and at least one generic outpatient prescription drug.

(2) The executive director shall not list any outpatient prescription drug under subdivision (1) of this subsection unless the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, (A) increased by at least (i) twenty per cent during the immediately preceding calendar year, or (ii) fifty per cent during the immediately preceding three calendar years, and (B) was not less than sixty dollars for (i) a thirty-day supply of such drug, or (ii) a course of treatment of such drug lasting less than thirty days.

(3) (A) The pharmaceutical manufacturer of an outpatient prescription drug included on a list prepared by the executive director pursuant to subdivision (1) of this subsection shall provide to the office, in a form and manner specified by the executive director, (i) a written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug, and (ii) aggregate, company-level research and development costs and such other capital expenditures that the executive director, in the executive director's discretion, deems relevant for the most recent year for which final audited data are available.

(B) The quality and types of information and data that a pharmaceutical manufacturer submits to the office under this subdivision shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes

in (i) such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (ii) any other public disclosure.

(4) The office shall establish a standardized form for reporting information and data pursuant to this subsection after consulting with pharmaceutical manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the office and pharmaceutical manufacturers.

(e) The office may impose a penalty of not more than seven thousand five hundred dollars on a pharmaceutical manufacturer or sponsor for each violation of this section by the pharmaceutical manufacturer or sponsor.

(f) The office may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to carry out the purposes of this section.

Sec. 11. Subsection (a) of section 38a-477d of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(a) Each insurer, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues a health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 in this state, shall:

(1) Make available to consumers, in an easily readable, accessible and understandable format, the following information for each such policy: (A) Any coverage exclusions; (B) any restrictions on the use or quantity of a covered benefit, including on prescription drugs or drugs administered in a physician's office or a clinic; (C) a specific

description of how prescription drugs are included or excluded from any applicable deductible, including a description of other out-of-pocket expenses that apply to such drugs; **[**and**]** (D) the specific dollar amount of any copayment and the percentage of any coinsurance imposed on each covered benefit, including each covered prescription drug; and (E) information regarding any process available to consumers, and all documents necessary, to seek coverage of a noncovered outpatient prescription drug;

(2) Make available to consumers a way to determine accurately (A) whether a specific prescription drug is available under such policy's drug formulary; (B) the coinsurance, copayment, deductible or other out-of-pocket expense applicable to such drug; (C) whether such drug is covered when dispensed by a physician or a clinic; (D) whether such drug requires prior authorization or the use of step therapy; (E) whether specific types of health care specialists are in-network; and (F) whether a specific health care provider or hospital is in-network.

Approved May 31, 2018

SPONSOR: Rep. Carson & Sen. Poore

HOUSE OF REPRESENTATIVES
149th GENERAL ASSEMBLY

HOUSE BILL NO. 441
AS AMENDED BY
HOUSE AMENDMENT NO. 1

AN ACT TO AMEND TITLE 18 OF THE DELAWARE CODE RELATING TO PHARMACY BENEFIT MANAGER PRIOR AUTHORIZATION OF EMERGENCY PRESCRIPTIONS AND PRESCRIPTIONS FOR CHRONIC OR LONG-TERM CONDITIONS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

Subchapter III. Prior Authorization of Emergency Prescriptions and Prescriptions for Chronic or Long-Term Conditions

§ 3331A Definitions.

As used in this subchapter:

(1) “Emergency” means a situation that will result in loss of life, limb or organ function.

(2) "Prior authorization" means a requirement by a carrier or health-insurance plan that providers submit a request or other prior notification to the carrier for evaluation of appropriateness of the request or if the prescription is medically necessary before treatment is rendered. Prior authorization lets the insured and provider know in advance which pharmaceuticals are considered by the insurer to be medically necessary.

(3) "Pharmacy benefit manager" has the meaning given in § 3302A of this title.

§ 3332A Prior Authorization of Emergency Prescriptions.

(a) A pharmacy benefit manager may not require prior authorization for coverage of a 72 hour supply of medication that is for a non-controlled substance in an emergency situation.

§ 3333A Prior Authorization of Prescriptions for Chronic or Long-Term Conditions.

(a) A prior authorization form for a prescription medication shall include a question regarding whether the prescription medication is for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient.

(b) If a prescriber indicates on a prior authorization form that the prescription medication is for a chronic or long-term condition for which the prescription medication may be necessary for the life of the patient, the pharmacy benefit manager may not request a reauthorization for the same prescription medication more frequently than every 12 months.

HD : MRS : TEH : 1031490502
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(c) In the same communication in which a pharmacy benefit manager or the pharmacy benefit manager's agent requests a prior authorization for a prescription medication that has therapeutically equivalent medications that do not require a prior authorization from a prescriber, the pharmacy benefit manager or the pharmacy benefit manager's agent shall provide the prescriber with a list of alternative prescription medications of the same class and family as the requested medication.

(d) Prescribers that utilize e-prescribing shall receive alternate medications from the pharmacy benefit manager for prescription medications that do not require a prior authorization before the completion of the e-prescribing transaction.

(e) A pharmacy benefit manager or the pharmacy benefit manager's agent shall provide alternative medications for therapeutically equivalent medications to the pharmacy that require prior authorization on the National Council for Prescription Drug Programs response transaction to a denied claim for prior authorization.

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Managed Care Reform and Patient Rights Act is amended by changing Section 25 as follows:

(215 ILCS 134/25)

Sec. 25. Transition of services.

(a) A health care plan shall provide for continuity of care for its enrollees as follows:

(1) If an enrollee's physician leaves the health care plan's network of health care providers for reasons other than termination of a contract in situations involving imminent harm to a patient or a final disciplinary action by a State licensing board and the physician remains within the health care plan's service area, the health care plan shall permit the enrollee to continue an ongoing course of treatment with that physician during a transitional period:

(A) of 90 days from the date of the notice of physician's termination from the health care plan to the enrollee of the physician's disaffiliation from the health care plan if the enrollee has an ongoing course of treatment; or

(B) if the enrollee has entered the third trimester of pregnancy at the time of the physician's disaffiliation, that includes the provision of post-partum care directly related to the delivery.

(2) Notwithstanding the provisions in item (1) of this subsection, such care shall be authorized by the health care plan during the transitional period only if the physician agrees:

(A) to continue to accept reimbursement from the health care plan at the rates applicable prior to the start of the transitional period;

(B) to adhere to the health care plan's quality assurance requirements and to provide to the health care plan necessary medical information related to such care; and

(C) to otherwise adhere to the health care plan's policies and procedures, including but not limited to procedures regarding referrals and obtaining preauthorizations for treatment.

(3) During an enrollee's plan year, a health care plan shall not remove a drug from its formulary or negatively change its preferred or cost-tier sharing unless, at least 60 days before making the formulary change, the health care plan:

(A) provides general notification of the change in its formulary to current and prospective enrollees;

(B) directly notifies enrollees currently receiving coverage for the drug, including information on the specific drugs involved and the steps they may take to request coverage determinations and exceptions, including a statement that a certification of medical necessity by the enrollee's prescribing provider will result in continuation of coverage at the existing level; and

(C) directly notifies by first class mail and through an electronic transmission, if available, the prescribing provider of all health care plan enrollees currently prescribed the drug affected by the proposed change; the notice shall include a one-page form by which the prescribing provider can notify the health care plan by first class mail that coverage of the drug for the enrollee is medically necessary.

The notification in paragraph (C) may direct the prescribing provider to an electronic portal through which the prescribing provider may electronically file a certification to the health care plan that coverage of the drug for the enrollee is medically necessary. The prescribing provider may make a secure electronic signature beside the words "certification of medical necessity", and this certification shall authorize continuation of coverage for the drug.

If the prescribing provider certifies to the health

care plan either in writing or electronically that the drug is medically necessary for the enrollee as provided in paragraph (C), a health care plan shall authorize coverage for the drug prescribed based solely on the prescribing provider's assertion that coverage is medically necessary, and the health care plan is prohibited from making modifications to the coverage related to the covered drug, including, but not limited to:

(i) increasing the out-of-pocket costs for the covered drug;

(ii) moving the covered drug to a more restrictive tier; or

(iii) denying an enrollee coverage of the drug for which the enrollee has been previously approved for coverage by the health care plan.

Nothing in this item (3) prevents a health care plan from removing a drug from its formulary or denying an enrollee coverage if the United States Food and Drug Administration has issued a statement about the drug that calls into question the clinical safety of the drug, the drug manufacturer has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by Section 506C of the Federal Food, Drug, and Cosmetic Act, as codified in 21 U.S.C. 356c, or the drug manufacturer has removed the drug from the market.

Nothing in this item (3) prohibits a health care plan, by contract, written policy or procedure, or any other agreement or course of conduct, from requiring a pharmacist to effect substitutions of prescription drugs consistent with Section 19.5 of the Pharmacy Practice Act, under which a pharmacist may substitute an interchangeable biologic for a prescribed biologic product, and Section 25 of the Pharmacy Practice Act, under which a pharmacist may select a generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration and in accordance with the Illinois Food, Drug and Cosmetic Act.

This item (3) applies to a policy or contract that is amended, delivered, issued, or renewed on or after January 1, 2019. This item (3) does not apply to a health plan as defined in the State Employees Group Insurance Act of 1971 or medical assistance under Article V of the Illinois Public Aid Code.

(b) A health care plan shall provide for continuity of care for new enrollees as follows:

(1) If a new enrollee whose physician is not a member of the health care plan's provider network, but is within the health care plan's service area, enrolls in the health care plan, the health care plan shall permit the enrollee to continue an ongoing course of treatment with the enrollee's current physician during a transitional period:

(A) of 90 days from the effective date of

enrollment if the enrollee has an ongoing course of treatment; or

(B) if the enrollee has entered the third trimester of pregnancy at the effective date of enrollment, that includes the provision of post-partum care directly related to the delivery.

(2) If an enrollee elects to continue to receive care from such physician pursuant to item (1) of this subsection, such care shall be authorized by the health care plan for the transitional period only if the physician agrees:

(A) to accept reimbursement from the health care plan at rates established by the health care plan; such rates shall be the level of reimbursement applicable to similar physicians within the health care plan for such services;

(B) to adhere to the health care plan's quality assurance requirements and to provide to the health care plan necessary medical information related to such care; and

(C) to otherwise adhere to the health care plan's policies and procedures including, but not limited to procedures regarding referrals and obtaining preauthorization for treatment.

(c) In no event shall this Section be construed to require a health care plan to provide coverage for benefits not

otherwise covered or to diminish or impair preexisting condition limitations contained in the enrollee's contract. In no event shall this Section be construed to prohibit the addition of prescription drugs to a health care plan's list of covered drugs during the coverage year.

(Source: P.A. 91-617, eff. 7-1-00.)

Section 99. Effective date. This Act takes effect upon becoming law.

ENROLLED

2018 Regular Session

ACT No. 597

HOUSE BILL NO. 436

BY REPRESENTATIVES JOHNSON AND LEBAS

AN ACT

To amend and reenact R.S. 22:1060.6(B), 1863(introductory paragraph), (1), and (6), 1864(A)(introductory paragraph) and (3) and (B)(introductory paragraph), and 1865 and to enact R.S. 22:1060.6(C), 1860.3, 1863(8), 1864(A)(4), and 1866, relative to coverage of prescription drugs; to prohibit limitations on certain disclosures by pharmacists; to update terminology; to provide for reimbursements to nonaffiliate pharmacies; to require disclosures by pharmacy benefit managers; to provide for appeals relative to maximum allowable cost; to impose a fee on pharmacy benefit managers; to provide for an effective date; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1060.6(B), 1863(introductory paragraph), (1), and (6), 1864(A)(introductory paragraph) and (3) and (B)(introductory paragraph) and 1865 are hereby amended and reenacted and R.S. 22:1060.6(C), 1860.3, 1863(8), 1864(A)(4), and 1866, are hereby enacted to read as follows:

§1060.6. Limitation; patient payment

* * *

B. ~~The provision established in Subsection A of this Section shall become effective on January 1, 2017.~~ No pharmacy benefit manager, insurer, or other entity that administers prescription drug benefits programs in this state shall prohibit by contract a pharmacy or pharmacist from informing a patient of all relevant options when acquiring his prescription medication, including but not limited to the cost and clinical efficacy of a more affordable alternative if one is available and the ability to pay cash if a cash price for the same drug is less than an insurance copayment or deductible payment amount.

C. Any provision of a contract that violates the provisions of this Section shall be unenforceable and shall be deemed an unfair or deceptive act and practice pursuant to R.S. 22:1961 et seq.

* * *

§1860.3. Reimbursements

A pharmacy benefit manager or person acting on behalf of a pharmacy benefit manager shall not reimburse a pharmacy or pharmacist in this state an amount less than the amount that the pharmacy benefit manager reimburses an affiliate of the pharmacy benefit manager for providing the same services. The amount shall be calculated on a per-unit basis using the same generic product identifier or generic code number.

* * *

§1863. Definitions

As used in this Subpart, the following definitions ~~shall~~ apply:

(1) "Maximum Allowable Cost List" means a listing of the National Drug Code used by a pharmacy ~~benefits~~ benefit manager setting the maximum allowable cost on which reimbursement to a pharmacy or pharmacist may be based.

* * *

(6) "Pharmacy ~~benefits~~ benefit manager" means an entity that administers or manages a pharmacy benefits plan or program.

* * *

(8) "Drug Shortage List" means a list of drug products posted on the United States Food and Drug Administration drug shortage website.

§1864. Requirements for use of the National Drug Code by a pharmacy ~~benefits~~ benefit manager

A. Before a pharmacy ~~benefits~~ benefit manager places or continues a particular NDC or Maximum Allowable Cost List, the following requirements shall be met:

* * *

(3) The prescription drug to which the NDC is assigned shall not be considered obsolete, temporarily unavailable, or listed on a drug shortage list.

(4) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all pharmacies both of the following:

(a) Information identifying the national drug pricing compendia or sources used to obtain the drug price data.

(b) The comprehensive list of drugs subject to maximum allowable cost by plan and the actual maximum allowable cost by plan for each drug.

B. A pharmacy ~~benefits~~ benefit manager shall ~~be required to~~ do all of the following:

* * *

§1865. Appeals

A. The pharmacy ~~benefits~~ benefit manager shall provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs for a specific NDC or NDCs as not meeting the requirements of this Subpart or being below the cost at which the pharmacy may obtain the NDC. Within ~~seven~~ fifteen business days after the applicable fill date, a pharmacy may file an appeal by following the appeal process as provided for in this Subpart. The pharmacy ~~benefits~~ benefit manager shall respond to a challenge within ~~seven~~ fifteen business days after receipt of the challenge.

B. If an appeal made pursuant to this Section is ~~upheld,~~ granted, the pharmacy ~~benefits~~ benefit manager shall take all of the following actions:

(1) Make the change in the Maximum Allowable Cost List to the initial date of service the appealed drug was dispensed.

(2) Permit the ~~challenging~~ appealing pharmacy ~~or pharmacist~~ and all other pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and ~~rebill the claim in question.~~ resubmit claims

and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed.

(3) Make the change effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List. and individually notify all pharmacies in the network of that pharmacy benefit manager of both of the following:

(a) That a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed.

(b) That the pharmacy may resubmit and receive payment based upon the adjusted maximum allowable cost price.

(4) Make retroactive price adjustments in the next payment cycle.

C. If an appeal made pursuant to this Section is denied, the pharmacy ~~benefits~~ benefit manager shall provide the challenging pharmacy or pharmacist the NDC number of a drug product and source where it may be purchased for a price at or below the maximum allowable cost from national or regional wholesalers operating in Louisiana.

D. A violation of this Subpart shall be deemed an unfair or deceptive act and practice pursuant to R.S. 22:1961 et seq.

E. For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to the commissioner, upon request, information that is needed to resolve the complaint. If the commissioner is unable to obtain information from the pharmacy benefit manager that is necessary to resolve the complaint, the reimbursement amount requested in the pharmacist's appeal shall be granted.

F.(1) A pharmacist or pharmacy may file a complaint with the commissioner following an appeal denied by the pharmacy benefit manager.

(2) A complaint shall be submitted to the commissioner, on a form and in a manner set forth by the commissioner, no later than fifteen business days from the date of the pharmacy benefit manager's final decision.

(3) The commissioner may request additional information necessary to investigate a complaint from any party.

(4) If the complaint investigation determines that the pharmacy benefit manager's final decision was not in compliance with the provisions of this Section, the appealing pharmacy shall be reimbursed the higher of the pharmacy's actual acquisition cost of the drug or the maximum allowable cost price.

(5) Information specifically designated as proprietary by the pharmacy benefit manager shall be given confidential treatment pursuant to R.S. 22:1656. The commissioner shall determine the appropriateness and validity of the designation.

G. The commissioner may impose a reasonable fee upon pharmacy benefit managers, in accordance with the Administrative Procedure Act, in addition to a license fee and annual report fee, in order to cover the costs of implementation and enforcement of this Section and R.S. 22:1641 through 1657, 1851 through 1864, and 1961 through 1995, including fees to cover the cost of all of the following:

(1) Salaries and related benefits paid to the personnel of the department engaged in the investigation and enforcement.

(2) Reasonable technology costs related to the investigatory and enforcement process. Technology costs shall include the actual cost of software and hardware used in the investigatory and enforcement process and the cost of training personnel in the proper use of the software or hardware.

(3) Reasonable education and training costs incurred by the state to maintain the proficiency and competence of investigatory and enforcement personnel.

§1866. Rulemaking authority; administrative appeals

A. The commissioner may promulgate rules and regulations in accordance with the Administrative Procedure Act that are necessary or proper to carry out the provisions of this Subpart.

B. Any pharmacy benefit manager, insurer, or other entity that administers prescription drug benefits programs in the state that is aggrieved by an act of the commissioner may apply for a hearing pursuant to Chapter 12 of this Title, R.S. 22:2191 et seq.

Section 2. This Act shall become effective on January 1, 2019.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

2018 Regular Session

ACT No. 423

ENROLLED

SENATE BILL NO. 29

BY SENATOR MILLS

AN ACT

To amend and reenact R.S. 22:1006.1(A)(4) and (B) and R.S. 46:460.33 and to enact R.S. 22:1006.1(C), (D), and (E), and 1651(J), relative to a single uniform prescription drug prior authorization form; to provide for applicability to health insurance issuers and Medicaid managed care organizations; to provide for promulgation of the form by the Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners; to provide for the authority to impose sanctions pursuant to current regulatory and contract authority; to provide for licensure requirement; to provide for an effective date; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1006.1(A)(4) and (B) are hereby amended and reenacted and R.S. 22:1006.1(C), (D), and (E) and 1651(J) are hereby enacted to read as follows:

§1006.1. Prior authorization forms required; criteria

A. As used in this Section:

* * *

(4) "Prior authorization form" shall mean a ~~standardized, uniform application developed by a health insurance issuer~~ **single uniform prescription drug prior authorization form used by all health insurance issuers, including any health insurance issuer pharmacy benefit managers,** for the purpose of obtaining prior authorization.

B. Notwithstanding any other provision of law to the contrary, in order to establish uniformity in the submission of **prescription drug** prior authorization forms, on and after January 1, ~~2013~~ **2019**, a health insurance issuer shall utilize only a single~~, standardized prior authorization~~ **uniform prescription drug prior authorization** form for obtaining any prior authorization for prescription drug benefits. **The requirement for a single uniform prescription drug prior authorization form shall not apply to prior authorization of specialty drugs or**

in cases where electronic prescriptions are utilized. The form shall not exceed two pages in length, excluding any instructions or guiding documentation. **The only form allowable for use shall be the form jointly promulgated by the Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners. A health insurance issuer may include issuer specific information on the form, including but not limited to the issuer's name, address, logo, and other contact information for the issuer.** A health insurance issuer may make the form accessible through multiple computer operating systems. ~~Additionally, the health insurance issuer shall submit its prior authorization forms to the Department of Insurance to be kept on file on or after January 1, 2013. A copy of any subsequent replacements or modifications of a health insurance issuer's prior authorization form shall be filed with the Department of Insurance within fifteen days prior to use or implementation of such replacements or modifications.~~

C. The Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners shall promulgate rules and regulations prior to January 1, 2019, that establish the form that shall be utilized by all health insurance issuers. The boards may consult with the health insurance issuers, Medicaid managed care organizations, Louisiana Department of Health, and Department of Insurance as necessary in development of the prior authorization form.

D. The Department of Insurance, under its authority in this Title, shall assess sanctions against any health insurance issuer that directly, or through its pharmacy benefit managers, utilizes any prescription drug prior authorization form other than the single uniform prescription drug prior authorization form provided for in this Section.

E. The single uniform prescription drug prior authorization form provided for in this Section shall be the same as provided for in R.S. 46:460.33.

§1651. Licensure required

* * *

J.(1) Notwithstanding any provision of law to the contrary, an insurer or pharmacy benefit manager shall not require any license, accreditation,

affiliation, or registration other than those required by federal or state government. Any contract provision in conflict with this Subsection shall be severable from the contract, considered null and void, and not enforceable in this state.

(2) If any insurer or pharmacy benefit manager denies the jurisdiction, regulatory, or licensing authority of the Department of Insurance, the attorney general shall have authority to enforce any provisions of this Subsection, as well as subjecting the insurer or pharmacy benefit manager to the provisions of R.S. 51:1401 et seq.

Section 2. R.S. 46:460.33 is hereby amended and reenacted to read as follows:

§460.33. Prior authorization form; requirements

A. **There shall be a single uniform prescription drug prior authorization form used by all Medicaid managed care organizations, including any Medicaid managed care organization pharmacy benefit managers. The requirement for a single uniform prescription drug prior authorization form shall not apply to prior authorization of specialty drugs or in cases where electronic prescriptions are utilized.** All managed care organizations shall ~~accept, in addition to any currently accepted facsimile and electronic prior authorization forms, a standard~~ **use a single uniform prescription drug** prior authorization form, not to exceed two pages, excluding guidelines or instructions, that has been ~~duly~~ **jointly** promulgated by the ~~department~~ **Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners** in accordance with the Administrative Procedure Act. **A Medicaid managed care organization may include organization specific information on the form, including but not limited to the organization's name, address, logo, and other contact information for the organization.** A health care provider may submit the prior authorization form electronically if the **Medicaid** managed care organization allows for submission of the form in this manner.

B. The ~~department~~ **Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners** shall promulgate rules and regulations prior to January 1, ~~2014~~ **2019**, that establish the form which shall be utilized by all **Medicaid**

managed care organizations. The ~~department~~ **boards** may consult with the **health insurance issuers, Medicaid** managed care organizations**, Louisiana Department of Health, and Department of Insurance** as necessary in development of the prior authorization form.

C. Pursuant to its contract with any Medicaid managed care organization, the department shall assess sanctions against any Medicaid managed care organization that directly or through its pharmacy benefit managers, utilizes any prescription drug prior authorization form other than the single uniform prescription drug prior authorization form provided for in this Section.

D. The single uniform prescription drug prior authorization form provided for in this Section shall be the same as provided for in R.S. 22:1006.1.

Section 3. The provisions of this Section and Section 1 of this Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Section and Section 1 of this Act shall become effective on the day following such approval.

Section 4. The provisions of this Section and Section 2 of this Act shall become effective on January 1, 2019.

_____
PRESIDENT OF THE SENATE

_____
SPEAKER OF THE HOUSE OF REPRESENTATIVES

_____
GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

2018 Regular Session

ACT No. 482

ENROLLED

SENATE BILL NO. 108

BY SENATOR JOHNS

AN ACT

To amend and reenact R.S. 40:1253.2(A)(1)(g) and (h) and (B) and to enact R.S. 40:1253.2(A)(3)(g)(v) through (vii), (C), and (D), relative to the Medicaid managed care annual report; to provide for report data; to provide for quarterly submission of certain data regarding Medicaid expansion population and services; to provide for quarterly submission of certain data regarding pharmacy benefit managers; to provide for an effective date; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1253.2(A)(1)(g) and (h) and (B) are hereby amended and reenacted and R.S. 40:1253.2(A)(3)(g)(v) through (vii), (C), and (D) are hereby enacted to read as follows:

§1253.2. Medicaid managed care program; reporting

A. The Louisiana Department of Health shall submit an annual report concerning the Louisiana Medicaid managed care program and, if not included within that program, any managed care program providing dental benefits to Medicaid enrollees to the ~~Senate~~ **senate** and ~~House~~ **house** committees on health and welfare. The department shall submit the report by June thirtieth every year, and the applicable reporting period shall be for the previous state fiscal year except for those measures that require reporting of health outcomes which shall be reported for the calendar year prior to the current state fiscal year. The report shall include:

(1) Except when inapplicable due to the types of healthcare benefits administered by the particular managed care organization, the following information related to the managed care organizations contracted with the state to provide Medicaid-covered healthcare services to Medicaid enrollees:

* * *

(g)**(i)** The medical loss ratio of each managed care organization and the amount of any refund to the state for failure to maintain the required medical loss

ratio.

(ii) With respect to the monies comprising the managed care organization's medical loss ratio, the report shall include the following information:

(aa) Total expenditures on patient care.

(bb) Total expenditures on healthcare quality improvements.

(cc) Total expenditures on healthcare information technology.

(dd) Total expenditures on goods and services other than patient care, healthcare quality improvements, and healthcare information technology.

(h) ~~A comparison of health outcomes, which includes but is not limited to the following, among each managed care organization:~~

~~(i) Adult asthma admission rate.~~

~~(ii) Congestive heart failure admission rate.~~

~~(iii) Uncontrolled diabetes admission rate.~~

~~(iv) Adult access to preventative/ambulatory health services.~~

~~(v) Breast cancer screening rate.~~

~~(vi) Well child visits.~~

~~(vii) Childhood immunization rates~~ **A copy of the annual external quality review technical report produced pursuant to 42 CFR 438.364**.

* * *

(3) The following information related to healthcare services provided by healthcare providers to Medicaid enrollees enrolled in each of the managed care organizations:

* * *

(g) The following information concerning pharmacy benefits delineated by each managed care organization and by month:

* * *

(v) The average and range of times for responding to prior authorization requests.

(vi) The number of prior authorization requests denied, delineated by

the reasons for denial.

(vii) The number of claims denied after prior authorization was approved, delineated by the reasons for denial.

B.**(1) The Louisiana Department of Health shall submit quarterly reports to the senate and house committees on health and welfare concerning the Medicaid expansion population and service utilization. The reports shall include all of the following:**

(a) Medicaid expansion population data which shall include the following:

(i) Number of individuals enrolled in Medicaid for the reporting period who are eligible as part of the expansion population.

(ii) Number of individuals in the expansion population age nineteen to forty-nine and number of individuals age fifty to sixty-four.

(iii) Number of individuals in the expansion population in each age category with earned income.

(iv) Number of individuals in the expansion population in each age category assigned to a Medicaid managed care organization, identified by each individual managed care organization.

(v) The per-member per-month cost paid to each managed care organization to manage the care of the individuals in the expansion population assigned to their plan, identified by each individual managed care organization.

(b) Medicaid expansion population utilization data shall include the following:

(i) Comparison of individuals age nineteen to forty-nine, age fifty to sixty-four, and those who are covered by Medicaid who are not part of the expansion population utilizing the following services during the reporting period:

(aa) Emergency department.

(bb) Prescription drugs.

(cc) Physician services.

(dd) Hospital services.

(ee) Nonemergency medical transportation.

(ii) Expenditures associated with each service for individuals in the expansion population age nineteen to forty-nine, age fifty to sixty-four, and those who are covered by Medicaid who are not part of the expansion population during the reporting period.

(2) The quarterly reports required in this Subsection shall be submitted on the twentieth day of July, October, January, and April of each year, to include the data required in this Subsection, identified by month for the prior three months, with a collective chart of all data submitted to be included in the annual report provided for in Subsection A of this Section.

C.(1) The Louisiana Department of Health shall submit quarterly reports to the senate and house committees on health and welfare encompassing the following data regarding the Medicaid managed care organizations' pharmacy benefit managers:

(a) The name of each pharmacy benefit manager, identified as contracted or owned by the Medicaid managed care organization.

(b) Whether the pharmacy benefit manager is a subsidiary of the parent company of the Medicaid managed care organization.

(c) The total dollar amount paid to the pharmacy benefit manager by the Medicaid managed care organization as a transaction fee for each processed claim.

(d) The total dollar amount of the Medicaid drug rebates and manufacturer discounts collected and retained by the Medicaid managed care organization and pharmacy benefit manager.

(e) The total dollar amount of the Medicaid drug rebates and manufacturer discounts collected by the Medicaid managed care organization and pharmacy benefit manager and remitted to the Louisiana Department of Health.

(f) The total dollar amount retained by the pharmacy benefit manager

through spread pricing. For purposes of this Subparagraph, "spread pricing" means the actual amount paid as reimbursement to a pharmacist as compared to the amount the pharmacy benefit manager charged to and was reimbursed by the Medicaid managed care organization to identify the excess amount paid to the pharmacy benefit manager above what was paid to the pharmacist.

(g) Identification of any other monies retained by the pharmacy benefit manager not otherwise provided for in this Subsection that are not reimbursed to pharmacists.

(2) The quarterly reports required in this Subsection shall be submitted on the twentieth day of July, October, January, and April of each year, to include the data required in this Subsection, identified by month for the prior three months, with a collective chart of all data submitted to be included in the annual report provided for in Subsection A of this Section.

D. To the greatest extent possible, the Louisiana Department of Health shall include in the report at least three years of historical data for each of the measures set forth in Subsection A of this Section.

Section 2. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

_____

PRESIDENT OF THE SENATE

_____

SPEAKER OF THE HOUSE OF REPRESENTATIVES

_____

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

2018 Regular Session

ACT No. 579

ENROLLED

SENATE BILL NO. 282

BY SENATORS MILLS AND BARROW

AN ACT

To amend and reenact R.S. 44:4.1(B)(11) and to enact R.S. 22:976, relative to prescription drug pricing; to provide for confidentiality; to provide for disclosure; to provide for information available to the commissioner of insurance; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:976 is hereby enacted to read as follows:

§976. Disclosure of prescription drug consumer cost burden; certification

A. As used in this Section:

(1) "Excess consumer cost burden" means an amount charged to an enrollee for a covered prescription drug that is greater than the amount that an enrollee's health insurance issuer pays, or would pay absent the enrollee cost sharing, after accounting for an issuer's estimate of at least fifty percent of future rebate payments for that enrollee's actual point of sale prescription drug claim.

(2) "Health benefit plan", "plan", "benefit", or "health insurance coverage" means services consisting of medical care provided directly through insurance, reimbursement, or other means, and including items and services paid for as medical care under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization contract, or health maintenance organization contract offered by a health insurance issuer. However, excepted benefits are not included as a "health benefit plan".

(3) "Health insurance issuer" means any entity that offers health insurance coverage through a plan, policy, or certificate of insurance subject to

state law that regulates the business of insurance. "Health insurance issuer" shall also include a health maintenance organization, as defined and licensed pursuant to Subpart I of Part I of Chapter 2 of this Code. "Health insurance issuer" shall not include the Office of Group Benefits.

(4) "Rebates" means both of the following:

(a) Negotiated price concessions, including but not limited to base rebates and reasonable estimates of any price protection rebates and performance-based rebates that may accrue directly or indirectly to the health insurance issuer as a result of point of sale prescription drug claims processing during the coverage year from a manufacturer, dispensing pharmacy, or other party to the transaction.

(b) Reasonable estimates of any fees and other administrative costs that are passed through to the health insurance issuer as a result of point of sale prescription drug claims processing and serve to reduce the health insurance issuer's prescription drug liabilities for the coverage year.

B. In the case of a health insurance issuer that offers or renews a health benefit plan for sale in the state on or after January 1, 2020, if the health insurance issuer may charge enrollees cost-sharing amounts that may result in an excess consumer cost burden for covered prescription drugs, the health insurance issuer shall disclose to enrollees and prospective enrollees the fact that enrollees may be subject to an excess consumer cost burden. The notice shall be provided in the coverage agreement, formulary, or preferred drug guide issued by the health plan.

C. A health insurance issuer that offers or renews a health benefit plan for sale in the state on or after January 1, 2020, shall annually make available to the commissioner of insurance information regarding the value of rebates expressed as a percentage that the health insurance issuer made available to enrollees at the point of sale.

D. In complying with the provisions of this Section a health insurance issuer shall not publish or otherwise reveal information regarding the actual

amount of rebates the health insurance issuer receives, including but not limited to information regarding the amount of rebates it receives on a product, manufacturer, or pharmacy specific basis. Such information is a trade secret, is not a public record as defined in R.S. 44:1 et seq., and shall not be disclosed directly or indirectly. A health insurance issuer shall impose the confidentiality protections of this Section on any third parties or vendors with which it contracts that may receive or have access to rebate information.

Section 2. R.S. 44:4.1(B)(11) is hereby amended and reenacted to read as follows:

§4.1. Exceptions

* * *

B. The legislature further recognizes that there exist exceptions, exemptions, and limitations to the laws pertaining to public records throughout the revised statutes and codes of this state. Therefore, the following exceptions, exemptions, and limitations are hereby continued in effect by incorporation into this Chapter by citation:

* * *

(11) R.S. 22:2, 14, 31, 42.1, 88, 244, 263, 265, 461, 550.7, 571, 572, 572.1, 574, 618, 639, 691.4, 691.5, 691.6, 691.7, 691.8, 691.9, 691.9.1, 691.10, 691.38, 691.56, 732, 752, 753, 771, 834, 972(D), **976,** 1008, 1019.2, 1203, 1460, 1464, 1466, 1488, 1546, 1559, 1566(D), 1644, 1656, 1723, 1796, 1801, 1808.3, 1927, 1929, 1983, 1984, 2036, 2045, 2056, 2085, 2091, 2293, 2303

* * *

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

2018 Regular Session

ACT No. 371

ENROLLED

SENATE BILL NO. 283

BY SENATOR MILLS

AN ACT

To amend and reenact R.S. 22:1657 and R.S. 44:4.1(B)(11) and to enact R.S. 22:1657.1, relative to pharmacy benefit managers; to provide for internet publication of formularies; to provide for transparency reporting; to provide for certain reportable aggregate data; to provide for internet publication of the transparency report; to provide for definitions; to provide for the duties of the commissioner of insurance relative thereto; to provide for confidentiality; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1657 is hereby amended and reenacted and R.S. 22:1657.1 is hereby enacted to read as follows:

§1657. Pharmacy benefit managers

A. A pharmacy benefit manager shall be deemed to be a third-party administrator for purposes of this Part. As such, all provisions of this Part shall apply to pharmacy benefit managers; however, notwithstanding the provisions of R.S. 22:1651(F), every pharmacy benefit manager shall be required to be licensed by the commissioner of insurance.

B. The commissioner of insurance shall provide a dedicated location on the department's website for pharmacy benefit manager information and links.

C. For each of a pharmacy benefit manager's contractual or other relationships with a health benefit plan or health insurance issuer, the pharmacy benefit manager shall provide the department with the health benefit plan's formulary and provide timely notification of formulary changes and product exclusions. The information provided pursuant to this Subsection shall be made available in a centralized location on the department's website in a format that allows for consumer access, including links to pharmacy benefit

manager websites.

§1657.1. Pharmacy benefit manager rebate transparency report

A. Each pharmacy benefit manager licensed by the commissioner of insurance shall submit an annual transparency report as a condition of maintaining licensure.

B. As used in this Section, the following definitions shall apply:

(1) "Aggregate retained rebate percentage" means the percentage calculated for each prescription drug for which a pharmacy benefit manager receives rebates under a particular health benefit plan expressed without disclosing any identifying information regarding the health benefit plan, prescription drug, or therapeutic class. The percentage shall be calculated by dividing the aggregate rebates that the pharmacy benefit manager received during the prior calendar year from a pharmaceutical manufacturer related to utilization of the manufacturer's prescription drug by health benefit plan enrollees that did not pass through to the health benefit plan or health insurance issuer by the aggregate rebates that the pharmacy benefit manager received during the prior calendar year from a pharmaceutical manufacturer related to utilization of the manufacturer's prescription drug by health benefit plan enrollees.

(2) "Health benefit plan", "plan", "benefit", or "health insurance coverage" means services consisting of medical care provided directly through insurance, reimbursement, or other means, and including items and services paid for as medical care under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization contract, or health maintenance organization contract offered by a health insurance issuer. However, excepted benefits are not included as a "health benefit plan".

(3) "Health insurance issuer" means any entity that offers health insurance coverage through a plan, policy, or certificate of insurance subject to state law that regulates the business of insurance. "Health insurance issuer"

shall also include a health maintenance organization, as defined and licensed pursuant to Subpart I of Part I of Chapter 2 of this Code.

(4) "Rebates" means all rebates, discounts, and other price concessions, based on utilization of a prescription drug and paid by the manufacturer or other party other than an enrollee, directly or indirectly, to the pharmacy benefit manager after the claim has been adjudicated at the pharmacy. Rebates shall include a reasonable estimate of any volume-based discount or other discounts.

C.(1) Beginning June 1, 2020, and annually thereafter, each licensed pharmacy benefit manager shall submit a transparency report containing data from the prior calendar year to the department. The transparency report shall contain the following information for each of the pharmacy benefit manager's contractual or other relationships with a health benefit plan or health insurance issuer:

(a) The aggregate amount of all rebates that the pharmacy benefit manager received from pharmaceutical manufacturers.

(b) The aggregate administrative fees that the pharmacy benefit manager received.

(c) The aggregate rebates that the pharmacy benefit manager received from pharmaceutical manufacturers and did not pass through to the health benefit plan or health insurance issuer.

(d) The highest, lowest, and mean aggregate retained rebate percentage.

(2) The transparency report shall be made available in a form that does not disclose the identity of a specific health benefit plan, the prices charged for specific drugs or classes of drugs, or the amount of any rebates provided for specific drugs or classes of drugs.

(3) Within sixty days of receipt, the Department of Insurance shall publish the transparency report on the department's website in a location designated for pharmacy benefit manager information pursuant to R.S. 22:1657(B).

(4) The pharmacy benefit manager and the Department of Insurance shall not publish or disclose any information that would reveal the identity of a specific health benefit plan, the prices charged for a specific drug or class of drugs, or the amount of any rebates provided for a specific drug or class of drugs. Any such information shall be protected from disclosure as confidential and proprietary information and shall not be regarded as a public record pursuant to the Public Records Law.

(5) Not more than thirty days after an increase in wholesale acquisition cost of fifty percent or greater for a drug with a wholesale acquisition cost of one hundred dollars or more for a thirty-day supply, a pharmaceutical drug manufacturer shall notify the commissioner of insurance by electronic mail of any such change.

Section 2. R.S. 44:4.1(B)(11) is hereby amended and reenacted to read as follows:

§4.1. Exceptions

A.

* * *

B. The legislature further recognizes that there exist exceptions, exemptions, and limitations to the laws pertaining to public records throughout the revised statutes and codes of this state. Therefore, the following exceptions, exemptions, and limitations are hereby continued in effect by incorporation into this Chapter by citation:

* * *

(11) R.S. 22:2, 14, 31, 42.1, 88, 244, 263, 265, 461, 550.7, 571, 572, 572.1, 574, 618, 639, 691.4, 691.5, 691.6, 691.7, 691.8, 691.9, 691.9.1, 691.10, 691.38, 691.56, 732, 752, 753, 771, 834, 972(D), 1008, 1019.2, 1203, 1460, 1464, 1466, 1488, 1546, 1559, 1566(D), 1644, 1656, **1657.1,** 1723, 1796, 1801, 1808.3, 1927, 1929, 1983, 1984, 2036, 2045, 2056, 2085, 2091, 2293, 2303

* * *

Section 3. If any rules or regulations are necessary to effectuate the provisions of this Act, the commissioner of insurance shall promulgate and adopt those rules or regulations in

accordance with the Administrative Procedure Act prior to January 1, 2020.

Section 4.(A) This Section and Section 3 of this Act shall become effective on August 1, 2018.

(B) Sections 1 and 2 of this Act shall become effective on January 1, 2020.

_____
PRESIDENT OF THE SENATE

_____
SPEAKER OF THE HOUSE OF REPRESENTATIVES

_____
GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____

Chapter 451

(House Bill 1349)

AN ACT concerning

Pharmacy Benefits Managers – Revisions

FOR the purpose of ~~altering the application fee for a pharmacy benefits manager to register with the Maryland Insurance Commissioner; requiring a pharmacy benefits manager applying to register to file a certain financial statement with the Commissioner;~~ authorizing the Maryland Insurance Commissioner to require certain additional information from a pharmacy benefits manager in a certain application; ~~altering the date on which the registration of a pharmacy benefits manager expires unless the registration is renewed; altering the length of the term for which a pharmacy benefits manager may renew a certain registration; altering the circumstances under which a pharmacy benefits manager may renew a registration; authorizing the Commissioner to impose certain fees under certain circumstances;~~ authorizing the Commissioner to require certain information or certain submissions from a pharmacy benefits manager for a certain purpose; ~~authorizing a pharmacy benefits manager to pay a certain fee in lieu of a certain suspension under certain circumstances; authorizing a pharmacy benefits manager to reapply for a registration under certain circumstances;~~ clarifying that certain actions of the Commissioner are subject to certain hearing provisions; providing that a certain provision prohibiting reimbursements in a certain amount does not apply to reimbursement for certain drugs or to certain chain pharmacies; prohibiting ~~certain reimbursement from~~ a pharmacy benefits manager ~~to~~ from reimbursing a pharmacy or pharmacist for a certain product or certain service in a certain amount; ~~prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from providing a beneficiary with certain information regarding a certain retail price or certain cost–share for a prescription drug; prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from discussing with a beneficiary a certain retail price or certain cost–share for a prescription drug; prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from selling a certain alternative prescription drug under certain circumstances; prohibiting a pharmacy benefits manager from prohibiting a pharmacy or pharmacist from offering and providing store direct delivery services as an ancillary service of the pharmacy; requiring each contract between a pharmacy benefits manager and a contracted pharmacy to include the methodology used to determine maximum allowable cost pricing; requiring a pharmacy benefits manager to disclose certain information to a contracted pharmacy under certain circumstances; requiring a pharmacy benefits manager to provide a certain means on its website by which certain contracted pharmacies may promptly review certain pricing updates, to use certain pricing information to calculate certain payments, and to disclose certain information in certain contracts; requiring a pharmacy benefits manager to disclose a certain maximum allowable cost list under certain circumstances;~~ requiring a pharmacy benefits manager to establish a certain process

by which a certain pharmacy has access to certain maximum allowable cost price lists in a certain format as updated in accordance with certain requirements; requiring a pharmacy benefits manager to use updated pricing information in calculating certain payments immediately after a certain update; altering a certain procedure that a pharmacy benefits manager is required to maintain; altering certain requirements that a pharmacy benefits manager must meet before placing a prescription drug on a certain list; ~~prohibiting a pharmacy benefits manager from setting a maximum allowable cost for certain drugs, products, and devices that are placed on a certain list that is below a certain amount;~~ altering a certain process that must be included in each contract between a pharmacy benefits manager and a contracted pharmacy; ~~authorizing a contracted pharmacy to file a certain complaint with the Commissioner; requiring a contracted pharmacy to exhaust a certain appeal process before filing a certain complaint; requiring the Commissioner to hold a certain hearing and issue a certain order in accordance with certain procedures; providing that an appeal of a certain order may be taken in accordance with certain statutory provisions;~~ prohibiting a pharmacy benefits manager from retaliating against a contracted pharmacy for exercising a certain right to appeal or filing a certain complaint; prohibiting a pharmacy benefits manager from charging a contracted pharmacy a certain fee; ~~establishing a certain civil penalty for a violation of certain provisions of this Act;~~ requiring the Commission to review a certain compensation program for a certain purpose and take certain action on appeal and order a pharmacy benefits manager to pay a certain claim under certain circumstances; providing that certain information is considered to be confidential and proprietary information and is not subject to disclosure under certain provisions of law; authorizing the Commissioner, under certain circumstances, to issue an order that requires a pharmacy benefits manager to pay a certain fine; authorizing the Commissioner to adopt certain regulations and establish a certain complaint process; defining a certain term; altering a certain definition; providing for the construction of certain provisions of this Act; providing for the application of this Act; ~~providing for a delayed effective date;~~ and generally relating to pharmacy benefits managers.

BY repealing and reenacting, with amendments,
Article – Insurance
Section 15–1604, 15–1605, 15–1607, 15–1628.1, and ~~15–1642(c)~~ 15–1642
Annotated Code of Maryland
(2017 Replacement Volume)

BY adding to
Article – Insurance
Section 15–1611~~, 15–1612, and 15–1613~~
Annotated Code of Maryland
(2017 Replacement Volume)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Insurance

15–1604.

(a) A pharmacy benefits manager shall register with the Commissioner as a pharmacy benefits manager before providing pharmacy benefits management services in the State to purchasers.

(b) An applicant for registration shall:

(1) file with the Commissioner an application on the form that the Commissioner provides; **[**~~and~~**]**

(2) pay to the Commissioner a registration fee **[**~~set by the Commissioner~~**]** ~~**OF $1,000; AND**~~

~~**(3) FILE WITH THE COMMISSIONER A FINANCIAL STATEMENT, CERTIFIED BY A CERTIFIED PUBLIC ACCOUNTANT WITHIN THE IMMEDIATELY PRECEDING 6 MONTHS, THAT PRESENTS, IN ACCORDANCE WITH GENERALLY ACCEPTED ACCOUNTING PRINCIPLES, THE FINANCIAL POSITION OF THE APPLICANT AND CONTAINS THE INFORMATION THAT THE COMMISSIONER REQUIRES**~~.

(C) THE COMMISSIONER MAY REQUIRE ANY ADDITIONAL INFORMATION OR SUBMISSIONS FROM A PHARMACY BENEFITS MANAGER THAT MAY BE REASONABLY NECESSARY TO VERIFY THE INFORMATION CONTAINED IN THE APPLICATION.

[(c)**]** **(D)** Subject to the provisions of § 15–1607 of this part, the Commissioner shall register each pharmacy benefits manager that meets the requirements of this section.

15–1605.

(a) A pharmacy benefits manager registration expires on **[**~~the second~~**]** September 30 after its effective date unless it is renewed as provided under this section.

(b) A pharmacy benefits manager may renew its registration for an additional **[**~~2–year~~**]** ~~**1–YEAR**~~ term, if the pharmacy benefits manager:

(1) otherwise is entitled to be registered;

(2) files with the Commissioner a renewal application on the form that the Commissioner requires; **[**~~and~~**]**

(3) pays to the Commissioner a renewal fee **[**~~set by the Commissioner~~**]** ~~**OF $1,000; AND**~~

~~(4) FILES WITH THE COMMISSIONER A FINANCIAL STATEMENT CERTIFIED BY A CERTIFIED PUBLIC ACCOUNTANT WITHIN THE IMMEDIATELY PRECEDING 6 MONTHS, THAT PRESENTS, IN ACCORDANCE WITH GENERALLY ACCEPTED ACCOUNTING PRINCIPLES, THE FINANCIAL POSITION OF THE APPLICANT AND CONTAINS THE INFORMATION THAT THE COMMISSIONER REQUIRES~~.

(c) An application for renewal of a pharmacy benefits manager registration shall be considered made in a timely manner if it is postmarked on or before the date the pharmacy benefits manager's registration expires.

~~(D) IF A PHARMACY BENEFITS MANAGER FAILS TO PAY THE RENEWAL FEE REQUIRED UNDER SUBSECTION (B)(3) OF THIS SECTION WHEN THE PHARMACY BENEFITS MANAGER SUBMITS AN APPLICATION FOR RENEWAL, THE COMMISSIONER MAY IMPOSE AN ADDITIONAL APPLICATION FEE OF $500.~~

~~[~~(d)~~]~~ ~~(E)~~ Subject to the provisions of § 15–1607 of this part, the Commissioner shall renew the registration of each pharmacy benefits manager that meets the requirements of this section.

~~(F)~~ **(E) THE COMMISSIONER MAY REQUIRE ANY ADDITIONAL INFORMATION OR SUBMISSIONS FROM A PHARMACY BENEFITS MANAGER THAT MAY BE REASONABLY NECESSARY TO VERIFY THE INFORMATION CONTAINED IN THE APPLICATION.**

15–1607.

(a) ~~(1)~~ Subject to ~~PARAGRAPH (2) OF THIS SUBSECTION AND~~ the **APPLICABLE** hearing provisions of Title 2 of this article, the Commissioner may deny a registration to a pharmacy benefits manager applicant or refuse to renew, suspend, or revoke the registration of a pharmacy benefits manager if the pharmacy benefits manager, or an officer, director, or employee of the pharmacy benefits manager:

~~[~~(1)~~]~~ ~~(I)~~ makes a material misstatement or misrepresentation in an application for registration;

~~[~~(2)~~]~~ ~~(II)~~ fraudulently or deceptively obtains or attempts to obtain a registration;

~~[~~(3)~~]~~ ~~(III)~~ in connection with the administration of pharmacy benefits management services, commits fraud or engages in illegal or dishonest activities; or

~~[~~(4)~~]~~ ~~(IV)~~ violates any provision of this part or a regulation adopted under this part.

~~(2) SUBJECT TO THE APPROVAL OF THE COMMISSIONER, A PHARMACY BENEFITS MANAGER MAY, IN LIEU OF PART OR ALL OF THE DAYS OF ANY SUSPENSION PERIOD IMPOSED BY THE COMMISSIONER, PAY A FEE OF $1,000 PER DAY OF THE SUSPENSION PERIOD.~~

~~(B) IF THE COMMISSIONER'S DENIAL OR REVOCATION OF A PHARMACY BENEFITS MANAGER'S REGISTRATION IS SUSTAINED BY THE COMMISSIONER AFTER A HEARING IN ACCORDANCE WITH TITLE 2 OF THIS ARTICLE, A PHARMACY BENEFITS MANAGER MAY REAPPLY FOR A REGISTRATION NO EARLIER THAN 1 YEAR AFTER THE DATE ON WHICH A DENIAL OR REVOCATION WAS SUSTAINED BY THE COMMISSIONER.~~

~~[~~(b)~~]~~ ~~(C)~~ This section does not limit any other regulatory authority of the Commissioner under this article.

15–1611.

(A) THIS SECTION DOES NOT APPLY TO REIMBURSEMENT:

(1) FOR SPECIALTY DRUGS;

(2) FOR MAIL ORDER DRUGS; OR

(3) TO A CHAIN PHARMACY WITH MORE THAN 15 STORES OR A PHARMACIST WHO IS AN EMPLOYEE OF THE CHAIN PHARMACY.

(B) A PHARMACY BENEFITS MANAGER MAY NOT REIMBURSE A PHARMACY OR PHARMACIST FOR A PHARMACEUTICAL PRODUCT OR PHARMACIST SERVICE IN AN AMOUNT LESS THAN THE AMOUNT THAT THE PHARMACY BENEFITS MANAGER REIMBURSES ITSELF OR AN AFFILIATE FOR PROVIDING THE SAME PRODUCT OR SERVICE.

~~**15–1612.**~~

~~IN ADDITION TO THE REGISTRATION AND RENEWAL FEES ESTABLISHED UNDER §§ 15–1604 AND 15–1605 OF THIS SUBTITLE, THE COMMISSIONER MAY REQUIRE A PHARMACY BENEFITS MANAGER TO PAY A FEE SET BY THE COMMISSIONER TO COVER THE COSTS OF IMPLEMENTATION AND ENFORCEMENT OF THIS SUBTITLE, INCLUDING FEES TO COVER THE COSTS OF:~~

~~(1) SALARIES AND BENEFITS PAID TO PERSONNEL ENGAGED IN THE IMPLEMENTATION AND ENFORCEMENT OF THIS SUBTITLE;~~

~~(2) REASONABLE TECHNOLOGY COSTS RELATING TO THE ENFORCEMENT OF THIS SUBTITLE, INCLUDING THE COSTS OF:~~

~~(I) SOFTWARE AND HARDWARE USED IN THE ENFORCEMENT PROCESS; AND~~

~~(II) TRAINING PERSONNEL IN THE PROPER USE OF THE SOFTWARE OR HARDWARE; AND~~

~~(3) EDUCATION AND TRAINING FOR PERSONNEL ENGAGED IN THE ENFORCEMENT OF THIS SUBTITLE TO MAINTAIN PROFICIENCY AND COMPETENCE.~~

~~15–1613.~~

~~(A) A PHARMACY BENEFITS MANAGER MAY NOT PROHIBIT A PHARMACY OR PHARMACIST FROM:~~

~~(1) PROVIDING A BENEFICIARY WITH INFORMATION REGARDING THE RETAIL PRICE FOR A PRESCRIPTION DRUG OR THE AMOUNT OF THE COST SHARE FOR WHICH THE BENEFICIARY IS RESPONSIBLE FOR A PRESCRIPTION DRUG;~~

~~(2) DISCUSSING WITH A BENEFICIARY INFORMATION REGARDING THE RETAIL PRICE FOR A PRESCRIPTION DRUG OR THE AMOUNT OF THE COST SHARE FOR WHICH THE BENEFICIARY IS RESPONSIBLE FOR A PRESCRIPTION DRUG;~~

~~(3) IF A MORE AFFORDABLE DRUG IS AVAILABLE THAN ONE ON THE PURCHASER'S FORMULARY AND THE REQUIREMENTS FOR A THERAPEUTIC INTERCHANGE UNDER §§ 15–1633 THROUGH 15–1639 OF THIS SUBTITLE ARE MET, SELLING THE MORE AFFORDABLE ALTERNATIVE TO THE BENEFICIARY; OR~~

~~(4) OFFERING AND PROVIDING STORE DIRECT DELIVERY SERVICES TO AN ENROLLEE AS AN ANCILLARY SERVICE OF THE PHARMACY.~~

~~(B) THIS SECTION MAY NOT BE CONSTRUCTED TO ALTER THE REQUIREMENTS FOR A THERAPEUTIC INTERCHANGE UNDER §§ 15–1633 THROUGH 15–1639 OF THIS SUBTITLE.~~

15–1628.1.

(a) (1) In this section the following words have the meanings indicated.

(2) "Contracted pharmacy" means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

(i) the pharmacy benefits manager; or

(ii) a pharmacy services administration organization or a group purchasing organization.

(3) "DRUG SHORTAGE LIST" MEANS A LIST OF DRUG PRODUCTS ~~SOLD AT A DISCOUNT WITH AN EXPIRATION DATE OF LESS THAN 1 YEAR FROM THE DATE OF PURCHASE BY THE CONTRACTED PHARMACY~~ LISTED ON THE FEDERAL FOOD AND DRUG ADMINISTRATION'S DRUG SHORTAGES WEBSITE.

[(3)**] (4) (I)** "Maximum allowable cost" means the maximum amount that a pharmacy benefits manager or a purchaser will reimburse a contracted pharmacy for the cost of a multisource generic drug, a medical product, or a device.

(II) "MAXIMUM ALLOWABLE COST" DOES NOT INCLUDE DISPENSING FEES.

[(4)**] (5)** "Maximum allowable cost list" means a list of multisource generic drugs, medical products, and devices for which a maximum allowable cost has been established by a pharmacy benefits manager or a purchaser.

(b) In each contract between a pharmacy benefits manager and a contracted pharmacy, the pharmacy benefits manager shall include the ~~METHODOLOGY AND~~ sources used to determine maximum allowable cost pricing.

~~(C) (1) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE CONTRACTED PHARMACY WHETHER THE PHARMACY BENEFITS MANAGER IS USING AN IDENTICAL MAXIMUM ALLOWABLE COST LIST WITH ANY OTHER CONTRACTED PHARMACY.~~

~~(2) IF A PHARMACY BENEFITS MANAGER USES A DIFFERENT MAXIMUM ALLOWABLE COST LIST WITH ANOTHER CONTRACTED PHARMACY, THE PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO THE CONTRACT PHARMACY ANY DIFFERENCES BETWEEN THE AMOUNT PAID TO ANY CONTRACTED PHARMACY AND THE AMOUNT CHARGED TO THE PURCHASER.~~

~~[~~(c)~~]~~ ~~(D)~~ A pharmacy benefits manager shall**:**

(1) update its pricing information at least every 7 days ~~and provide a means ON THE PHARMACY BENEFITS MANAGER'S WEBSITE by which ALL contracted pharmacies may promptly review pricing updates in a format that is readily available and accessible AT THE TIME THE PHARMACY BENEFITS MANAGER UPDATES THE LIST FOR ITS OWN USE~~**;**

(2) **ESTABLISH A REASONABLE PROCESS BY WHICH A CONTRACTED PHARMACY HAS ACCESS TO THE CURRENT AND APPLICABLE MAXIMUM ALLOWABLE COST PRICE LISTS IN AN ELECTRONIC FORMAT AS UPDATED IN ACCORDANCE WITH THE REQUIREMENTS OF THIS SECTION; AND**

~~(2)~~ **(3)** **IMMEDIATELY AFTER A PRICING INFORMATION UPDATE UNDER ITEM (1) OF THIS SUBSECTION, USE THE UPDATED PRICING INFORMATION IN CALCULATING THE PAYMENTS MADE TO ALL CONTRACTED PHARMACIES~~; AND~~.**

~~(3) DISCLOSE IN EACH CONTRACT BETWEEN THE PHARMACY BENEFITS MANAGER AND A CONTRACTED PHARMACY WHETHER THE PHARMACY BENEFITS MANAGER USES A DIFFERENT MAXIMUM ALLOWABLE COST LIST FOR DRUGS, PRODUCTS, OR DEVICES DISPENSED AT RETAIL PHARMACIES THAN FOR DRUGS, PRODUCTS, OR DEVICES DISPENSED BY MAIL.~~

~~(E) A PHARMACY BENEFITS MANAGER SHALL DISCLOSE TO A CONTRACTED PHARMACY A MAXIMUM ALLOWABLE COST LIST USED BY THE PHARMACY BENEFITS MANAGER FOR DRUGS, PRODUCTS, OR DEVICES DISPENSED BY MAIL IF THE MAXIMUM ALLOWABLE COST LIST IS:~~

~~(1) DIFFERENT THAN THE MAXIMUM ALLOWABLE COST LIST USED BY THE PHARMACY BENEFITS MANAGER FOR DRUGS, PRODUCTS, OR DEVICES DISPENSED AT RETAIL PHARMACIES; AND~~

~~(2) ADOPTED BY THE PHARMACY BENEFITS MANAGER AFTER EXECUTING A CONTRACT WITH THE CONTRACTED PHARMACY.~~

[(d)**]** ~~(F)~~ **(1)** A pharmacy benefits manager shall maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing **[**in a timely manner**]** **AS NECESSARY** to**:**

(I) remain consistent with pricing changes**;**

(II) REMOVE FROM THE LIST DRUGS THAT NO LONGER MEET THE REQUIREMENTS OF SUBSECTION ~~(G)~~ (E) OF THIS SECTION; AND

(III) ~~ENSURE THE~~ **REFLECT THE CURRENT AVAILABILITY OF DRUGS** in the marketplace.

(2) A PRODUCT ON THE MAXIMUM ALLOWABLE COST LIST SHALL BE ELIMINATED FROM THE LIST BY THE PHARMACY BENEFITS MANAGER WITHIN ~~24 HOURS~~ 7 DAYS AFTER THE PHARMACY BENEFITS MANAGER KNOWS ~~OR SHOULD HAVE KNOWN~~ OF A CHANGE IN THE ~~PRICING OR~~ AVAILABILITY OF THE PRODUCT.

~~[~~(e)~~]~~ ~~(G)~~ Before placing a prescription drug on a maximum allowable cost list, a pharmacy benefits manager shall ensure that:

(1) the drug is listed as "A" or "B" rated in the most recent version of the U.S. Food and Drug Administration's approved drug products with therapeutic equivalence evaluations, also known as the Orange Book, or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; **[**and**]**

(2) **(I) IF A DRUG IS MANUFACTURED BY MORE THAN ONE MANUFACTURER,** the drug is ~~[~~generally~~]~~ available ~~IN AT LEAST THREE GENERICALLY EQUIVALENT OR BIOEQUIVALENT VERSIONS~~ for purchase by contracted pharmacies**, INCLUDING CONTRACTED RETAIL PHARMACIES,** in the State from a **[**national or regional**]** wholesale distributor **[**and is not obsolete**] WITH A PERMIT IN THE STATE; OR**

(II) IF A DRUG IS MANUFACTURED BY ONLY ONE MANUFACTURER, THE DRUG IS GENERALLY AVAILABLE FOR PURCHASE BY CONTRACTED PHARMACIES, INCLUDING CONTRACTED RETAIL PHARMACIES, IN THE STATE FROM AT LEAST TWO WHOLESALE DISTRIBUTORS WITH A PERMIT IN THE STATE; AND

(3) THE DRUG IS NOT OBSOLETE, TEMPORARILY UNAVAILABLE, OR LISTED ON A DRUG SHORTAGE LIST AS CURRENTLY IN SHORTAGE.

~~(II) A PHARMACY BENEFITS MANAGER MAY NOT SET THE MAXIMUM ALLOWABLE COST FOR ANY DRUG, PRODUCT, OR DEVICE IT PLACES ON A MAXIMUM ALLOWABLE COST LIST IN AN AMOUNT THAT IS BELOW THE AMOUNT ESTABLISHED IN THE SOURCE USED BY THE PHARMACY BENEFITS MANAGER TO SET THE MAXIMUM ALLOWABLE COST FOR THE DRUG, PRODUCT, OR DEVICE.~~

~~[~~(f)~~]~~ ~~(H)~~ Each contract between a pharmacy benefits manager and a contracted pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a requirement that an appeal be filed **BY THE CONTRACT PHARMACY** no later than 21 days after the date of the initial **ADJUDICATED** claim;

(2) a requirement that **[**an appeal be investigated and resolved**],** within ~~[~~21~~]~~ ~~7~~ days after the date the appeal is filed**, THE PHARMACY BENEFITS MANAGER INVESTIGATE AND RESOLVE THE APPEAL AND REPORT TO THE CONTRACTED PHARMACY ON THE PHARMACY BENEFITS MANAGER'S DETERMINATION ON THE APPEAL**;

(3) **A REQUIREMENT THAT A PHARMACY BENEFITS MANAGER MAKE AVAILABLE ON ITS WEBSITE INFORMATION ABOUT THE APPEAL PROCESS, INCLUDING:**

(I) a ~~**DIRECT**~~ telephone number at which the contracted pharmacy may **DIRECTLY** contact the **DEPARTMENT OR OFFICE RESPONSIBLE FOR PROCESSING APPEALS FOR *THE*** pharmacy benefits manager to speak to an individual ~~**SPECIFICALLY**~~ **OR LEAVE A MESSAGE FOR AN INDIVIDUAL WHO IS** responsible for processing appeals**;**

(II) AN E–MAIL ADDRESS OF THE DEPARTMENT OR OFFICE RESPONSIBLE FOR PROCESSING APPEALS TO WHICH AN INDIVIDUAL WHO IS RESPONSIBLE FOR PROCESSING APPEALS HAS ACCESS; **AND**

~~**(II)**~~ **(III) A NOTICE INDICATING THAT THE INDIVIDUAL ~~SPECIFICALLY~~ RESPONSIBLE FOR PROCESSING APPEALS SHALL RETURN ~~CALLS~~ A CALL OR AN E–MAIL MADE BY A CONTRACTED PHARMACY TO THE INDIVIDUAL WITHIN 3 BUSINESS DAYS OR LESS OF RECEIVING THE CALL OR E–MAIL;**

(4) a requirement that a pharmacy benefits manager provide:

(i) a reason for any appeal denial; and

(ii) the national drug code of a drug ~~that IS READILY AVAILABLE FOR PURCHASE~~ **AND THE NAME OF THE WHOLESALE DISTRIBUTOR FROM WHICH THE DRUG** ~~may be purchased by the contracted pharmacy~~ **WAS AVAILABLE ON THE DATE THE CLAIM WAS ADJUDICATED** at a price at or below the **[**benchmark price**]** **MAXIMUM ALLOWABLE COST** determined by the pharmacy benefits manager; and

(5) if an appeal is upheld, a requirement that a pharmacy benefits manager:

~~(i) make the change in the maximum allowable cost no later than 1 business day after the date of determination on the appeal; and~~

~~(ii) permit the appealing contracting pharmacy to reverse and rebill the claim, and any subsequent similar claims.~~

(I) FOR THE APPEALING PHARMACY:

1. ADJUST THE MAXIMUM ALLOWABLE COST FOR THE DRUG AS OF THE DATE OF THE ORIGINAL CLAIM FOR PAYMENT; AND

2. WITHOUT REQUIRING THE APPEALING PHARMACY TO REVERSE AND REBILL THE CLAIMS, PROVIDE REIMBURSEMENT FOR THE CLAIM AND

ANY SUBSEQUENT AND SIMILAR CLAIMS UNDER SIMILARLY APPLICABLE CONTRACTS WITH THE PHARMACY BENEFITS MANAGER:

A. FOR THE ORIGINAL CLAIM, IN THE FIRST REMITTANCE TO THE PHARMACY AFTER THE DATE THE APPEAL WAS DETERMINED; AND

B. FOR SUBSEQUENT AND SIMILAR CLAIMS UNDER SIMILARLY APPLICABLE CONTRACTS, IN THE SECOND REMITTANCE TO THE PHARMACY AFTER THE DATE THE APPEAL WAS DETERMINED; AND

(II) FOR A SIMILARLY SITUATED CONTRACTED PHARMACY IN THE STATE:

1. ADJUST THE MAXIMUM ALLOWABLE COST FOR THE DRUG AS OF THE DATE THE APPEAL WAS DETERMINED; AND

2. PROVIDE NOTICE TO THE PHARMACY OR PHARMACY'S CONTRACTED AGENT THAT:

A. AN APPEAL HAS BEEN UPHELD; AND

B. WITHOUT FILING A SEPARATE APPEAL, THE PHARMACY OR THE PHARMACY'S CONTRACTED AGENT MAY REVERSE AND REBILL A SIMILAR CLAIM.

~~**(J) (1) WITHIN 30 CALENDAR DAYS AFTER A PHARMACY BENEFITS MANAGER DENIES AN APPEAL BY A CONTRACTED PHARMACY UNDER SUBSECTION (I) OF THIS SECTION, THE CONTRACTED PHARMACY MAY FILE A COMPLAINT WITH THE COMMISSIONER FOR REVIEW OF THE DECISION BY THE PHARMACY BENEFITS MANAGER.**~~

~~**(2) A CONTRACTED PHARMACY SHALL EXHAUST THE APPEAL PROCESS ESTABLISHED BY THE PHARMACY BENEFITS MANAGER UNDER SUBSECTION (I) OF THIS SECTION BEFORE FILING A COMPLAINT WITH THE COMMISSIONER UNDER THIS SUBSECTION.**~~

~~**(3) THE COMMISSIONER SHALL HOLD A HEARING ON THE COMPLAINT AND ISSUE AN ORDER IN ACCORDANCE WITH THE HEARING AND REVIEW PROCEDURES ESTABLISHED UNDER §§ 2–210 THROUGH 2–214 OF THIS ARTICLE.**~~

~~**(4) AN APPEAL OF AN ORDER OF THE COMMISSIONER UNDER THIS SUBSECTION MAY BE TAKEN IN ACCORDANCE WITH § 2–215 OF THIS ARTICLE.**~~

~~(5)~~ (G) A PHARMACY BENEFITS MANAGER MAY NOT RETALIATE AGAINST A CONTRACTED PHARMACY FOR EXERCISING ITS RIGHT TO APPEAL UNDER THIS SECTION OR FILING A COMPLAINT WITH THE COMMISSIONER UNDER THIS SUBSECTION.

~~(K)~~ (H) A PHARMACY BENEFITS MANAGER MAY NOT CHARGE A CONTRACTED PHARMACY A FEE RELATED TO ~~AN ADJUDICATION OF A CLAIM UNDER~~ THE READJUDICATION OF A CLAIM OR CLAIMS RESULTING FROM CARRYING OUT THE REQUIREMENT OF A CONTRACT SPECIFIED IN SUBSECTION (F)(5) OF THIS SECTION OR THE UPHOLDING OF AN APPEAL UNDER SUBSECTION (I) OF THIS SECTION.

~~(L) (1) A PHARMACY BENEFITS MANAGER THAT VIOLATES THIS SECTION IS SUBJECT TO A CIVIL PENALTY OF NOT LESS THAN $1,000 FOR EACH VIOLATION.~~

~~(2) EACH DAY THAT A VIOLATION CONTINUES SHALL BE A SEPARATE VIOLATION.~~

(I) (1) IF A PHARMACY BENEFITS MANAGER DENIES AN APPEAL AND A CONTRACTED PHARMACY FILES A COMPLAINT WITH THE COMMISSIONER, THE COMMISSIONER SHALL:

(I) REVIEW THE COMPENSATION PROGRAM OF THE PHARMACY BENEFITS MANAGER TO ENSURE THAT THE REIMBURSEMENT FOR PHARMACY BENEFITS MANAGEMENT SERVICES PAID TO THE PHARMACIST OR A PHARMACY COMPLIES WITH THIS SUBTITLE AND THE TERMS OF THE CONTRACT; AND

(II) BASED ON A DETERMINATION MADE BY THE COMMISSIONER UNDER ITEM (I) OF THIS PARAGRAPH, DISMISS THE APPEAL OR UPHOLD THE APPEAL AND ORDER THE PHARMACY BENEFITS MANAGER TO PAY THE CLAIM OR CLAIMS IN ACCORDANCE WITH THE COMMISSIONER'S FINDINGS.

(2) ALL PRICING INFORMATION AND DATA COLLECTED BY THE COMMISSIONER DURING A REVIEW REQUIRED BY PARAGRAPH (1) OF THIS SUBSECTION:

(I) IS CONSIDERED TO BE CONFIDENTIAL AND PROPRIETARY INFORMATION; AND

(II) IS NOT SUBJECT TO DISCLOSURE UNDER THE PUBLIC INFORMATION ACT.

15–1642.

(a) If the Commissioner determines that a pharmacy benefits manager has violated any provision of this subtitle or any regulation adopted under this subtitle, the Commissioner may issue an order that requires the pharmacy benefits manager to:

(1) cease and desist from the identified violation and further similar violations;

(2) take specific affirmative action to correct the violation; **[**or**]**

(3) make restitution of money, property, or other assets to a person that has suffered financial injury because of the violation**; OR**

(4) PAY A FINE IN AN AMOUNT DETERMINED BY THE COMMISSIONER.

(b) (1) An order of the Commissioner issued under this section may be served on a pharmacy benefits manager that is registered under Part II of this subtitle in the manner provided in § 2–204 of this article.

(2) An order of the Commissioner issued under this section may be served on a pharmacy benefits manager that is not registered under Part II of this subtitle in the manner provided in § 4–206 or § 4–207 of this article for service on an unauthorized insurer that does an act of insurance business in the State.

(3) A request for a hearing on any order issued under this section does not stay that portion of the order that requires the pharmacy benefits manager to cease and desist from conduct identified in the order.

(4) The Commissioner may file a petition in the circuit court of any county to enforce an order issued under this section, whether or not a hearing has been requested or, if requested, whether or not a hearing has been held.

(5) If the Commissioner prevails in an action brought under this section, the Commissioner may recover, for the use of the State, reasonable attorney's fees and the costs of the action.

(c) In addition to any other enforcement action taken by the Commissioner under this section ~~**AND SUBJECT TO § 15–1628.1(L) OF THIS SUBTITLE**~~, the Commissioner may impose a civil penalty not exceeding $10,000 for each violation of this subtitle.

(D) THE COMMISSIONER MAY ADOPT REGULATIONS:

(1) TO CARRY OUT THIS SUBTITLE; AND

(2) TO ESTABLISH A COMPLAINT PROCESS TO ADDRESS GRIEVANCES AND APPEALS BROUGHT IN ACCORDANCE WITH THIS SUBTITLE.

[(d)**] (E)** This section does not limit any other regulatory authority of the Commissioner under this article.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all contracts between a pharmacy benefits manager and a pharmacy entered into~~, modified, amended, or renewed~~ *or in effect* on or after January 1, 2019.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~January~~ *June* 1, ~~2019~~ *2018*.

Approved by the Governor, May 8, 2018.

HOUSE BILL No. 6435

October 4, 2018, Introduced by Reps. Canfield and Vaupel and referred to the Committee on Health Policy.

A bill to amend 1984 PA 218, entitled

"Third party administrator act,"

by amending section 2 (MCL 550.902) and by adding sections 25, 26, and 27.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 2. As used in this act:

(a) "Administrative services manager" or "manager" means an individual responsible for conducting the daily operations of a third party administrator.

(b) "Benefit plan" or "plan" means a medical, surgical, dental, vision, or health care benefit plan and may include coverage under a policy or certificate issued by a carrier.

(c) "Board" means the TPA advisory board created under section 19.

HOUSE BILL No. 6435

(d) "Carrier" means ~~any of the following:~~

~~(*i*) An~~ **AN** insurer, ~~which is~~ **INCLUDING A HEALTH MAINTENANCE ORGANIZATION,** regulated ~~pursuant to~~ **UNDER** the insurance code of 1956, ~~Act No. 218 of the Public Acts of 1956, being sections~~ **1956 PA 218, MCL** 500.100 to 500.8302, ~~of the Michigan Compiled Laws.~~

~~(*ii*) A medical care corporation regulated pursuant to Act No. 108 of the Public Acts of 1939, being sections 550.301 to 550.316 of the Michigan Compiled Laws.~~

~~(*iii*) A hospital service corporation regulated pursuant to Act No. 109 of the Public Acts of 1939, being sections 550.501 to 550.517 of the Michigan Compiled Laws.~~

~~(*iv*) A health care corporation regulated pursuant to the nonprofit health care corporation reform act, Act No. 350 of the Public Acts of 1980, being sections 550.1101 to 550.1704 of the Michigan Compiled Laws.~~

~~(*v*) A health maintenance organization regulated under part 210 of the public health code, Act No. 368 of the Public Acts of 1978, being sections 333.21001 to 333.21099 of the Michigan Compiled Laws.~~

~~(*vi*) A~~ **OR A** dental care corporation regulated ~~pursuant to Act No. 125 of the Public Acts of 1963, being sections~~ **UNDER 1963 PA 125, MCL** 550.351 to 550.373. ~~of the Michigan Compiled Laws.~~

(e) "Commissioner" means the ~~commissioner of insurance of this state.~~**DIRECTOR.**

(F) "DEPARTMENT" MEANS THE DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES.

(G) "DIRECTOR" MEANS THE DIRECTOR OF THE DEPARTMENT.

(H) ~~(f)~~ "ERISA" means the employee retirement income security act of 1974, ~~as amended,~~ Public Law 93-406. ~~, 88 Stat. 829.~~

(I) "MANUFACTURER" MEANS THAT TERM AS DEFINED IN SECTION 17706 OF THE PUBLIC HEALTH CODE, 1978 PA 368, MCL 333.17706.

(J) ~~(g)~~ "Person" means an individual, sole proprietorship, partnership, corporation, association, or any other legal entity.

(K) ~~(h)~~ "Personal data" means any record or information pertaining to the diagnosis, treatment, or health of an individual covered by a plan.

(*l*) "PHARMACY" MEANS THAT TERM AS DEFINED IN SECTION 17707 OF THE PUBLIC HEALTH CODE, 1978 PA 368, MCL 333.17707.

(M) "PHARMACY BENEFIT MANAGER" MEANS A PERSON THAT CONTRACTS WITH A PHARMACY ON BEHALF OF AN EMPLOYER, MULTIPLE EMPLOYER WELFARE ARRANGEMENT, PUBLIC EMPLOYEE BENEFIT PLAN, STATE AGENCY, INSURER, MANAGED CARE ORGANIZATION, OR OTHER THIRD-PARTY PAYER TO PROVIDE PHARMACY HEALTH BENEFIT SERVICES OR ADMINISTRATION.

(N) ~~(i)~~ "Processes claims" means the administrative services performed in connection with a claim for benefits under a plan.

(O) ~~(j)~~ "Service contract" means the written agreement for the provision of administrative services between the TPA and a plan, a sponsor of a plan, or a carrier.

(P) ~~(k)~~ "Third party administrator" or "TPA" means a person ~~who~~ **THAT** processes claims pursuant to a service contract and ~~who~~ **THAT** may also provide 1 or more other administrative services pursuant to a service contract, other than under a worker's compensation self-insurance program pursuant to section 611 of the worker's disability compensation act of 1969, ~~Act No. 317 of the~~

~~Public Acts of 1969, being section~~ **1969 PA 317, MCL** 418.611. ~~of the Michigan Compiled Laws.~~ **THIRD PARTY ADMINISTRATOR INCLUDES A PHARMACY BENEFIT MANAGER.** Third party administrator does not include a carrier or employer sponsoring a plan.

SEC. 25. A PERSON SHALL NOT ESTABLISH OR OPERATE AS A PHARMACY BENEFIT MANAGER UNLESS THE PERSON REGISTERS WITH THE DIRECTOR. A PERSON THAT VIOLATES THIS SECTION IS SUBJECT TO A CIVIL FINE OF NOT MORE THAN $7,500.00.

SEC. 26. (1) BY MAY 1 OF EACH YEAR, A PHARMACY BENEFIT MANAGER SHALL PROVIDE THE DEPARTMENT WITH A REPORT CONTAINING THE FOLLOWING INFORMATION FROM THE PRIOR CALENDAR YEAR:

(A) FOR EACH OF THE PHARMACY BENEFIT MANAGER'S CONTRACTUAL OR OTHER RELATIONSHIPS WITH AN INSURER, THE AGGREGATE AMOUNT OF ALL REBATES THAT THE PHARMACY BENEFIT MANAGER RECEIVED FROM PHARMACEUTICAL MANUFACTURERS OTHER THAN ANY OF THE FOLLOWING REBATES:

(*i*) A PHARMACEUTICAL REBATE PROVIDED UNDER THE MEDICAID REBATE PROGRAM UNDER 42 USC 1396R-8.

(*ii*) A PHARMACEUTICAL REBATE PROVIDED UNDER THE MEDICARE DRUG DISCOUNT PROGRAM UNDER THE SOCIAL SECURITY ACT UNDER TITLE XVIII OF THE SOCIAL SECURITY ACT, 42 USC 1395 TO 1395JJJ, AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT, PUBLIC LAW 111-148, AS AMENDED BY THE HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010, PUBLIC LAW 111-152.

(*iii*) A PHARMACEUTICAL REBATE PROVIDED UNDER THE 340B DRUG PRICING PROGRAM UNDER 42 USC 256B.

(*iv*) A PHARMACEUTICAL REBATE PROVIDED UNDER THE FEDERAL

PRESCRIPTION DRUG PROGRAM AS PAID BY THE DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS.

(B) FOR EACH OF THE PHARMACY BENEFIT MANAGER'S CONTRACTUAL OR OTHER RELATIONSHIPS WITH AN INSURER, THE AGGREGATE REBATES THAT THE PHARMACY BENEFIT MANAGER RECEIVED FROM PHARMACEUTICAL MANUFACTURERS AND DID NOT PASS THROUGH TO THE INSURER.

(C) FOR EACH OF THE PHARMACY BENEFIT MANAGER'S CONTRACTUAL OR OTHER RELATIONSHIPS WITH AN INSURER, THE HIGHEST AGGREGATE RETAINED REBATE PERCENTAGE, LOWEST AGGREGATE RETAINED REBATE PERCENTAGE, AND THE MEAN AGGREGATE RETAINED REBATE PERCENTAGE.

(2) THE DEPARTMENT SHALL PUBLISH IN A TIMELY MANNER THE INFORMATION THAT IT RECEIVES UNDER SUBSECTION (1) ON A PUBLICLY AVAILABLE WEBSITE. HOWEVER, THE INFORMATION MUST BE MADE AVAILABLE IN A FORM THAT DOES NOT DISCLOSE THE IDENTITY OF A SPECIFIC INSURER OR HEALTH PLAN, THE PRICES CHARGED FOR SPECIFIC DRUGS OR CLASSES OF DRUGS, OR THE AMOUNT OF ANY REBATES PROVIDED FOR SPECIFIC DRUGS OR CLASSES OF DRUGS. IN DEVELOPING THE INFORMATION TO BE PUBLISHED IN THIS SECTION, THE DEPARTMENT SHALL CONSULT WITH THE 5 LARGEST CARRIERS IN THIS STATE, TO BE DETERMINED BY THE NUMBER OF ENROLLEES, TO ENSURE THEIR IDENTITY IS NOT ABLE TO BE INFERRED UNKNOWINGLY ON PUBLIC DISCLOSURE.

(3) THE PHARMACY BENEFIT MANAGER AND THE DEPARTMENT SHALL NOT PUBLISH OR DISCLOSE ANY INFORMATION THAT WOULD REVEAL THE IDENTITY OF A SPECIFIC INSURER OR HEALTH PLAN, A PRICE CHARGED FOR A SPECIFIC DRUG OR CLASS OF DRUGS, OR THE AMOUNT OF ANY REBATES PROVIDED FOR A SPECIFIC DRUG OR CLASS OF DRUGS. THE INFORMATION DESCRIBED IN THIS SUBSECTION MUST BE PROTECTED FROM DISCLOSURE AS

CONFIDENTIAL AND PROPRIETARY INFORMATION, AND IS EXEMPT FROM DISCLOSURE AS A PUBLIC RECORD UNDER SECTION 13 OF THE FREEDOM OF INFORMATION ACT, 1976 PA 442, MCL 15.243.

(4) AS USED IN THIS SECTION:

(A) "AGGREGATED RETAINED REBATE PERCENTAGE" MEANS THE FOLLOWING PERCENTAGE, CALCULATED FOR EACH PRESCRIPTION DRUG FOR WHICH A PHARMACY BENEFIT MANAGER RECEIVES REBATES UNDER A HEALTH PLAN, AND EXPRESSED WITHOUT DISCLOSING ANY IDENTIFYING INFORMATION REGARDING THE HEALTH PLAN, PRESCRIPTION DRUG, OR THERAPEUTIC CLASS:

(*i*) CALCULATE THE AGGREGATE REBATES THAT THE PHARMACY BENEFIT MANAGER RECEIVED DURING THE PRIOR CALENDAR YEAR FROM A PHARMACEUTICAL MANUFACTURER RELATED TO UTILIZATION OF THE MANUFACTURER'S PRESCRIPTION DRUG BY HEALTH PLAN INSUREDS AND DID NOT PASS THROUGH TO THE HEALTH PLAN OR INSURER.

(*ii*) DIVIDE THE RESULT OF THE CALCULATION UNDER SUBPARAGRAPH (*i*) BY THE AGGREGATE REBATES THAT THE PHARMACY BENEFIT MANAGER RECEIVED DURING THE PRIOR CALENDAR YEAR FROM A PHARMACEUTICAL MANUFACTURER RELATED TO UTILIZATION OF THE MANUFACTURER'S PRESCRIPTION DRUG BY HEALTH PLAN INSUREDS.

(B) "REBATES" MEANS ALL REBATES, DISCOUNTS, EDUCATION OR PROMOTIONAL FUNDS, AND OTHER PRICE CONCESSIONS, BASED ON UTILIZATION OF A PRESCRIPTION DRUG AND PAID BY THE MANUFACTURER OR OTHER PARTY, OTHER THAN AN INSURED, DIRECTLY OR INDIRECTLY, TO THE PHARMACY BENEFIT MANAGER AFTER THE CLAIM HAS BEEN ADJUDICATED AT THE PHARMACY. REBATES INCLUDE A REASONABLE ESTIMATE OF ANY VOLUME-BASED OR OTHER DISCOUNTS.

SEC. 27. A CONTRACT BETWEEN A PHARMACY BENEFIT MANAGER AND A

PHARMACY OR BETWEEN A PHARMACY BENEFIT MANAGER AND ANY OTHER ENTITY, INCLUDING, BUT NOT LIMITED TO, A MANUFACTURER, MUST NOT PROHIBIT OR PENALIZE A PHARMACY OR ANY OTHER ENTITY FOR DOING ANY OF THE FOLLOWING:

(A) DISCLOSING TO A CUSTOMER INFORMATION REGARDING EITHER OF THE FOLLOWING:

(*i*) THE COST SHARING AMOUNTS THAT THE CUSTOMER MUST PAY FOR A PARTICULAR PRESCRIPTION DRUG UNDER HIS OR HER HEALTH PLAN'S PRESCRIPTION DRUG BENEFIT OR, WITHOUT REQUESTING ANY HEALTH PLAN REIMBURSEMENT, OUTSIDE HIS OR HER HEALTH PLAN'S PRESCRIPTION DRUG BENEFIT, OR BOTH.

(*ii*) THE EXISTENCE AND CLINICAL EFFICACY OF A THERAPEUTICALLY EQUIVALENT DRUG THAT WOULD BE LESS EXPENSIVE TO THE CUSTOMER UNDER HIS OR HER HEALTH PLAN'S PRESCRIPTION DRUG BENEFIT OR OUTSIDE HIS OR HER HEALTH PLAN'S PRESCRIPTION DRUG BENEFIT, OR BOTH, WITHOUT REQUESTING ANY HEALTH PLAN REIMBURSEMENT, THAN THE DRUG THAT WAS ORIGINALLY PRESCRIBED.

(B) SELLING TO A CUSTOMER, INSTEAD OF A PARTICULAR PRESCRIBED DRUG, A THERAPEUTICALLY EQUIVALENT DRUG THAT WOULD BE LESS EXPENSIVE TO THE CUSTOMER UNDER HIS OR HER HEALTH PLAN'S PRESCRIPTION DRUG BENEFIT OR OUTSIDE HIS OR HER HEALTH PLAN'S PRESCRIPTION DRUG BENEFIT, WITHOUT REQUESTING ANY HEALTH PLAN REIMBURSEMENT, THAN THE DRUG THAT WAS ORIGINALLY PRESCRIBED.

Enrolled
House Bill 4005

Sponsored by Representatives NOSSE, NOBLE, Senators BEYER, LINTHICUM, STEINER HAYWARD; Representatives ALONSO LEON, BARNHART, FAHEY, HOLVEY, KENY-GUYER, KOTEK, LIVELY, MARSH, MCKEOWN, MCLAIN, MEEK, POWER, SALINAS, SMITH DB, SOLLMAN, Senators BOQUIST, JOHNSON, MONNES ANDERSON, TAYLOR (Presession filed.)

CHAPTER .....

AN ACT

Relating to the price of prescription drugs; creating new provisions; amending ORS 743.018 and 750.055; and declaring an emergency.

Whereas the state has a substantial public interest in the price and cost of prescription drugs; and

Whereas the state is a major purchaser of prescription drugs through the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services and the Department of Corrections; and

Whereas the state also provides major tax expenditures for health care through the tax exclusion of employer-sponsored health insurance coverage and the deductibility of the excess medical costs of individuals and families; and

Whereas the Legislative Assembly intends by sections 2, 3 and 5 of this 2018 Act to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing; and

Whereas the Legislative Assembly intends by this 2018 Act to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including decisions that result in price increases; and

Whereas the Legislative Assembly intends by this 2018 Act to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates for prescription drugs consistent with existing state and federal law; now, therefore,

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 and 3 of this 2018 Act shall be known and may be cited as the Prescription Drug Price Transparency Act.

SECTION 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or inde-

pendently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) Beginning March 15, 2019, 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 3. (1) A manufacturer that fails to report or provide information as required by section 2 of this 2018 Act may be subject to a civil penalty as provided in this section.

(2) The Department of Consumer and Business Services shall adopt a schedule of penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(3) The department shall impose civil penalties under this section as provided in ORS 183.745.

(4) The department may remit or mitigate civil penalties under this section upon terms and conditions the department considers proper and consistent with the public health and safety.

(5) Civil penalties collected under this section shall be paid over to the State Treasurer and deposited in the General Fund to be made available for general governmental expenses.

SECTION 4. Section 5 of this 2018 Act is added to and made a part of the Insurance Code.

SECTION 5. **(1) An insurer shall include with any filing under ORS 743.018 the following information regarding drugs reimbursed by the insurer under policies or certificates issued in this state:**

(a) The 25 most frequently prescribed drugs;

(b) The 25 most costly drugs as a portion of total annual spending;

(c) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and

(d) The impact of the costs of prescription drugs on premium rates.

(2) The Department of Consumer and Business Services shall conduct a public hearing annually on prescription drug prices, information reported to the department under section 2 of this 2018 Act and information described in subsection (1) of this section.

(3) The department shall regularly update the interim committees of the Legislative Assembly related to health on the information described in subsection (1) of this section.

(4) Subsection (1) of this section applies to an insurer that issues policies or certificates of health insurance for sale in this state that include a prescription drug benefit.

SECTION 6. Section 2 of this 2018 Act is amended to read:

Sec. 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) [*Beginning March 15, 2019, 30 days or less*] **No later than 30 days** after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on con-

sumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 7. Section 2 of this 2018 Act, as amended by section 6 of this 2018 Act, is amended to read:

Sec. 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than [*July 1, 2019*] **March 15 of each year**, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 8. ORS 743.018 is amended to read:

743.018. (1) Except for group life and health insurance, and except as provided in ORS 743.015, every insurer shall file with the Director of the Department of Consumer and Business Services all schedules and tables of premium rates for life and health insurance to be used on risks in this state, and shall file any amendments to or corrections of such schedules and tables. Premium rates are subject to approval, disapproval or withdrawal of approval by the director as provided in ORS 742.003, 742.005, 742.007 and 743.019.

(2) Except as provided in ORS 743B.013 and subsection (3) of this section, a rate filing by a carrier for any of the following health benefit plans subject to ORS 743.004, 743.022, 743.535 and

743B.003 to 743B.127 shall be available for public inspection immediately upon submission of the filing to the director:

(a) Health benefit plans for small employers.

(b) Individual health benefit plans.

(3) The director may by rule:

(a) Specify all information a carrier must submit as part of a rate filing under this section; and

(b) Identify the information submitted that will be exempt from disclosure under this section because the information constitutes a trade secret and would, if disclosed, harm competition.

(4) The director, after conducting an actuarial review of the rate filing, may approve a proposed premium rate for a health benefit plan for small employers or for an individual health benefit plan if, in the director's discretion, the proposed rates are:

(a) Actuarially sound;

(b) Reasonable and not excessive, inadequate or unfairly discriminatory; and

(c) Based upon reasonable administrative expenses.

(5) In order to determine whether the proposed premium rates for a health benefit plan for small employers or for an individual health benefit plan are reasonable and not excessive, inadequate or unfairly discriminatory, the director may consider:

(a) The insurer's financial position, including but not limited to profitability, surplus, reserves and investment savings.

(b) Historical and projected administrative costs and medical and hospital expenses**, including expenses for drugs reported under section 5 of this 2018 Act**.

(c) Historical and projected loss ratio between the amounts spent on medical services and earned premiums.

(d) Any anticipated change in the number of enrollees if the proposed premium rate is approved.

(e) Changes to covered benefits or health benefit plan design.

(f) Changes in the insurer's health care cost containment and quality improvement efforts since the insurer's last rate filing for the same category of health benefit plan.

(g) Whether the proposed change in the premium rate is necessary to maintain the insurer's solvency or to maintain rate stability and prevent excessive rate increases in the future.

(h) Any public comments received under ORS 743.019 pertaining to the standards set forth in subsection (4) of this section and this subsection.

(6) The requirements of this section do not supersede other provisions of law that require insurers, health care service contractors or multiple employer welfare arrangements providing health insurance to file schedules or tables of premium rates or proposed premium rates with the director or to seek the director's approval of rates or changes to rates.

SECTION 9. ORS 750.055 is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 735.600 to 735.650.

(g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

(i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260 and section 2, chapter 771, Oregon Laws 2013.

(j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 **and section 5 of this 2018 Act**.

(k) The following provisions of ORS chapter 744:

(A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 10. ORS 750.055, as amended by section 21, chapter 771, Oregon Laws 2013, section 7, chapter 25, Oregon Laws 2014, section 82, chapter 45, Oregon Laws 2014, section 9, chapter 59, Oregon Laws 2015, section 7, chapter 100, Oregon Laws 2015, section 7, chapter 224, Oregon Laws 2015, section 11, chapter 362, Oregon Laws 2015, section 10, chapter 470, Oregon Laws 2015, section 30, chapter 515, Oregon laws 2015, section 10, chapter 206, Oregon Laws 2017, section 6, chapter 417, Oregon Laws 2017, and section 22, chapter 479, Oregon Laws 2017, is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 735.600 to 735.650.

(g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

(i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260.

(j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 **and section 5 of this 2018 Act**.

(k) The following provisions of ORS chapter 744:

(A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 11. (1) The Task Force on the Fair Pricing of Prescription Drugs is established.

(2) The task force consists of 18 members appointed as follows:

(a) The President of the Senate shall appoint:

(A) One member from the Senate who is a member of the majority party.

(B) One member from the Senate who is a member of the minority party.

(b) The Speaker of the House of Representatives shall appoint:

(A) One member from the House of Representatives who is a member of the majority party.

(B) One member from the House of Representatives who is a member of the minority party.

(c) The Governor shall appoint the following members:

(A) One representative from the Department of Consumer and Business Services;

(B) One representative from the Oregon Health Authority;

(C) One representative from the Oregon Health Policy Board; and

(D) Individuals representing:

(i) Pharmaceutical manufacturers;

(ii) Insurance companies offering health insurance in this state;

(iii) Pharmacy benefit managers;

(iv) Prescription drug wholesalers;

(v) Consumers;

(vi) Independent pharmacies;

(vii) Large retail pharmacy chains;

(viii) Hospitals;

(ix) Biopharmaceutical companies based in Oregon;

(x) Coordinated care organizations; and

(xi) Medical providers.

(3) The task force shall develop a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products, including but not limited to manufacturers, insurers, pharmacy benefit managers, distributors, wholesalers and retail pharmacies.

(4) A majority of the voting members of the task force constitutes a quorum for the transaction of business.

(5) Official action by the task force requires the approval of a majority of the voting members of the task force.

(6) The task force shall elect one of its members to serve as chairperson.

(7) If there is a vacancy for any cause, the appointing authority shall make an appointment to become immediately effective.

(8) The task force shall meet at times and places specified by the call of the chairperson or of a majority of the voting members of the task force.

(9) The task force may adopt rules necessary for the operation of the task force.

(10) The task force shall submit a report in the manner provided by ORS 192.245, and may include recommendations for legislation, to the interim committees of the Legislative Assembly related to health no later than November 1, 2018. The report must contain a cost-effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.

(11) The Legislative Policy and Research Director shall provide staff support to the task force.

(12) Members of the Legislative Assembly appointed to the task force are nonvoting members of the task force and may act in an advisory capacity only.

(13) Members of the task force who are not members of the Legislative Assembly are not entitled to compensation or reimbursement for expenses and serve as volunteers on the task force.

(14) All agencies of state government, as defined in ORS 174.111, are directed to assist the task force in the performance of the task force's duties and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the task force consider necessary to perform their duties.

SECTION 12. Section 11 of this 2018 Act is repealed on December 31, 2020.

SECTION 13. (1) Sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act become operative on January 1, 2019.

(2) The Department of Consumer and Business Services shall take all steps necessary before January 1, 2019, to carry out the provisions of sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act on and after January 1, 2019.

(3) The amendments to section 2 of this 2018 Act by section 6 of this 2018 Act become operative on March 15, 2019.

(4) The amendments to section 2 of this 2018 Act by section 7 of this 2018 Act become operative on July 2, 2019.

SECTION 14. Notwithstanding any other law limiting expenditures, the limitation on expenditures established by section 1 (5), chapter 372, Oregon Laws 2017, for the biennium ending June 30, 2019, as the maximum limit for payment of expenses from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by the Department of Consumer and Business Services, for the Division of Financial Regulation, is increased by $425,022 for carrying out sections 2, 3 and 5 of this 2018 Act.

SECTION 15. This 2018 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2018 Act takes effect on its passage.

Passed by House February 28, 2018

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Tina Kotek, Speaker of House

Passed by Senate March 2, 2018

.....
Peter Courtney, President of Senate

Received by Governor:

.....M.,....., 2018

Approved:

.....M.,....., 2018

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2018

.....
Dennis Richardson, Secretary of State

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend the Code of Virginia by adding a section numbered 38.2-3407.15:4, relating to carrier business practices; contracts with pharmacies and pharmacists; amounts charged to an enrollee for covered prescription drugs; disclosure of less expensive alternatives to using enrollee's health plan.

[H 1177]

Approved

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 38.2-3407.15:4 as follows:

§ 38.2-3407.15:4. Limit on copayment for prescription drugs; permitted disclosures.

A. As used in this section:

"Carrier" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15.

"Copayment" means an amount an enrollee is required to pay at the point of sale in order to receive a covered prescription drug.

"Enrollee" means a policyholder, subscriber, participant, or other individual covered by a health benefit plan.

"Health plan" means any health benefit plan, as defined in § 38.2-3438, that provides coverage for prescription drugs.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of enrollees.

"Pharmacy benefits manager" means an entity that performs pharmacy benefits management. The term includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a carrier.

"Provider contract" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15.

B. No provider contract between a health carrier or its pharmacy benefits manager and a pharmacy or its contracting agent shall contain a provision (i) authorizing the carrier or its pharmacy benefits manager to charge, (ii) requiring the pharmacy or pharmacist to collect, or (iii) requiring an enrollee to make, a copayment for a covered prescription drug in an amount that exceeds the least of:

1. The applicable copayment for the prescription drug that would be payable in the absence of this section; or

2. The cash price the enrollee would pay for the prescription drug if the enrollee purchased the prescription drug without using the enrollee's health plan.

C. Provider contracts between a health carrier or its pharmacy benefits manager and a pharmacy or its contracting agent shall contain specific provisions that allow a pharmacy to:

1. Disclose to an enrollee information relating to (i) the provisions of this section and (ii) the availability of a more affordable therapeutically equivalent prescription drug;

2. Sell a more affordable therapeutically equivalent prescription drug to an enrollee if one is available in accordance with § 54.1-3408.03; and

3. Offer and provide direct and limited delivery services to an enrollee as an ancillary service of the pharmacy in accordance with § 54.1-3420.2.

D. A pharmacy shall not be penalized by a pharmacy benefits manager or a carrier for discussing information or for selling a more affordable alternative as described in subsection C.

E. Provider contracts between a health carrier or its pharmacy benefits manager and a pharmacy or its contracting agent shall contain specific provisions that prohibit the carrier or the pharmacy benefit manager from charging a fee to a pharmacy or otherwise holding a pharmacy responsible for a fee relating to the adjudication of a claim unless the fee is reported on the remittance advice of the adjudicated claim or is set out in contract between the pharmacy benefits manager and the pharmacy or its contracting agent.

F. This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974, Medicaid, or Medicare Part D.

G. This section shall apply with respect to provider contracts entered into, amended, extended, or renewed on or after January 1, 2019.

H. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and regulations as it may deem necessary to implement this section.

I. The Commission shall have no jurisdiction to adjudicate individual controversies arising out of this section.

H-3309.1

HOUSE BILL 2296

State of Washington 65th Legislature 2018 Regular Session

By Representatives Slatter, Schmick, Cody, Robinson, Dolan, Orwall, Tharinger, Macri, Young, Kloba, Appleton, Jinkins, Ormsby, Pollet, and Doglio

Prefiled 12/15/17. Read first time 01/08/18. Referred to Committee on Health Care & Wellness.

AN ACT Relating to protecting consumers from excess charges for prescription medications; adding a new section to chapter 19.340 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** A new section is added to chapter 19.340 RCW to read as follows:

(1) A contract entered into or renewed on or after the effective date of this section between a pharmacy benefit manager or insurer and a pharmacist or pharmacy may not penalize, including through increased utilization review, reduced payments, or other financial disincentives, a pharmacist's or pharmacy's disclosure to a person purchasing prescription medication of information regarding:

(a) The cost of the prescription medication to the person; or

(b) The availability of any therapeutically equivalent alternative medications or alternative methods of purchasing the prescription medication, including, but not limited to, paying the cash price, that are less expensive than the cost of the prescription medication to the person.

(2) On or after January 1, 2019, the maximum amount a pharmacy benefit manager or insurer may require a person to pay at the point of sale for a covered prescription medication is the lesser of:

(a) The applicable cost sharing for the prescription medication;

(b) The amount the pharmacy benefit manager or insurer reimburses the pharmacy or pharmacist for the prescription medication; or

(c) The amount the person would pay for the prescription medication if the person purchased the prescription medication without using a health plan or any other source of prescription medication benefits or discounts.

NEW SECTION. **Sec. 2.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. **Sec. 3.** This act may be known and cited as the affordable medication for patients act.

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S-3192.2

SENATE BILL 6147

State of Washington 65th Legislature 2018 Regular Session

By Senators Rivers, Cleveland, Walsh, Kuderer, Nelson, Carlyle, Angel, Hasegawa, and Keiser

Read first time 01/10/18. Referred to Committee on Health & Long Term Care.

AN ACT Relating to prescription drug insurance continuity of care; adding a new section to chapter 48.43 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** INTENT. The legislature finds that innovation has become a growing tool in modern medicine, which has allowed Washington's citizens to lead a better quality of life. The legislature further finds that these medical innovations are tools that should be encouraged and fostered. The legislature also recognizes that innovation often increases the overall cost of health care, and both costs and innovations should be balanced carefully.

The legislature finds that managing diseases, particularly for chronic or debilitating conditions, is often a difficult process that may require physicians to make several changes to a patient's medication before finding the one that is the most effective for the patient with the least amount of side effects. The legislature finds many patients have been through years of trial-and-error with their health care providers to find the therapy that works for them and on which they are stable.

The legislature further finds that patients' formularies often change during the plan year, which leads to less access, inefficient

use of services, and overall instability of a patient's condition. The legislature further finds that Washington's patients deserve consistent protections that patients enjoy in medicare and other states, which ensures the best use of health care dollars, maintenance of health, and stability of patients.

The legislature further finds that putting the patient first by ensuring access to a recommended course of therapy that the patient has been stabilized on is imperative, especially for patients fighting chronic, debilitating conditions that affect their ability to work or be contributing family or community members. Therefore, it is the intent of the legislature to implement a cost-effective requirement that ensures patients can rely on the prescription formulary they enter into with their insurance carrier through the entirety of the plan year.

NEW SECTION. **Sec. 2.** A new section is added to chapter 48.43 RCW to read as follows:

(1) Except as provided in subsection (2) of this section, for health plans that include prescription drug coverage, an issuer may not, outside of an open enrollment period, deny continued coverage or increase the copayment or coinsurance amount for a prescription drug to a medically stable enrollee if:

(a) The drug had previously been covered by the plan for the enrollee's medical condition during the enrollee's current plan year;

(b) A participating provider continues to prescribe the drug for the enrollee's medical condition and the drug is a maintenance medication or for the treatment of a chronic condition;

(c) The drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition; and

(d) The enrollee continues to be enrolled in the plan.

(2) Nothing in this section prohibits:

(a) The issuer from requiring generic substitution during the current plan year;

(b) The issuer from adding new drugs to its formulary during the current plan year, as long as the changed formulary applies only to new prescriptions and not existing prescriptions in violation of subsection (1) of this section;

(c) A participating prescribing provider from prescribing a different drug that is covered by the plan and medically appropriate for the enrollee; or

(d) The issuer from removing a drug from its formulary for reasons of patient safety concerns, drug recall, or removal from the market as determined by the United States food and drug administration.

(3) This section applies to plans issued or renewed on or after January 1, 2019.

--- END ---

NCOIL Model Act Materials

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National Council of Insurance Legislators (NCOIL)

Pharmacy Benefits Manager Licensure and Regulation Model Act

Sponsored by Sen. Jason Rapert (AR)
Discussion Draft as of May 8, 2018

Table of Contents

Section 1. Title

This Act shall be known as and may be cited as the "[State] Pharmacy Benefits Manager Licensure and Regulation Act."

Section 2. Purpose

(a) This Act establishes the standards and criteria for the regulation and licensure of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans.

(b) The purpose of this Act is to:

(1) Promote, preserve, and protect the public health, safety, and welfare through effective regulation and licensure of pharmacy benefits managers;

(2) Provide for powers and duties of the Insurance Commissioner, the State Insurance Department; and

(3) Prescribe penalties and fines for violations of this Act.

Section 3. Definitions

For purposes of this Act:

(a) "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both subdivisions (a)(1) and (2) of this section.

(b) (1) "Health benefit plan" means any individual, blanket, or group plan, policy, or contract for healthcare services issued or delivered by a healthcare insurer in this state.

(2) “Health benefit plan” does not include:

(i) Accidental-only plans;

(ii) Specified disease plans;

(iii) Disability income plans;

(iv) Plans that provide only for indemnity for hospital confinement;

(v) Long-term care only plans that do not include pharmacy benefits;

(vi) Other limited-benefit health insurance policies or plans; or

(vii) Health benefit plans provided under the Workers’ Compensation Laws of this State

(viii) Health benefit plans that are self-funded and specifically exempted from regulation by this State by The Employee Retirement Income Security Act of 1974 (ERISA)

(c) "Healthcare insurer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

(d) “Independent pharmacy” means a pharmacy that is not in any way affiliated with a pharmacy benefits manager.

(e) “Maximum Allowable Cost List” means a listing of drugs used by a pharmacy benefits manager setting the maximum allowable cost on which reimbursement to a pharmacy or pharmacist may be used.

(f) "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including without limitation:

(1) Negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(2) Disbursing or distributing rebates;

(3) Managing or participating in incentive programs or arrangements for pharmacist services;

(4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) Developing formularies;

(6) Designing prescription benefit programs; or

(7) Advertising or promoting services.

(g) “Pharmaceutical wholesaler” means a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy

(h) "Pharmacist" means an individual licensed as a pharmacist by the State Board of Pharmacy.

(i) "Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy.

(j) "Pharmacy" means the place licensed by the State Board of Pharmacy in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail.

(k) “Pharmacy acquisition cost” means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy’s invoice.

(l) (1) "Pharmacy benefits manager" means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans.

(2) "Pharmacy benefits manager" does not include any:

(i) Healthcare facility licensed in [this State];

(ii) Healthcare professional licensed in [this State];

(iii) Consultant who only provides advice as to the selection or performance of a pharmacy benefits manager; or

(iv) Entity that provides claims processing services or other prescription drug or device services for the fee-for-service [State]Medicaid Program only in that capacity.

(m) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager.

(n) “Pharmacy benefits manager network” means a network of pharmacists or pharmacies that are offered by an agreement or insurance contract to provide pharmacist services for health benefit plans.

(o) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services under a health benefit plan.

(p) "Pharmacy services administrative organization" means an organization that helps independent pharmacies and pharmacy benefits managers, or third-party payers achieve administrative efficiencies, including contracting and payment efficiencies.

(q) (1) "Rebate" means a discount or other price concession based on utilization of a prescription drug that is paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

(2) "Rebate" includes without limitation incentives, disbursements, and reasonable estimates of a volume-based discount.

(r) "Third party" means a person, business, or entity other than a pharmacy benefits manager that is not an enrollee or insured in a health benefit plan.

Section 4. License to do business – Annual statement – Assessment

(a) (1) A person or organization shall not establish or operate as a pharmacy benefits manager in this State for health benefit plans without obtaining a license from the Insurance Commissioner under this Act.

(2) The commissioner shall prescribe the application for a license to operate in this State as a pharmacy benefits manager and may charge application fees and renewal fees as established by rule.

(b) (1) The commissioner shall issue rules establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers under this Act and not inconsistent herewith.

Section 5. Pharmacy Benefit Manager Network Adequacy

A pharmacy benefits manager shall provide:

(a) (1) A reasonably adequate and accessible pharmacy benefits manager network for the provision of prescription drugs for a health benefit plan that shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence.

(2) A mail-order pharmacy shall not be included in the calculations determining pharmacy benefits manager network adequacy; and

(b) A pharmacy benefits manager network adequacy report describing the pharmacy benefits manager network and the pharmacy benefits manager network's accessibility in this state in the time and manner required by rule issued by the State Insurance Department.

Section 6. Compensation – Prohibited Practices

(a) (1) The Insurance Commissioner may review and approve the compensation program of a pharmacy benefits manager with a health benefit plan to ensure that the reimbursement for pharmacist services paid to a pharmacist or pharmacy is fair and reasonable to provide an adequate pharmacy benefits manager network for a health benefit plan under the standards issued by rule of the State Insurance Department.

(2) All information and data acquired during the review under subdivision (a)(1) of this section is:

(A) Considered proprietary and confidential; and

(B) Not subject to the [Freedom of Information Act][1] of this State.

(b) A pharmacy benefits manager or representative of a pharmacy benefits manager shall not:

(1) Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;

(2) Unless reviewed and approved by the commissioner, charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including without limitation a fee for:

(A) The receipt and processing of a pharmacy claim;

(B) The development or management of claims processing services in a pharmacy benefits manager network; or

(C) Participation in a pharmacy benefits manager network;

(3) Unless reviewed and approved by the commissioner in coordination with the State Board of Pharmacy, require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the board;

(4) (A) Reimburse an independent pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(B) The amount shall be calculated on a per-unit basis using the same generic product identifier or generic code number; or

(5) Do any combination of the actions listed in subdivisions (b)(1)-(4) of this section.

(c) A claim for pharmacist services shall not be retroactively denied or reduced after adjudication of the claim, unless:

(1) The original claim was submitted fraudulently;

(2) The original claim payment was incorrect because the pharmacy or pharmacist had already been paid for the pharmacist services; or

(3) The pharmacist services were not properly rendered by the pharmacy or pharmacist.

[1] DRAFTING NOTE: State FOIAs have different names in different states, often called Open Records Acts, Public Records Act, Public Records Law, etc. and thus the specific title used in this subsection needs to be tailored accordingly.

(d) Termination of a pharmacy or pharmacist from a pharmacy benefits manager network shall not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services properly rendered.

(e) The commissioner may issue a rule establishing prohibited practices of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans.

Section 7. Gag clauses prohibited

(a) In any participation contracts between pharmacy benefits managers and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted, or penalized in any way from disclosing to any covered person any healthcare information that the pharmacy or pharmacist deems appropriate regarding the nature of treatment, risks, or alternatives thereto, the availability of alternate therapies, consultations, or tests, the decision of utilization reviewers or similar persons to authorize or deny services, the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer.

(b) A pharmacy or pharmacist may provide to an insured information regarding the insured's total cost for pharmacist services for a prescription drug.

(c) A pharmacy or pharmacist shall not be proscribed by a pharmacy benefits manager from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if a more affordable alternative is available.

(d) A pharmacy benefits manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Insurance Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements under this Act.

Section 8. Enforcement

(a) The Insurance Commissioner shall enforce this Act.

(b) (1) The commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine if the pharmacy benefits manager is in compliance with this Act.

(2) The information or data acquired during an examination under subdivision (b)(1) of this section is:

(A) Considered proprietary and confidential; and

(B) Not subject to the [Freedom of Information Act][2] of this State

Section 9. Rules

(a) (1) The Insurance Commissioner may adopt rules regulating pharmacy benefits managers that are not inconsistent with this Act.

(2) Rules that the commissioner may adopt under this Act include without limitation rules relating to:

(A) Licensing;

(B) Application fees;

(C) Financial solvency requirements;

(D) Pharmacy benefits manager network adequacy;

(E) Prohibited market conduct practices;

(F) Data reporting requirements under State price-gouging laws

(G) Compliance and enforcement requirements under State laws concerning Maximum Allowable Cost Lists;

(H) Rebates;

(I) Prohibitions and limitations on the corporate practice of medicine (CPOM)[3];

(J) Compensation; and

(K) Lists of health benefit plans administered by a pharmacy benefits manager in this state.

(b) Rules adopted under this Act shall set penalties or fines, including without limitation monetary fines, suspension of licensure, and revocation of licensure for violations of this

[2] DRAFTING NOTE: State FOIAs have different names in different states, often called Open Records Acts, Public Records Act, Public Records Law, etc. and thus the specific title used in this subsection needs to be tailored accordingly.

[3] DRAFTING NOTE: Commissioners may wish to evaluate whether PBMs disregarding of physicians' prescribing practices and substituting their (PBMs') own judgment through the use of mandated step therapy constitutes the practice of medicine.

Act and rules adopted under this Act.

Section 10. Applicability

(a) This Act is applicable to a contract or health benefit plan issued, renewed, recredentialed, amended, or extended on and after _____.

(b) A contract existing on the date of licensure of the pharmacy benefits manager shall comply with the requirements of this Act as a condition of licensure for the pharmacy benefits manager.

(c) This Act is not applicable to health benefit plans that are self-funded and specifically exempted from regulation by this State by The Employee Retirement Income Security Act of 1974 (ERISA).

Section 11. Annual Report

(a)(1) Unless otherwise required more frequently by the Insurance Commissioner, a pharmacy benefits manager shall file an annual report with the commissioner pursuant to the timing, format, and requirements issued by rule of the State Insurance Department.

(2) The annual report shall contain information regarding:

(i) when seeking payment or reimbursement for pharmacist services provided in connection with a pharmacy benefits plan or program or reporting expenditures for pharmacist services provided in connection with a pharmacy benefits plan or program, a pharmacy benefits manager shall itemize by individual claim:

(1) The amount actually paid or to be paid to the pharmacy or pharmacist for the pharmacist services;

(2) The identity of the pharmacy or pharmacist actually paid or to be paid; and

(3) The prescription number or other identifier of the pharmacist services.

(b) The annual report shall be considered proprietary and confidential and not subject to the [Freedom of Information Act][4] of this State.

Section 12. Maximum Allowable Cost Lists

(a) Before a pharmacy benefits manager places or continues a particular drug on a Maximum Allowable Cost List, the drug:

[4] DRAFTING NOTE: State FOIAs have different names in different states, often called Open Records Acts, Public Records Act, Public Records Law, etc. and thus the specific title used in this subsection needs to be tailored accordingly.

(1) Shall be listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or "Green Book" or has an NR or NA rating by Medi-span, Gold Standard, or a similar rating by a nationally recognized reference;

(2) Shall be available for purchase by each pharmacy in the state from national or regional wholesalers operating in this State; and

(3) Shall not be obsolete.

(b) A pharmacy benefits manager shall:

(1) Provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;

(2) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology;

(3) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and

(4) (A) (i) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as:

(a) Not meeting the requirements of this section; or

(b) Being below the pharmacy acquisition cost.

(ii) The reasonable administrative appeal procedure shall include the following:

(a) A dedicated telephone number and email address or website for the purpose of submitting administrative appeals;

(b) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and

(c) No less than seven (7) business days to file an administrative appeal.

(B) The pharmacy benefits manager shall respond to the challenge under subdivision (c)(4)(A) of this section within seven (7) business days after receipt of the challenge.

(C) If a challenge is under subdivision (c)(4)(A) of this section, the pharmacy benefits manager shall within seven (7) business days after receipt of the challenge either:

(i) If the appeal is upheld:

(a) Make the change in the maximum allowable cost;

(b) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Provide the National Drug Code number that the increase or change is based on to the pharmacy or pharmacist; and

(d) Make the change under subdivision (c)(4)(C)(i)(a) of this section effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code number and the name of the national or regional pharmaceutical wholesalers operating in this State that have the drug currently in stock at a price below the Maximum Allowable Cost List; or

(iii) If the National Drug Code number provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

(c) (1) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(2) The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

(d) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

(e) (1) This section does not apply to a Maximum Allowable Cost List maintained by the State Medicaid Program or the Employee Benefits Division.

(2) This section shall apply to the pharmacy benefits manager employed by the State Medicaid Program or the Employee Benefits Division if, at any time, the State Medicaid Program or the Employee Benefits Division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.

(f) A violation of this section is a deceptive and unconscionable trade practice under the [State] Deceptive Trade Practices Act, a prohibited practice under this Act, and the [State] Trade Practices Act.

Section 13. Severability Clause

If any provision of this act or the application of this act to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this act are declared severable.

Section 14. Effective Date

This Act is effective immediately.

PCMA

NCOIL PROPOSED MODEL ACT

A PRESCRIPTION FOR RISKING PATIENT SAFETY WHILE INCREASING COSTS

NCOIL PROPOSED MODEL ACT PUTS SAFETY & ACCESS TO NEEDED MEDICATIONS AT RISK

The Model Act would allow a network pharmacy to decline to dispense a medication to a patient if the reimbursement to the pharmacy is less than its acquisition cost. This will lead to patients going without important medications and endangering their safety. *(Maximum Allowable Costs List –Section 12)*

- It would also interfere with medication adherence and the treatment of serious illnesses. Not only does this provision put pharmacy profits ahead of patients, it fails to recognize that overall pharmacy profits on the dispensing of drugs are measured on the dispensing of all drugs, brand and generic, and not on a particular drug.

NCOIL PROPOSED MODEL ACT PUTS PATIENT SAFETY AT RISK

The Model Act prohibits PBMs from requiring pharmacy credentialing and accreditation standards unless approved by both the Department and Board of Pharmacy (BOP) (*Accreditation – Section 6)*

- Specialty pharmacies are held to a higher standard of care and plan sponsors have the right to require accreditation to ensure that pharmacies dispensing to their beneficiaries meet such higher standards.
- Insurance plans and other payers routinely use credentialing to validate and approve facilities and practitioners to be in their networks as participating providers of healthcare services, across the healthcare system. This is not a unique requirement for pharmacies.

NCOIL PROPOSED MODEL ACT IGNORES EXISTING REGULATIONS

The Model Act requires PBMs to be licensed to do business in a state, ignoring any other state requirements such as the requirement to be registered as a Third Party Administrator. *(Licensure –Section 4)*

- Health Insurers design the pharmacy benefit and are appropriately regulated by a state's Department of Insurance.

NCOIL PROPOSED MODEL ACT GRANTS EXCESSIVE RULEMAKING AUTHORITY

The Model Act grants the Department broad and excessive rulemaking authority to essentially re-define the entire marketplace delivery of pharmacy benefits and regulate private commercial market contracts between health plans and insurers, pharmacies, and PBMs. *(Rules –Section 9)*

- Not only is this unprecedented, it is clear government overreach into private marketplace contracting. Government agencies should not have the unfettered ability to re-define private marketplace contracts through rulemaking -- especially related to compensation and other financial terms of private contracts.

NCOIL PROPOSED MODEL ACT REMOVES FREE MARKET INCENTIVES

The Model Act reduces the effectiveness of a PBMs' MAC lists (Maximum Allowable Costs), which encourage drugstores to purchase generic drugs at the most competitive prices. *(Maximum Allowable Costs List –Section 12)*

- In January of 2018 the Eighth Circuit heard the state of Arkansas' appeal of the Arkansas District Court's opinion striking down Arkansas Act 900 of 2015 as preempted by ERISA because the statute interfered with key matters of plan administration. The Maximum Allowable Costs provision of the NCOIL Model Act mirror the provisions of Act 900.
- The Model Act guarantees profit on every transaction at the expense of consumers and plan sponsors. No other businesses are granted such a privileged position in any supply chain.
- This windfall of profits for pharmacies will be at the expense of consumers and plan sponsors.

NCOIL PROPOSED MODEL ACT RAISES COSTS FOR EMPLOYERS WHILE PROVIDING PROTECTION FOR STATE RUN PROGRAMS

The Model Act differentiates among programs by placing the burden to pay pharmacies a guaranteed profit on PBM-administered benefits only, exempting a state run Medicaid program or state run state employee benefit program. *(Maximum Allowable Costs List –Section 12)*

NCOIL MODEL ACT SUMMARY

Link to NCOIL Model ACT

SECTION 1 – Title ***– (pg. 1)***

This Act shall be known as and may be cited as the "[State] Pharmacy Benefits Manager Licensure and Regulation Act."

SECTION 2 – Purpose - ***– (pg. 1-2)***

Section 2 establishes the standards and criteria for the regulation and licensure of PBMs providing claims processing services or other prescription drug or device services for health benefit plans. The purpose is to promote, preserve, and protect the public health, safety, and welfare through effective regulation and licensure of pharmacy benefits managers; Provide for powers and duties of the Insurance Commissioner, the State Insurance Department; and prescribes penalties and fines for violations of this Act.

SECTION 3 - Definitions– ***(pg. 2-5)***

Section 3 includes the following definitions: Claims Processing Services; Health Benefit Plan; Healthcare Insurer; Independent Pharmacy; Maximum Allowable Cost; Other Prescription drug or device services; Pharmaceutical Wholesaler; Pharmacist; Pharmacy; Pharmacists Services; Pharmacy Acquisition Costs; Pharmacy Benefits Manager; Pharmacy Benefits Manager Affiliate; Pharmacy Benefits Manager Network; Pharmacy Benefits Plan or program; Pharmacy Services Administrative Organization; Rebate; and Third Party.

Section 3 contains three definitions that are not included in the Arkansas bill. Section 3d defines an "independent pharmacy" as a pharmacy that is not in any way affiliated with a PBM. Section 3e defines "Maximum Allowable Cost list" and Section 3g defines a "pharmaceutical wholesaler".

SECTION 4 – Licensure– ***(pg. 5)***

Section 4 requires a PBM to be licensed and gives the Commissioner of Insurance the authority to develop the application, application fees and renewal fees. Section 4 also requires the Commissioner to issue rules establishing the licensing, fees, application, financial standards and reporting requirements.

SECTION 5 – Network Adequacy *– (pg. 5)*

Section 5 requires a PBM to provide "a reasonably adequate and accessible network" for *"convenient patient access to pharmacies within a reasonable distance from a patient's residence".* A mail order pharmacy shall not be included in the calculations. The PBM must submit a network adequacy report.

SECTION 6 – Compensation and Prohibited Practices *– (pg. 5-7)*

Section 6a(1) allows the Insurance Commissioner to review and approve the compensation a PBM receives from a health benefit plan to ensure that the reimbursement paid for pharmacist services are fair and reasonable and will provide an adequate network of pharmacies. The legislation provides for the confidentiality of the information and prevents it from being subject to open records.

Section 6b(1) prohibits a PBM from knowingly permitting the use of any advertisement, promotion, solicitation, representation, proposal or offer that is untrue, deceptive or misleading.

Section 6b(2) prohibits a PBM, unless approved by the Commissioner, from charging a pharmacy a fee related to the adjudication of a claim or participation in a network.

Section 6b(3) prohibits a PBM, unless approved by the Commissioner in coordination with the Board of Pharmacy, from requiring pharmacy accreditation standards or certification requirements that are inconsistent or more stringent than the board.

Section 6b(4) prohibits a PBM from reimbursing a pharmacy in an amount less than the amount the PBM reimburses an affiliate pharmacy. The amount shall be calculated on a per-unit basis using certain identifiers.

Section 6c prohibits a PBM from retroactively denying or reducing a claim after adjudication unless: the original claim was submitted fraudulently; the claim was incorrect because the pharmacists had already been paid for the services; or the claim was incorrect because the services were not properly rendered.

Section 6d obligates a PBM to pay a pharmacy for a properly rendered service even if the pharmacy is terminated.

Section 6e allows the Commissioner to issue rules establishing prohibited practices of PBMs.

SECTION 7 – Gag Order*– (pg. 7)*

Section 7 prohibits PBMs from restricting pharmacies ability to disclose to patients *"any healthcare information that the participating provider deems appropriate regarding the nature of treatment, risk, or alternatives*" and the Pharmacies may provide information *"regarding the insured's total cost for pharmacist services"* and cannot be prohibited from discussing *"the total cost"* or selling a more affordable alternative.

Section 7 prohibits a PBM from restricting, or limiting disclosure of information to the Insurance Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a PBM.

SECTION 8 – Enforcement– *(pg. 7-8)*
Section 8 gives the Insurance Commissioner enforcement authority. In addition, the Commissioner may examine and audit the books and records of the PBM. The information obtained is proprietary and confidential and not subject to open records.

SECTION 9 – Rules– *(pg. 8)*
Section 9 gives the Insurance Commissioner the authority to adopt rules, without limitations, relating to the following: licensing; application fees; financial solvency requirements; pharmacy network adequacy; prohibited market conduct practices; data reporting requirement; compliances and enforcement requirements concerning MAC; rebates; compensation; and the lists of health benefit plans administered by PBMs.

Section 9 requires that the rules adopted under this subchapter shall also set penalties or fines, including and without limitation monetary fines, suspension of licensure, and revocation of licensure.

SECTION 10 – Applicability – *(pg. 9)*
Section 10 allows the state to determine the date that the act will apply to contracts or health benefit plan issued, renewed, re-credentialed, amended, or extended.

Section 10 requires that a contract existing on the date of licensure of the pharmacy benefits manager shall comply with the requirements of this Act as a condition of licensure for the PBM.

Section 10 states *"This Act is not applicable to health benefit plans that are self-funded and specifically exempted from regulation by this State by The Employee Retirement Income Security Act of 1974 (ERISA)."*

SECTION 11 – Annual Report– *(pg. 9)*
Section 11 requires all PBMs to file an annual report containing information by individual claim, the amount actually paid or to be paid to the pharmacy, the identity of the pharmacy paid, and the prescription number or other identifier of the pharmacist services. The annual report will be considered proprietary and confidential information.

SECTION 12 – Maximum Allowable Costs Lists– *(pg. 9-12)*
Section 12 sets the standards for developing and implementing a MAC lists.

Section 12 requires the drugs on the MAC list shall be A, B, NR or NA rated; available for purchase in the state; and not obsolete. The PBM shall provide access to the MAC list and update its MAC lists *"on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the MAC List is based or in the value of a variable involved in the methodology".*

Section 12 requires the PBM to provide access to the MAC lists and a reasonable administrative appeal procedure for the pharmacy to appeal if the PBM did not meet the requirements of this section or the reimbursement fell below the acquisition costs. The appeal process must include a dedicated phone number and email address or website for submitting the appeals. The PBM must accept the appeals from the pharmacy or the PSAO and must accept the appeal if it is filed in 7 days.

Section 12 requires the PBM to respond to the appeal within 7 days. If the PBM upholds the appeal then they must make the change to the MAC lists and allow the challenging pharmacy to reverse and rebill the claim and provide the pharmacy with the NDC number that the increase or change is based on and make the change for all similarly situated pharmacies. If the appeal is denied, the PBM must provide the challenging pharmacy the NDC number and the name of the national or regional pharmaceutical wholesalers operating in this State that have the drug currently in stock at a price below the Maximum Allowable Cost List; or If the National Drug Code number provided by the PBM is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the PBM shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

Section 12 prohibits a PBM from reimbursing a pharmacy in an amount less than the amount the PBM reimburses an affiliate pharmacy. The amount shall be calculated on a per-unit basis using certain identifiers.

Section 12 allows a pharmacy or pharmacist to decline to provide the pharmacist services to a patient or PBM if, as a result of a MAC List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

Section 12 provides for the exclusion of a state run Medicaid Program and the State Employee Benefits program. However, the MAC provisions apply if the state uses a PBM for the Medicaid program or the state employee benefits program.

Section 12 makes a violation of this section a deceptive trade practice.

SECTION 13 – Severability Clause– ***(pg. 12)***

Section 13 provides that in the event any provision of the Licensure Act is deemed invalid, the other provisions are severable and may continue to be enforced.

SECTION14 – Effective Date– ***(pg. 13)***

Section 14 requires the provisions of the Act to go into effect immediately.

PCMA and Third Party Ally Comment Letters

May 11, 2018

The Honorable Bill Walker
Office of the Governor
PO Box 110001
Juneau AK 99811-0001

Re: Veto Request for HB 240: Pharmacy Benefit Managers

Dear Governor Walker:

On behalf of the Pharmaceutical Care Management Association (PCMA), we must respectfully request your veto on HB 240 (pharmacy benefit managers). PCMA is the national trade association for America's Pharmacy Benefit Managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by plan sponsors such as large employers, health insurers, labor unions, and federal and state-sponsored health programs. Though unions, large employers, and public programs are not required to use PBMs, most choose to because PBMs help lower the costs of prescription drug coverage.

From the beginning of the legislative discussion on HB 240, PCMA and its member companies sought a stakeholder discussion to better understand the concerns behind this legislation and to discuss possibilities for solutions. Time and time again, our requests to meet with other stakeholders were rejected. Nonetheless, this bill advanced through the legislative session. Also from the beginning, PCMA and member companies supported some of the concepts in the bill that were focused on protecting consumers, such as the prohibition on gag orders and the practice of "clawback." However, HB 240 went significantly beyond these concepts by creating a new regulatory structure for PBMs, establishing barriers to weeding out fraud, waste, and abuse, and guaranteeing profit for pharmacies operating in Alaska. We outline some of our primary concerns below.

Perhaps most notable is the questionable legal basis of HB 240. In 2017, the Eighth Circuit Court of Appeals struck down a 2014 Iowa law very similar to HB 240, holding the law interfered with a PBM's discretion to negotiate prices with retail pharmacies, while requiring PBMs to report proprietary information and interfering with a PBM's claims-processing procedures. A unanimous Eighth Circuit panel held that the Iowa law "impermissibly interferes with the PBM function of ERISA plans . . . imposes mandates and restrictions on a PBM's relationship with Iowa and its pharmacies that run counter to ERISA's intent of making plan oversight and plan procedures uniform." (*Pharmaceutical Care Mgmt. Ass'n v. Gerhart, 2017 WL 104467 (8th Cir. 2017)).*

HB 240 also establishes a state-mandated pricing scheme for generic drugs that will increase costs for employers and consumers, reversing incentives for pharmacies to shop for the lowest priced generic drug for stocking in their drugstores, forcing the disclosure of proprietary information that serves as a cornerstone for competition in the PBM marketplace, and ultimately guaranteeing profits for pharmacies.

The bill requires a PBM, upon denying a pharmacy's appeal, to provide ". . . the national drug code of an equivalent multi-source generic drug that has been purchased by another network pharmacy located in the state at a price that is equal to or less than the pharmacy benefits manager's list price within seven days after the network pharmacy appeals the claim . . ." However, it will be virtually impossible for PBMs to comply with this section. PBMs use various sources to determine drug reimbursement, including, but not limited to, average pharmaceutical prices and other publicly available information, but PBMs have no way of knowing how much pharmacies have actually paid for pharmaceuticals.

HB 240 requires PBMs to grant reimbursement appeals in specified circumstances by requiring that pharmacies are reimbursed at the "cost" of the drugs to the pharmacy, even if the cost was inflated or not truly reflected on the invoice—ensuring pharmacy profit at the expense of consumers.

Academics have opined that there are dangers in reimbursing pharmacies based on their invoiced drug acquisition cost.[1] Dr. Hyman reports that cost-based reimbursement systems will "effectively function as a 'guaranteed profits' term," because the pharmacies will be "guaranteed they will be paid at least that amount, and likely more. And because of rebates and discounts [that pharmacies receive from their suppliers], invoiced prices may not reflect actual drug acquisition costs—further inflating the guaranteed profits."[2] In addition, he indicates that legislation mandating cost-based reimbursement is likely to cause:

- Increased spending on pharmaceuticals and the cost of pharmaceutical coverage
- Reduced competition at the wholesaler and manufacturer level;
- Increased use of off-invoice discounting
- Guaranteed profits for pharmacies, irrespective of their actual efficiency
- Reduced consumer welfare.

The State of Washington considered a pharmacy "reimbursement at cost" requirement for PBMs, and found that the fiscal impact would be between a 1 percent increase and 10 percent increase in pharmacy costs paid for by the State—up to $113 million annually. The state's Office of Financial Management fiscal analysis done on the original version of the bill it analyzed indicated that "if PBMs pay more for pharmaceuticals, the inventory management for pharmacies may also change. Removing price limits, such as those created by MAC lists, reduce the incentive for pharmacies to purchase pharmaceuticals at the lowest cost possible; demand for lower cost pharmaceuticals may be reduced."[3]

Contracts between PBMs and pharmacies are negotiated in good faith, outline expectations and reimbursement terms, and provide means for arbitration if a dispute arises. This legislation would establish an alternative forum for adjudicating disputes, circumventing agreed-upon arbitration processes, and entrusting the state with adjudicating contract pricing disputes.

[1] David A. Hyman, Professor of Medicine, University of Illinois, The Adverse Consequences of Mandating Reimbursement of Pharmacies Based on Their Invoice Drug Acquisition Costs, January 2016.
[2] Id. at 1.
[3] Washington State Office of Financial Management, "Multiple Agency Fiscal Note 5857 SSB Full" 3-8-2015, page 3, available at: http://app.leg.wa.gov/billinfo/summary.aspx?bill=5857&year=2015.

HB 240 also creates costly and unnecessary regulation. Given that the Division of Insurance already has jurisdiction over the pharmacy benefits of insured plans and the ability to enforce those requirements on plans providing those benefits in Alaska, the new regulatory structure outlined in HB 240 is duplicative and unnecessary. PBMs, through their contracts with health plans, cannot do anything that would bring their clients out of compliance with Alaska law. Thus, PBMs are required to comply with the same consumer protections governing utilization review, prior approval, and dispute resolution systems, among others.

The State of Alaska runs the risk of opening the door to health care fraud, waste, and abuse and adversely affecting patient safety by enacting HB 240. Health plans and employers that use PBMs to administer pharmacy benefits expect thorough audits of network pharmacies in order to recoup monies incorrectly paid for claims with improper quantity, duplicative claims, improper coding, and other irregularities. The comprehensive audits performed by PBMs also ensure that pharmacies are complying with board of pharmacy rules regarding the proper storage of drugs and posting of required signs, among other things. In fact, the State of Alaska's own RFP for PBM services specifically requires a "robust process for tracking and monitoring fraud and abuse." However, HB 240 takes a different turn and provides pharmacies engaging in fraud ample time to hide evidence and avoid responsibility for fraudulent activity because the bill expands the required notification for notice of audits, significantly restricts the number of prescriptions available to audit, and unreasonably limits who can perform an audit.

It is for these reasons that PCMA must respectfully request your veto of HB 240. Please contact me at 202-756-5743 if you would like to discuss our request further. Thank you.

Sincerely,

April C. Alexander
Assistant Vice President

PCMA

February 7, 2018

The Honorable Senator Jason Rapert
PO Box 10388
Conway, AR 72034

Re: Information Concerning Pharmacy Benefit Managers (PBMs)

Dear Senator Rapert:

Thank you for your service in the Arkansas General Assembly. Our industry, represented by the Pharmaceutical Care Management Association (PCMA), has closely followed the recent developments concerning the Arkansas Works program's pharmacy benefit program. We are not only concerned with issues raised about this program at the January 31 meeting of the Legislative Council's Health Insurance Marketplace Oversight Subcommittee, but would also be concerned if the discussion at that meeting should lead to any proposals for further regulation of PBMs in the commercial marketplace. Hundreds of Arkansas companies employing thousands of Arkansans utilize PBMs to keep the cost of their employee health benefits low, lowering health care costs and deductibles for their workers, while still offering the highest quality pharmaceutical care to their employees and their dependents. We certainly understand the concern many in the Legislature have expressed and hope to provide you with information you'll find useful as this discussion continues. As with any important public policy consideration, we urge caution and a careful examination of all aspects of the issue and the impact any change in policy would have on employers across the state, on your constituents and on all Arkansans.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, state and federal employee-benefit plans, and Medicare.

PBMs exist to meet the specific needs of our clients, employers, health insurance plans, labor unions, state and federal employee-benefit plans, Medicare and Medicaid managed care organizations that pay for the drug benefit. Today, the industry has a 40+ year track record of clinical and cost management innovation. PBMs offer proven tools which are recognized by consumers, employers, policymakers and others as key drivers in lowering prescription drug cost, increasing access, and improving outcomes. PBMs reduce drug cost through a variety of tools, including encouraging formulary compliance through the use of less expensive generics and more affordable brand medications, offering more cost-effective dispensing of medications for chronic use through mail service pharmacies, negotiating rebates and discounts from drug manufacturers, contracting with virtually all retail pharmacies in the country to participate in PBMs' pharmacy networks, and offering programs to reduce fraud, waste and abuse. We offer programs that reduce waste and increase drug therapy adherence that improve health

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outcomes through plan design, clinical management, step therapy and drug formularies. We work with our clients to ensure that their members and employees have access to necessary medications through a variety of high quality pharmacies, including retail, community, mail-order, and specialty pharmacies.

PBM Lower Costs for Patients and Payers

According to researchers, PBMs hired by plan sponsors to maximize the value of prescription drug benefits, help patients and payers save $941 per enrollee per year in prescription drug costs,[1] equaling $654 billion over the next 10 years.[2] Plan sponsors use these savings to benefit patients by lowering premiums or deductibles. According to one analysis, annual savings generated by PBMs for the commercial sector could cover the cost of more than 700,000 jobs on a national basis.[3] Each 1% decrease in prescription drug expenditures could cover the cost of 20,000 jobs nationwide.[4] Over the next decade, PBM's will save the citizens of Arkansas $6.6 billion, including $3.7 billion for commercial and private insurance, $2.7 billion for Medicare part D, and $182 million for Medicaid.[5]

Below are a number of tools that PBMs make available to their plan sponsor clients. Using these PBM tools, PBMs are able to generate $6 in savings for every dollar spent by patients and payers.[6]

- **Plan Design:** PBMs advise their clients on various options to structure their drug benefits to ensure appropriate use of resources, including encouraging the use of generic drugs and preferred brands. The plan sponsor can choose how they want to spread their cost savings across the drug benefit.

- **Pharmacy Networks:** PBMs contract with over 65,000 network pharmacies to ensure patient access to prescription drugs, to monitor drug safety, and to alert pharmacists to potential drug interactions. Retail pharmacies provide discounts to be included in a plan's pharmacy network in exchange for increased customer traffic.

- **Mail-service Pharmacy:** PBMs provide highly-efficient mail-service that offers safe and cost-effective home delivery of medication. Mail-service pharmacy channels typically give

[1] *Visante, Inc. "The Return on Investment (ROI) on PBM Services," Prepared by Visante on behalf of PCMA, November 2016. https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf*
[2] *Visante Inc., "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," Prepared for PCMA, February 2016. https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf*
[3] *Visante, Inc. "Pharmacy Benefit Managers (PBMs): Generating "Savings for Plan Sponsors and Consumers," Prepared for PCMA September 2011 https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-09-19-11-pbms-savings-study-2011-final.pdf*
[4] *Ibid..*
[5] *Visante, "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," February, 2016 https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf*
[6] *Visante, Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, February 2016*

plan sponsors deeper discounts than retail pharmacies, which are passed onto members in the form of lower copayments. These channels also help encourage the use of preferred products for additional savings. Data show that consumers also benefit from mail-service via increased adherence, which contributes to better health outcomes.

- **Formulary Management:** PBMs engage panels of independent physicians, pharmacists, and other experts to develop lists of drugs approved by the plan sponsor for reimbursement, and administer cost-sharing and utilization management (e.g., step therapy) criteria as directed by the plan sponsor.

- **Clinical Management:** PBMs use a variety of tools to encourage the best clinical outcomes for patients. These include drug utilization review and disease management programs, which are designed to improve medication adherence and health outcomes. For example, PBMs improve drug therapy and patient adherence in diabetes patients, helping to prevent 480,000 heart failures, 230,000 incidents of kidney disease, 180,000 strokes, and 8,000 amputations annually.[7]

- **Manufacturer Rebates and Discounts:** PBMs negotiate discounts from manufacturers of drugs that compete with therapeutically-similar brands and generics. More than 90% of those rebates and discounts are passed on to our clients to help lower out-of-pocket costs and premiums for their members. As a result of PBM roles in negotiating discounts from manufacturers, PBMs have been able to keep drug costs down and the growth in net prices for prescription drugs continues to fall.

PBMs Promote High Quality Pharmacy Care for Patients

As noted above, PBMs offer their clients a variety of clinical management solutions to help them provide the highest quality pharmaceutical care to their members, which improves outcomes and reduces costs, including:

- Providing patients 24/7/365 access to registered pharmacists and other pharmacy clinicians to provide counseling and answer questions about the patient's therapy
- Offering programs that encourage patients' adherence to their prescribed medication regimes, which address not only the impact on patient outcomes such as unnecessary hospitalizations, ER visits, strokes or heart attacks, but also the estimated $300 billion in annual medical costs associated with non-adherence
- Using evidence-based protocols to help ensure that patients are treated with the right drug, at the right time, and at the right price
- Providing integrated care programs for patients with complex conditions
- Monitoring patients' medication history regardless of how many different network

[7] *Visante, The Return on Investment (ROI) on PBM Services, November 2016*

PCMA

pharmacies they use, and instantaneously providing alerts to pharmacists about potentially harmful drug-drug interactions, drug-disease state interactions and other potential safety issues
- Promoting e-prescribing technology to reduce medication errors and prevent fraud

PBMs have a proven track record of delivering high-quality, affordable benefits that address the individual needs of our clients and patients.

With approximately 80 PBMs in the marketplace, the PBM industry is highly competitive; employer, union and government plans have a variety of choices when considering how best to manage their pharmacy benefit. In order to win business, PBMs have every incentive to reduce drug costs for their plan sponsors by eliminating excessive fees and passing rebate savings along to their plan sponsors and their beneficiaries, without compromising on the quality of care.

In closing, we respectfully urge caution when considering a change to such an important public policy. Any artificial inflation in pharmacy reimbursement could have a far reaching impact for your constituents and thousands of Arkansans.

Thank you for the opportunity to provide input. Please feel free to contact me with any questions.

Sincerely,

Melodie Shrader
Senior Director - State Affairs

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

March 15, 2018

Governor Asa Hutchinson
Office of the Governor, State of Arkansas
500 Woodlane Ave
Little Rock, AR 72201

Re: Veto Request for SB2 and HB1010 – AN ACT TO CREATE THE ARKANSAS PHARMACY BENEFITS MANAGER LICENSURE ACT

Dear Governor Hutchinson:

The Pharmaceutical Care Management Association ("PCMA") respectfully submits the following comments urging you to veto SB2 and HB1010, An Act to Create the Arkansas Pharmacy Benefits Manager Licensure Act. PCMA is the national trade association representing America's pharmacy benefit managers ("PBMs"), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.

SB2 and HB1010 restricts the tools that PBMs use to reduce prescription drug costs while still maintaining high-quality pharmaceutical care, leading to higher prescription drug costs for Arkansas residents and employers. SB2 and HB1010 interfere with business-to-business contracts and includes government rate setting for private businesses.

The provisions of SB2 and HB1010 interfere with PBMs' management and administration of prescription-drug benefits for health plans. PBMs are essential service providers to those benefit plans, and Arkansas cannot use its authority under the guise of licensing them to impose requirements that allow the State to "reach into" existing contracts and impose changes to how ERISA plan administrators choose to structure their benefit design or compensate PBMs for their services.

SB2 and HB1010 are ostensibly designed to simply provide for "regulation and licensure" of pharmacy benefit managers (PBMs) in the State, however, it improperly confers on the State Insurance Commissioner, State Insurance Department, and other state agencies the authority to regulate many aspects of a PBM's business, as well as the choices the PBMs, its clients and the pharmacies that participate in its networks choose to make in negotiations. These include forcing not only PBMs and their clients, but also PBMs and pharmacies, and potentially pharmaceutical manufacturers, to re-write all their present and future contracts to comply with the new requirements:

- PBM clients: SB2 and HB1010 seek to regulate how PBM clients (the employer plans and state and federal programs for which they administer prescription drug benefits) develop and manage their formularies, and how they choose to specify benefit design, pricing terms, levels of access to pharmacy networks, and pharmacy performance requirements.
- PBM-pharmacy networks: SB2 and HB1010 seek to regulate the terms of pharmacy contracts, including credentialing, accreditation, performance standards, reimbursement methodology, amounts and fees chargeable to plan members, and grievance procedures.
- Pharmaceutical manufacturers: SB2 and HB1010 convey authority to the Commissioner to promulgate rules regulating the pricing terms of those contracts, including "rebates, discounts, or other financial incentives and arrangements with drug companies."

SB2 and HB1010 are almost certain to be found unconstitutional for the following reasons:

ERISA Preemption

SB2 and HB1010 run afoul of ERISA, which preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[1] Arkansas cannot impose requirements upon PBMs, which administer pharmaceutical benefits for employee benefit plans if those requirements effectively either directly or indirectly regulate the administration of those ERISA plans.[2]

SB2 and HB1010 would almost certainly be deemed unconstitutional under recent rulings of the U.S. Supreme Court, the Eighth Circuit Court of Appeals, and the U.S. District Court for the Eastern District of Arkansas. The Supreme Court has stated that ERISA provides a "comprehensive system for the federal regulation of employee benefit plans"[3] and applies to all employer-based health plans, whether insured or self-insured. Its central design "is to provide a single national scheme for the administration of ERISA plans without interference from the laws of the several States."[4] No state mandate can directly or indirectly interfere with key matters of plan administration, such as dictating terms of PBM contracts with their clients.

In January of this year the Eighth Circuit heard the State of Arkansas's appeal of the Arkansas District Court's opinion striking down Arkansas Act 900 of 2015 as preempted by ERISA,

[1] 29 U.S.C. § 1144(a).
[2] See Pharm. Care Mgmt. Ass'n v. District of Columbia, 613 F.3d 179, 188 (D.C. Cir. 2010).
[3] District of Columbia v. Greater Was. Bd. of Trade, 606 U.S. 125, 127 (1992)
[4] Gobeille v. Liberty Mut. Ins. Co, 136 S.Ct. 936, 947 (2016).

because the statute interfered with key matters of plan administration.[5] Act 900 mandated that pharmacies be reimbursed for the generic pharmaceuticals they dispense at an artificial "acquisition cost." The Act also required PBMs to maintain an administrative appeal procedure to allow pharmacies to challenge reimbursements prospectively and retroactively, even to the point of declining to provide services to a patient or PBM. SB2 and HB1010 go even further than Act 900. This proposed bill would impose broad and unprecedented State oversight of both (I) how PBMs reimburse pharmacies in their networks and (2) how PBMs are compensated under contracts with their client health plans.

This bill facially interferes with the structure of ERISA plans in Arkansas by limiting plan choices, including how ERISA plan administrators choose to reimburse Arkansas pharmacies for member prescription drug benefits through their PBMs, as well as how they choose to compensate PBMs for their services.

Directly on point here-and binding in Arkansas-is the Eighth Circuit's 2017 opinion striking down a similar Iowa law which regulated how PBMs establish generic drug pricing and required that certain disclosures on drug pricing methodology be made to PBMs' network pharmacies as well as the Iowa insurance commissioner.[6] In that Case, the Court found that the Iowa law impermissibly regulated prescription drug benefits for ERISA plans because -like this Resolution-it dictated the manner and terms under which PBMs and pharmacies choose to agree on reimbursements for generic drugs. It also found that the Iowa law had an impermissible "connection with" ERISA plans because it "govern[ed] a central matter of plan administration" as well as "interfer[ed] with nationally uniform plan administration," quoting the Supreme Court in Gobeille. States simply cannot "undermine the congressional goal of minimizing the administrative and financial burden on plan administrators-burdens ultimately borne by the beneficiaries. "[7]

SB2 and HB1010 perversely confers enormous powers on the Commissioner, yet there is no way that the Commissioner's review of pharmacy reimbursement rates or PBM compensation can be accomplished without the reporting, disclosure, and recordkeeping that the Eighth Circuit in Gerhart held to be "fundamental aspects of ERISA", necessitating Federal preemption.

The District Court in Arkansas relied heavily on this Eighth Circuit opinion in Gerhart in invalidating Act 900 in the Rutledge case, as it is binding in Arkansas. It is almost certain that the Circuit Court panel will also rely heavily on that same precedent in upholding the District Court's result sometime this spring. Given that appeal, and the close similarities of SB2 and HB1010 to Arkansas Act 900 as well as the Iowa statute invalidated in Gerhart, we believe enactment of SB2 and HB1010 will be counterproductive legally as well as costly to the citizens of Arkansas

[5] Gobeille v. Liberty Mut. Ins. Co, 136 S.Ct. 936, 947 (2016).
[6] Pharm. Care Mgmt. Ass 'n v. Gerhart, __ (8th Cir. Jan. 11, 2017) reh 'g denied.
[7] Gobeille, 136 S. Ct. at 944.

PCMA

Legislation is Void Under the Contracts Clause of the Constitution

SB2 and HB1010 would also be void under the Contracts Clause of the U.S. Constitution, which provides that "no state shall…pass any…[l]aw impairing the Obligation of Contracts." The legislation fails the balancing test set up by the U.S. Supreme Court: the State cannot show that SB2 and HB1010 have a significant public purpose that justifies the substantial impairment of existing private contracts to conform to Arkansas' unique requirements.[8]

Section 7 of this legislation declares a "state of emergency" regarding the "sustainability of pharmacies in Arkansas", thus allowing SB2 and HB1010 to become effective on the date of approval by the Governor, or expiration of the period of time during which the Governor may veto it. Thus, it operates as a significant and substantial impairment to all of the pre-existing contractual relationships that PBMs have with their health plan clients and pharmacies, and pharmaceutical manufacturers.

It is not adequate for the Legislature to simply decree in Section 7 that an "emergency" exists without showing (1) that Arkansas residents in fact are lacking "continued access to pharmacy services", and (2) that the method chosen to address this supposed lack of access will be effective. Simply put, the State has not shown that citizens cannot access pharmacy services. And as for citizen health and safety, SB2 and HB1010 itself forbids pharmacy accreditation standards that are more stringent than requirements of the Arkansas State Board of Pharmacy for licensure, unless approved by the Commissioner, risking patient safety by prohibiting standards that are essential for the drug regimens of patients, especially those with complex chronic conditions.

In sum, SB2 and HB1010 is likely to be adjudicated as void by a Court, as it inappropriately inserts the State agencies into the details of the thousands of contracts PBMs have with pharmacies, their clients, and pharmaceutical manufacturers.

For the reasons cited above, PCMA respectfully asks that you veto SB2 and HB1010.

Sincerely,

Melodie Shrader
State Affairs

[8] See *Energy Reserves v. Kansas Power & Light*, Sup. Ct. 1983.

PCMA

April 4, 2018

Commissioner Allen Kerr
Arkansas Department of Insurance
1200 West Third St.
Little Rock AR 72201-1904
Delivered via email: Allen.kerr@arkansas.gov
c.c. Delivered via email: Booth.rand@arkansas.gov

RE: SB 2 & HB 1010 Implementation - Pharmacy Benefit Managers

Dear Commissioner Kerr:

On behalf of the Pharmaceutical Care Management Association (PCMA) I want to thank you, Booth Rand and your staff for your many long hours of dedicated work on what has now become Act 75. As you know, our industry has closely followed the passage of SB2 and HB1010, and now as we move into the critical implementation phase of this legislation, we respectfully submit the following comments and look forward to an open and constructive conversation that will promote market stability while protecting access and affordability for the over 600,000 Arkansans who receive health insurance coverage in the fully insured market.

PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage through large and small employers, health insurers, labor unions, Medicare, Medicaid, and other programs.

As you know, with the enactment of SB 2 and HB 1010 (Act 75), the legislature charged your department with drafting rules to implement the licensure and other provisions that will impact companies providing PBM services to Arkansas health plans. The legislature has outlined a very rapid timeframe for implementation. As is the case with any new regulatory environment, the businesses that operate in this space are concerned about the potential for regulatory uncertainty, which ultimately can cause disruption in the marketplace and confusion for health plan members. As such, PCMA looks forward to working with you as you develop rules to ensure that our member companies can clearly understand the path to compliance.

PCMA has identified several issues that we'd like to discuss with your office as you work to develop rules on such key items including:

- Standards for licensure
- Standards relating to network adequacy;
- Reporting requirements;
- Protections against public disclosure of any confidential materials submitted to the Department; and
- A process for approval of items in Section 1, including fees and programs for credentialing and accreditation, ensuring that patients are able to continue benefitting from the value that credentialing and accreditation programs provide.

PCMA

As your department considers standards for licensure for PBMs we understand that you will want and need to collect a certain set of data in order to facilitate communication between the department and the newly licensed entities. PBMs, as you know, are venders in a highly regulated marketplace. We do not collect premiums and are not risk bearing entities. PBMs have no power to make any decisions as to plan policy, interpretations, practices or procedures, but perform certain administrative functions for the regulated entity, the fully insured plans in Arkansas.

We encourage the department to consider a process that will ensure adequate notice of the new rules and adequate time for PBMs to comply with new licensing procedures, including opportunities to cure any deficiencies. We would also encourage a process for all entities currently licensed as a third party administrator seeking a new license under Act 75 to be afforded a safe harbor if they demonstrate a good faith effort to be licensed under the new rules but are unable to meet all the requirements on September 1st.

Act 75 requires the department to issue standards for an adequate pharmacy benefits manager network. PCMA would appreciate the opportunity to discuss how these standards would be developed and implemented in coordination with other standards that the health plans are currently subject to.

In addition to the adoption of the network adequacy rules, it is important that any rules adopted take into consideration the potential for manipulation. PBMs that make a good faith effort to contract with pharmacies should not be punished if pharmacies refuse to contract with the PBM in order to entangle the Department in the reimbursement clauses of private contracts. The rules must allow for flexibility when non-market based forces unnecessarily attempt to manipulate the network resulting in a possible disruption of services for the beneficiaries and an increase in cost for the health benefit plan.

Thank you for your consideration of these preliminary comments. We realize that there are many issues to discuss and look forward to starting a dialogue with your office. We will follow up with you in the coming weeks. In the meantime, if you have any questions please free to contact me with questions.

Sincerely,

Melodie Shrader
Senior Director – State Affairs
270-454-1773

c.c. Booth Rand

Proposed AID Rule 118, Pharmacy Benefits Managers Regulation

Public Comments Summary

The following are responses from AID related to public comments for proposed Rule 118, Pharmacy Benefits Managers. AID is herein responding to comments which address specific content related issues, or specific language, derived from the initially filed rule. Although received, reviewed and counted, in terms of gauging the public interest in the Rule, AID is not responding herein to comments which are simply general statements for or against the Rule, or comments, which urge support for or against a particular organization's comments. Also, where one organization raised the same concerns as another, AID will not duplicate the same response here under every organization's section here. Please consult the entire Public Comments Summary. These are also merely explanatory notes and should not be considered binding statements or interpretations of the PBM Licensure Act or proposed Rule.

PCMA, July 11, 2018.

Section 4(8) pass through pricing definition needs to be removed because it is not used in the Rule.

AID: We removed that definition.

Section 4(20) references fees in the spread pricing model definition, and fees are a separate and distinct issue [from spread pricing practices].

AID: We removed the last sentence in that definition but are keeping the spread-pricing definition.

Sections 5(A)(7) and 5(A)(10) should include Provider Manuals which address the MAC law and clawback law practices.

AID: We added Provider manuals to the list of items we can review for contracting compliance.

Section 5(A)(13) is unclear whether it is asking about assumption of insurance risk or operational business risk.

AID: We are referring to assumption of risk for the covered benefit (prescription drug) and added this clarification.

Section 5(A)(15) includes reporting terminations for "dishonest" activities, and is too broad and not defined.

AID: We removed the word, "dishonest."

Section 5(A)(15) needs a corrective plan step for for curing initial licensure and renewal issues.

AID: We added a corrective plan to cure administrative deficiencies; however, only for financial issues which may be curable, and failure to submit information. PBMs which are denied for violations of the law have adequate appeal procedures to contest those determinations.

Section 5(D) needs to also adopt 23-61-107 (a)(4) confidentiality standards for material transactions.

AID: We added this for reporting of financial material transactions. We are not removing 23-61-103 which is needed to maintain confidentiality for examinations and investigations.

Section 6(A)(3), related to the standard evaluating fees, and certification standards, the phrase "objective evidence," is extreme and unnecessary.

AID: We will describe it as "specific and detailed," the intent of this section is the same, and that is, we do not want merely conclusory statements or representations that a fee or standard improves quality or reduces costs.

Section 7(B). Reimbursement must be evaluated in the aggregate.

AID: Although we envision reviewing or measuring the entire reimbursement transactions with pharmacies as one barometer to ensure network adequacy, we are keeping the current language, to allow our network adequacy staff sufficient flexibility to determine the adequacy of pharmacy reimbursement.

Section 7(B)(1). The Rule should reflect that PBMs contract with "pharmacies" not individual "pharmacists."

AID: we made the correction throughout the Rule, replacing "pharmacies," with "Pharmacists or Pharmacies." This is consistent with the PBM Licensure Act.

Section 7(B)(2)(b) should keep a consistent standard of review, in that the impact on pharmacy participation in health plans, should be either on a state-wide basis, or "in a significant geographical area."

AID: we agree and adopted this change.

Section 7(B)(2)(b) should address or provide a timeframe of measurement related to the 10% reduction and should consider removing the phrase, "solely, due to a reduction in compensation."

AID: we intend for the time frame specifics to be explained and addressed by our network adequacy division, after issuance of this rule. For issues related to reasons for pharmacy termination, AID intends to work with the PBMs and plans to track, monitor and gather sufficient information from the pharmacy, to determine whether compensation reduction, was the sole reason for the termination.

Section 7(B)(2) should count or consider the times the same pharmacy submitted prescriptions without any issue, not just the declinations, in network adequacy measurements.

AID: Although, in general, we intend for the network adequacy division to address the extent to which, if any, the overall prescriptions serviced by a pharmacist in reviewing declinations, however the Department may want to review declinations for certain drugs, or may want to review individual or geographic levels of pharmacies should the need arise.

AID should make confidential information gathered during a compensation review under Section 7.

AID: we added a confidentiality Section in 7(B)(6).

Section 7(B)(5) should be consistent and refer to "adverse impact."

AID: We agree and now refer to "adverse impact."

Section 9 related to MAC and Spread reporting, is pre-empted by Federal law and PCMA v Rutledge.

AID: AID will follow or adhere to federal law; however, it is our understanding that for the MAC law reporting, in terms of finality of this ruling, the Eighth Circuit Case may be appealed. Secondly, on spread reporting the obligation, as well as compensation review mechanism, these are also aimed at the healthcare insurers or HMOs. Finally, it is our understanding that the validity or legality of the Provider Licensure Act, as to other requirements which are not MAC law related, either in part, or in its entirety, as to group ERISA plans is not before the Court(s), . AID is not a party to such proceedings but will defer to the subsequent rulings of the Court(s).

<u>Pharmaceutical Research and Manufacturers of America (Pharma), June 29, 2018</u>

Pharma submitted various rule section additions which require tracking, reporting and monitoring by AID of PBM rebates.

AID: AID believes tracking or monitoring rebates is important; however, at this time, we believe adding these sections would involve a significant, substantive change to the rule, possibly necessitating re-noticing the public rule. Given that our priority at this time has been providing licensing standards, financial solvency standards, and addressing compensation and contracting issues in a rule requiring issuance before September 1 of this year, we would prefer addressing this at a later time.

<u>The Surety & Fidelity Association of America, July 5, 2018</u>

The Surety & Fidelity Association of America ("SFAA") has concerns with the availability of the bond amount and in addition that the amount of the bond may be excessive for a PBM with limited net worth and working capital.

AID: we believe from our research with surety bond issuers that this amount is available. This amount was copied from the State of Kentucky. We are willing however to work with PBMs as to language issues triggering the bond amounts; however, we borrowed the same language used in other States. As to it being excessive relative to the size of operations of the PBM in this State, the Commissioner may reduce

the amounts for smaller PBMs, please see Section 5(B)(4): "The Commissioner may however reduce the amount of the bond requirement in Section 5(A)(2) if the amount required is unreasonable relative to the size of the PBM's business operations in this State and would cause a significant financial hardship."

National Association of Mutual Insurance Companies, July 10, 2018

The National Association of Mutual Insurance Companies (NAMIC) supports the (PBM Licensure Act) Legislation and AID Rule, for specifically excluding workers' compensation plans.

Arkansas Pharmacists Association, July 2, 2018

Section 11 limits penalties, actions, or orders for violations of this Rule, to 23-66-209 and 210, and thus a violation of Rule 118 would only result in a Cease and Desist order

AID: We have corrected this by designating that a violation of this Rule shall be considered an unfair and deceptive Act under 23-66-206 which would trigger all of the penalties, actions, including monetary fines, revocation and suspension under 23-66-210 and 209. There is no need to copy and paste the entire 23-66-210 statute.

Section 23-92-506(b)-(d) set forth specific practices the PBM may not engage in, yet with the Exceptions of Section 6(B) and Section (7)(C) there is no express prohibition of the practices set forth in 23-92-506(b)-(d)

AID: We disagree. Starting with 23-92-506 (b)(1) prohibits deceptive advertising and marketing, See Section 6(b);

23-92-506(b) (2) restricts fees, See Section 6(A) (3);

23-92-506(b) (3) restricts certification standards. See Section 6(A)(3).

23-92-506(b)(4) on affiliate reimbursement restriction. See Section 7(C).

There is no specific complaint mechanism process under the Rule to provide a mechanism for pharmacists to notify of violations.

AID: There is no need for a pharmacist specific complaint mechanism. Our consumer services division and legal division accept, review and investigate medical provider complaints, physicians, and hospitals on a daily basis without a specific provider type process. Pharmacists can file their complaints with either the Arkansas Insurance Department Consumer Services Division or Legal Division.

Suggestion to add a new section to evaluate pass-through and spread pricing.

AID: we are not evaluating pass-through pricing at this time; however, if that becomes an issue we may consider it for later rule-making.

Exclusion of Medicare Advantage Plans and Medicare Programs. Section 4(4)(B)(vii) excludes from the definition of "health benefit plan," "Medicare Advantage Plans or Medicare programs which provide pharmacy or prescription drug coverage. This exclusion needs to be removed because it is not in the PBM Licensure Act.

AID: We agree the exclusion is not in the PBM Licensure Act. It is added out of an abundance of caution to avoid possible pre-emption claims or actions. In addition, this is consistent with AID's history of not applying State based network laws and medical mandates, to Medicare Advantage plans, due to federal pre-emption under the Medicare Modernization Act, and rules issued by CMS. Our position has been, at least for Medicare Advantage Plans, the networking requirements and benefit requirements are regulated by CMS, however AID may regulate the financial solvency and licensing of the marketing representatives.

AID should adopt the pharmacy network standards, in its compensation review of adverse impact, for Medicare Part D set forth in 42 CFR 423.120(a)(1).

AID: our staff considered these metrics; however, given these might be considered substantive or significant metric distance reductions from a PCP's, and what was in the filed rule, requiring re-notice, we would prefer to possibly address this later, as our network adequacy division develops and reviews data on terminations and compensation following issuance of this Rule.

AID should provide in the Rule that a "PBM shall provide a reasonably adequate network for the provision of prescription drugs for a health benefit plan that shall provide for convenient patient access to pharmacies within a reasonable distance from the patient's residence."

AID: our view of this issue is that the health insurers and HMOs, simply contract with PBMs, for drug networks, and it is these entities which should ultimately be responsible for establishing adequate networks to provide benefits for their members.

There should be a provision for commissioner investigation, action, hearing and penalties for violations of network access requirements.

AID: The rule provides ample examination and investigation authority for the Commissioner to review compliance with the PBM Act and this proposed Rule.

APA suggests various language changes to the PCP metrics under Rule 106(5)(B)(2).

AID: We reviewed these suggested changes, and at this time, because they may be viewed as substantive changes to the proposed Rule, requiring re-notice, we would defer to reviewing them, for change, possibly, at a later time, as our network adequacy division reviews implementing the PCP metrics.

APA suggests there should be tests in Proposed Rule 118 that determine prospectively whether compensation is sufficient to provide prospectively whether compensation is sufficient on initial application, renewed application and during the year.

AID: it is not the desire or policy of the Department to pre-approve, or review medical provider compensation programs, or contracting in advance, which have not yet gone into effect, and, for pharmacies, without seeing an adverse impact.

The adverse impact of 10% is confusing in terms of its relationship with the 80% tolerance in Rule 106.

AID: we agree, and have removed the 10% requirement and the standards or requirements are entirely what a PCP or physician's metrics are.

The last two paragraphs in Section 7(B)(2)(b) appear negated by Section 7(B)(5) restricting review of compensation to compliance with Rule 106 network adequacy.

AID: we disagree, the adverse impact standards must first exist to ultimately implicate the Rule 106 metrics, and corrective actions under Rule 106(7)(B)(5).

Section 7(B)(5) of the proposed Rule merely refers back to 23-66-210 that is limited to a Cease and Desist Order.

AID: We do not see this reference but see a reference to Ark. Code Ann. §§ 23-61-201, which is our examinations provision.

Arkansas Pharmacy Association Second Comment, July 6, 2018

APA submitted language for Section 11. Hearings and Penalties.

AID response: we believe we have adequately addressed this in restating it:

Violations of this Rule shall constitute an unfair or deceptive act under Ark. Code Ann. §23-66-206; therefore, the penalties, actions or orders, including but not limited to monetary fines, suspension, or revocation of license, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

America's Health Insurance Plans, July 10, 2018

America's Health Insurance Plans ("AHIP") advises that litigation preempts the applicability of this Rule to Certain Insurers and PBMS.

AID response: Please see our response to this issue previously in the section addressing PCMA comments.

Proposed Rule 118 exceeds the scope of the PBM Licensure Act by requiring various actions and reporting to be the responsibility of health insurers.

AID response: we believe there is adequate authority in the rule to apply those various requirements under our general powers to effectuate provisions of the Arkansas Insurance Code and Rules. As stated in the rule, for both reporting and pharmacy compensation review, because prescription drug benefits and networks are a significant component of a health benefit plan issued by the healthcare insurers, the healthcare insurers should have responsibility or share responsibility for administration of the prescription drug benefits to ensure there are adequate pharmacies participating for members purchasing these benefits from health insurance policies, and that, if compensation reductions cause disruption or lack of adequacy, the healthcare insurers should help share responsibility for correction.

Section 7 requires healthcare insurers to file and report its pharmacy network in lieu of the PBMs obligation to do so under the PBM licensure Act, and this exceeds the scope of the PBM Licensure Act.

AID response: we disagree. The purpose of this provision was not to overly burden the healthcare insurers but to proved that a PBM should not have to file pharmacy network information if the healthcare insurer already provides this network information to us.

Section 8 allows for examinations on healthcare insurers for compliance with provisions of the Rule, and it is not equitable to hold insurers responsible for compliance with statutory mandates which do not apply to them.

AID response: we disagree, in our examination of a PBM compensation program, it may be imperative for AID to also have access to and to review the entire prescription drug compensation program, including reviewing the facets of it, issued or contracted by the healthcare insurer.

Section 9(C)(2) requires PBMs and Healthcare Insurers to joint coordinate to facilitate the PBMS required filing of a report on state funded payments under 4-88-803. This exceeds the authority of the PBM licensure Act to apply it to healthcare insurers.

AID response: we disagree. The report will necessitate a comparison between what the healthcare insurer paid the PBM and what the PBM paid the pharmacist in drug reimbursement programs; given this dynamic it is imperative for the healthcare insurer or HMO to contribute to the data in the report, for its information item.

Section 9(A)(2)(c) requires tracking and monitoring of various items which is beyond the scope of this Act but also will be difficult to track or report.

AID response: we do not believe requesting data to determine if there are compliant MAC processes exceeds the scope of the Act, as it is in the Act that AID enforce compliance. The report simply allows us to see if the PBM has developed compliant MAC processes. Secondly, we understand that some of the tracking and reporting may involve resource issues, but, we believe the various parties can obtain this information.

AHIP: Proposed Rule 118 Lacks sufficient protections for Health Insurers following Loss of PBM Licensure

AID: We disagree. We believe the health insurers would already be aware of, or notified of any significant loss of licensure by one of its PBM for ongoing administrative actions we are undertaking.

AHIP: Section 4(8), (20), Section 5(A)(7), Section 5(A)(10), Section 5(A)(13), Section 5(A)(15), Section (5)(D), please see same corrections we have made in PCMA section in this document.

AHIP requests removing 4-88-1004 in Section 6(A)(3)(A) be stricken because is not intended to protect patient rights, and its application exceeds statutory scope.

AID: we disagree. The anti-Clawback law in 4-88-1105, is also prohibited by law, just as the other listed prohibitions. Clawback is regulated by AID. PBMs should not have contractual provisions in violation of the clawback prohibition.

Section 6(A)(3)(A) should be expanded to permit contractual language for issues not contemplated by the Act.

AID: we understand the concerns, however the Act does not address this, but only review of prohibited contracts for fees and certification standards.

Section 7(B)(1) needs trade secret information protection needed.

AID response: we added additional protections at the end of that section.

Section 7(B)(1) ignores the fact that health insurers are not party to contracts between PBMs and Pharmacists and do not set reimbursement rates for pharmacies unless the health plan has an integrated PBM.

AID response: We agree that the health insurers are not setting the reimbursement rates between PBMs and Pharmacists, however, as stated previously, PBMs are vendors in contract with the healthcare insurers. Healthcare insurers are ultimately responsible for providing prescription drug benefits to consumers who have purchased health insurance policies and therefore should have some responsibilities to ensure their exist adequate pharmacy networks.

AHIP page 6 suggested corrections and clarifications to Section 7(B)(2), related to definition needed for service areas, and for the phrase, "reduction in compensation or reimbursement," and that invoices reflect actual "net" price a pharmacy paid.

AID response: We modified the rule that AID will issue a bulletin after review and development of the service area metric by the network adequacy division staff. For the other phrasing concerns, the network adequacy staff and Department will try to clarify or provide specifics in a bulletin.

AHIP, we have significant concerns on Section 7(B)(4), regarding how the database in this section will protect proprietary and confidential information.

AID response: We added the full host of confidentiality protections at the end of that Section.

AHIP: Section 7(B)(5) exceeds legislative Scope as it applies to healthcare insurers.

AID response: see early comments related to the jurisdiction by the Department over healthcare insurers here because they are ultimately responsible to consumers who buy those policies for providing drug benefits.

AHIP: Section 7(C) requests adding the MAC list statute.

AID: we agree and have done so.

AHIP: Section 8(A)(2) has a citation error.

AID: we agree and have added an et. seq.

AHIP: Section 9(B)(2) should address a failure of the PSAO to effectuate an appeal.

AID: see the recent amendment to this Section.

Section 9(C)(1) should remove Arkansas works from the spread pricing law reporting requirements.

AID response: we disagree, at this time, believe that an argument can be made it is a program which is state funded due to matching.

Comment from Todd Burrow, July 10, 2018:

Requests adding more specific language in Rule 118, on reimbursement formula pharmacies not allowing Maximum Allowable Cost or generic effective rate as a basis of payment.

AID Response: We could not do this by rule, unless there is a change in the MAC law.

On claims adjudicated below cost, the Commissioner needs the ability to verify the PBMs claims on the cost of the drug in question, this should include specific NDC number, wholesale house, the price, date and quantity in warehouse.

AID Response: We believe we have adequate investigative powers to request such information in the event of a MAC compliance review.

Comment related to the health plans ABCBS, Ambetter and Qualchoice repaying for all of the below cost losses which were inflicted "illegally" by these plans.

AID Response: We have not investigated or concluded this, but will be glad to visit with the APA or pharmacists about these concerns.

Comment related to fines going to the PBMs who lost funds owed to the pharmacy and the time required to file the appeal.

AID Response: This would require a change in the law.

Comment from Joseph Burrow, July 11, 2018.

Comment that the fines need to be significant to comport with the fact that some PBMs are multi-million dollar companies.

AID Response: The fines and penalties we attach here to our TPA in this Rule, for violations to be considered trade practicee violations and deceptive acts are the highest or largest fine section in the Arkansas Insurance Code.

Comment from Adam Wheeler, July 11, 2018

Comment in favor of the APA draft suggestions.

Comment from James Sheets, July 11, 2018

Comment complaining of accreditation standards higher than those of the pharmacy board, and requiring access to drugs limited to 10 pharmacies or less, and delaying tactics on applications for specialty network certifications.

AID Response: Thank you, we will review these specialty contracting standards and your issues as we regulate this industry.

Comment from Jack Lemley, July 11, 2018

Complaint on specialty contract limitations on limited distribution drugs and complaint on the "anti-competitive environment from "vertical integration of CVS/Optum/Humana.

AID Response: we are monitoring the vertical integration issues and anti-competitive structures.

Comment from Qualchoice, June 19, 2018

QCA comment: what is the impact of the PCMA vs. Rutledge Decision related to Act 900.

AID response: See AID's previous response in this Public Comments Summary.

QCA comment related to receiving advance notice of when a PBM may lose its license.

AID response: See AID's response to this concern in the AHIP section.

QCA comment on Section 7(B)(2)(b)

AID Response: This would require a change in the law.

Comment from Joseph Burrow, July 11, 2018.

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AID Response: The fines and penalties we attach here to our TPA in this Rule, for violations to be considered trade practicee violations and deceptive acts are the highest or largest fine section in the Arkansas Insurance Code.

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AID Response: we are monitoring the vertical integration issues and anti-competitive structures.

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QCA comment: what is the impact of the PCMA vs. Rutledge Decision related to Act 900.

AID response: See AID's previous response in this Public Comments Summary.

QCA comment related to receiving advance notice of when a PBM may lose its license.

AID response: See AID's response to this concern in the AHIP section.

QCA comment on Section 7(B)(2)(b)

AID response: See response in AHIP section. We intend to issue a bulletin on what is meant by service area and address these other issues after our staff analyzes the best approach.

QCA Comment on Section 9(C) issues.

AID Response: See response to this issue made to AHIP. And the report due date should be timed to coincide with the QHP rate filing deadline.

QCA Comment to make confidential compensation review between Healthcare insurer and PBM.

AID Response. See added sections for confidentiality provided after public comments, we believe there is sufficient confidentiality protections to make that review confidential.

Comments 15E are AID network adequacy staff comments we are not adopting because these would involve substantive changes to the rule.

Arkansas Blue Cross and Blue Shield, July 5, 2018

Arkansas Blue Cross and Blue Shield comment, Proposed Rule 118 exceeds the scope of the PBM Licensure Act by requiring various actions and reporting to be the responsibility of health insurers.

AID Response: See Page 7 in this document to response to AHIP on this issue.

PCMA

May 16, 2018

The Honorable Dannell P. Malloy
Office of the Governor
State Capitol
Hartford CT 06106

Re: Request for Veto on HB 5384: An Act Concerning Prescription Drug Costs

Dear Governor Malloy:

On behalf of the Pharmaceutical Care Management Association (PCMA) we are submitting this letter to express our concerns regarding HB 5384 (Prescription Drug Costs). PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PBMs exist to make drug coverage more affordable, by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help health care consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Though unions, large employers, and public programs are not *required* to use PBMs, most *choose* to because PBMs help lower the costs of prescription drug coverage.

We agree that the rising cost of pharmaceuticals in this country is a serious problem, but we believe that parts of HB 5384 are counterproductive because they present significant legal problems and could actually *raise* drug prices.

The Employee Retirement Income Security Act of 1974 (ERISA) preempts state reporting and disclosure requirements such as the ones included in HB 5384. ERISA is the federal law that governs all employer-based health plans, including both insured and self-insured plans, and Connecticut residents who work for private sector employers are for the most part enrolled in ERISA plans. PBMs provide administrative services to those ERISA plans. ERISA provides a "comprehensive system for the federal regulation of employee benefit plans,"[1] and as the Supreme Court recently noted, there must be a "single uniform national scheme for the administration of ERISA plans without interference from the laws of several states."[2] No state mandate can directly or indirectly interfere with key matters of plan administration. As the Supreme Court noted in *Gobeille*, ERISA's "reporting, disclosure, and recording requirements for welfare benefit plans are extensive," and states cannot impose differing or parallel regulations on administrators.

[1] District of Columbia v. Greater Was. Bd. Of Trade, 606 U.S. 125, 127 (1992).
[2] Gobeille v. Liberty Mutual Ins. Co., 577 US _____ (2016).

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HB 5384 Section 2 requires PBMs to report pharmaceutical rebate data to the insurance commissioner. Requiring reporting and disclosures to a state official or agency about the economic bases for plan's provision of prescription drug benefits in Connecticut intrudes on what the federal courts have called "a matter central to plan administration," and further "interferes with nationally uniform plan administration."[3] Because PBMs are performing key administrative functions for ERISA plans, states cannot impose mandates—either directly or indirectly—that interfere with that administration, or that result in the imposition of a patchwork of differing regulatory requirements on PBMs.

HB 5384's call for revealing rebate amounts to the state is likely under the mistaken belief that this type of information would benefit consumers. We believe that it is important that there be a competitive marketplace among drug manufacturers in order to drive down the cost of prescription medications. Though HB 5384 directs the commissioner to keep the data confidential, the risk of accidental public disclosure still exists. Any public disclosure of rebate information would allow manufacturers to learn what type of price concessions other manufacturers are giving, thus establishing a disincentive from offering deeper discounts. The Federal Trade Commission (FTC) has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and "[w]henever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely."[4]

The FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[5] Finally, the Department of Justice and the FTC issued a report noting that "states should consider the potential costs and benefits of regulating pharmacy benefit transparency" while pointing out that "vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."[6]

It is for these reasons that PCMA must respectfully ask for your veto of HB 5384. Please contact me at 202-756-5743 if you would like to discuss our concerns. Thank you.

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

[3] Gobeille, 577 US _____ (2016),136 S.Ct at 945.
[4] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).
[5] Id.
[6] US Federal Trade Commission & US Department of Justice Antitrust Division, "Improving Health Care: A Dose of Competition," July 2004.

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PCMA

October 3, 2018

Ms. Kim Bimestefer
Executive Director
Department of Health Care Policy and Financing
1570 Grant Street
Denver, CO 80203

Via email: kim.bimestefer@state.co.us

RE: Revision to the Rule Concerning All-Payers Claims Database
Rule Number: ED 18-04-28-A

Dear Director Bimestefer:

On behalf of the Pharmaceutical Care Management Association (PCMA) we would like to express our concerns over the proposed changes in the data submission requirements for Colorado's All-Payer Claims Database (APCD). PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PBMs exist to make drug coverage more affordable, by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help health care consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Although unions, large employers, and public programs are not *required* to use PBMs, most *choose* to because PBMs help lower the costs of prescription drug coverage.

We agree that the rising cost of pharmaceuticals in this country is a serious problem. However, we believe that the rebate data collection contemplated by this proposed rule is counterproductive and could actually *raise* drug prices.

The proposed requirement to have Colorado health plans report pharmaceutical rebate data is most likely based on the mistaken belief that this type of information would lower drug prices. We believe that it is important that there be a competitive marketplace among drug manufacturers in order to drive down the cost of prescription medications. Any public disclosure of rebate information would allow manufacturers to learn what type of price concessions their competitor manufacturers are giving, thus establishing a disincentive from offering deeper discounts. The Congressional Budget Office (CBO) has noted that disclosure requirements could allow companies to "observe the prices charged by their rivals, which could lead to reduced competition." [1] According to CBO, the "disclosure of rebate data would probably cause

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the variation in rebates among purchasers to decline" leading to a "compression in rebates."[2] Additionally, The Federal Trade Commission (FTC) has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and "[w]henever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely." [3] The FTC has also warned that legislation requiring disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[4]

PCMA appreciates CIVHC's July 11, 2018 detailed response to the comments on the stakeholder draft, but respectfully disagrees that CIVHC's considerations on keeping sensitive information confidential are sufficient. First, the data protection requirements of HIPAA are irrelevant because rebates are not considered protected health information, nor are they necessarily associated with a particular patient or particular claim. Second, although PCMA still believes there is a risk that rebate data could be obtained directly from CIVHC by bad actors and used for anticompetitive purposes, there is also a significant risk that information will be released to someone who signs the required non-disclosure agreement (NDA), who then inadvertently uses the data in a way that could be used by bad actors for anticompetitive or other unlawful purposes. That is, while there is an NDA with the person that obtained the information from CIVHC, the researcher or other person inadvertently uses the data in a way that ends up revealing drug-specific rebates, and other bad actors, who have not signed NDAs, use the information to act unfairly in the marketplace.

In some drug categories, there are only a handful of competing drugs. It would not be difficult for a business with sophisticated data analytics skills to back into drug-specific rebates for a particular plan or PBM based on an analysis of public data if they had the rebate information as well. PCMA believes—and the FTC and CBO agree—that the consequence of either purposeful or inadvertent disclosure of rebate data could be a *reduction of rebates and higher costs for payers and consumers*. Once a manufacturer has discovered the rebate its competitor is offering, there is no longer an incentive to offer the best possible deal to the payer/PBM. The incentive at that point is to simply offer a rebate that is slightly below the competitor's. And once the drug-specific rebate is discovered, there is no ability to walk back that information and keep it confidential going forward.

Finally, PCMA questions the appropriateness of collecting rebate information for inclusion in a claims database. Rebates are not paid claims and are part of private contracts between two businesses, made outside of the claims processing cycle, and therefore, should not be included in the submission guidelines.

Although PCMA believes rebate data should not be collected, if the proposal moves forward, PCMA has the following technical suggestions for the proposal.

1. Section 1.200.1 Definitions

   a. PCMA believes that the definition of "rebate" goes beyond actual rebates into other contractual arrangements between PBMs, payers, and manufacturers. PCMA proposes the following amendment:

   "Prescription Drug Rebate" means aggregated information regarding the total amount of any prescription drug rebates ~~and other pharmaceutical manufacturer price concessions~~ paid by pharmaceutical manufacturers to a payer or their pharmacy benefit manager(s).

   b. The definition of "Alternative Payment Model" (APM) includes pay-for-performance programs, and Section 1.200.2.A of the proposal requires APM data to be submitted to the APCD. Pay-for-performance programs in the pharmacy benefit are outside of the claims payment process and do not qualify as rebate information. PCMA suggests that "pay-for-performance" be stricken from the APM definition.

2. In its response to PCMA's comments regarding the sensitivity of rebate information CIVHC seeks to collect, CIVHC indicates its intent to keep sensitive information confidential and not subject to public disclosure. PCMA respectfully requests a clear statement of that intent in the language of the rule, and proposes the following new subsections:

   1.200.4.C

   Notwithstanding the foregoing subsections, the APCD reports shall not disclose financial, competitive, or proprietary information that would enable a third party to identify a health care plan, health carrier, pharmacy benefit manager, pharmaceutical manufacturer, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

   1.200.5.D

   The data release review committee shall not permit the disclosure of financial, competitive, or proprietary information that would enable a third party to identify a health care plan, health carrier, pharmacy benefit manager, pharmaceutical manufacturer, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

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PCMA

1.200.5.E

Prescription Drug Rebate aggregated data is exempt from open inspection under Colorado Stat. §24-72-201, et seq. as trade secret and confidential commercial financial data under Colorado Stat. §24-72-204.

We appreciate CIVHC's thoughtful response to PCMA's concerns identified in the informal rulemaking process. However, PCMA respectfully remains concerned for the above reasons. Please contact me at 202-756-5743 if you would like to discuss our concerns. Thank you.

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

cc: Ana English, Center for Improving Value in Health Care, aenglish@civhc.org

[1] "Increasing transparency in the pricing of health care services and pharmaceuticals," Congressional Budget Office, Jun. 5, 2008.
[2] Letter to Rep. Joe Barton and Rep. Jim McCrery, U.S. House of Representatives, Congressional Budget Office, Mar. 12, 2007.
[3] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).
[4] US Federal Trade Commission & US Department of Justice Antitrust Division, "Improving Health Care: A Dose of Competition," July 2004.

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June 19, 2017

Via: Hand-Delivery

The Honorable Jeff Landry
Attorney General
P.O. Box 94005
Baton Rouge, LA 70804

RE: Request for an opinion on the inappropriateness for the Board of Pharmacy to regulate PBMs

Dear Attorney General Landry:

I am writing, respectfully, in response to Representative Robert Johnson (D) request "for an attorney general opinion as to whether pharmacy benefit managers (PBMs) are subject to regulation by the Louisiana Pharmacy Board."[1] As background, PCMA is the national trade association representing America's pharmacy benefit managers ("PBMs"), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D.

Employers and health insurers contract with PBMs to manage prescription drug benefits for their employees or enrollees. In addition to negotiating price concessions with pharmacies and drug manufacturers, PBMs handle a range of administrative functions including verifying eligibility, processing pharmacy claims, administering prior authorization and utilization review programs, auditing pharmacies for fraud and abuse, suggesting drug formularies to clients and handling grievances and appeals when requested to by the client. Since PBM benefit management supports health plans , they are required to comply with state insurance laws and regulations on behalf of their clients.

Federal Trade Commission (FTC) Opines Board of Pharmacy Regulation of PBMs is Anti-Competitive and Could Raise Drug Costs

In 2011, Mississippi Representative Mark Formby (R) received a letter from the FTC regarding legislation granting the Mississippi Board of Pharmacy regulatory oversight of PBMs. The FTC warned that, "If pharmaceutical manufacturers, pharmacists, and pharmacies gain access to whatever information the Pharmacy Board requires the PBMs to produce, they could have access to competitively sensitive information, potentially facilitate collusion, and increase prescription drug prices."[2] The FTC further cautioned Representative Formby that the regulation of PBMs by the Board of Pharmacy would contribute to anti-competitive practices, because "pharmacists, who negotiate retail prescription drug prices with PBMs and compete against PBM-owned mail-order pharmacies, would now be regulating PBMs."[3] PBMs negotiate rates for prescription drugs with pharmacies and, later, audit pharmacies for activities such as fraud, waste and abuse. Consequently, a Board of Pharmacy which is composed of pharmacists cannot impartially regulate PBMs. The FTC concluded that "pharmacists and PBMs have a competitive, and at times, adversarial relationship, we are concerned that giving the pharmacy board regulatory power over PBMs may create tensions and conflicts of interest for the pharmacy

[1] The Honorable Robert Johnson letter to Attorney General Jeff Landry, May 15, 2017 Re: Request for an attorney general opinion as to whether pharmacy benefit managers are subject to regulation by the Louisiana Pharmacy Board.
[2] FTC letter to Representative Mark Formby (R-MS), March 22, 2011 https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippipbm.pdf.
[3] *Ibid*

board. Indeed, the antitrust laws recognize that there is a real danger that regulatory boards composed of market participants may pursue their own interests rather than those of the state."[4]

Additionally, the Supreme Court of the United States ruled in *North Carolina Board of Dental Examiners vs. Federal Trade Commission*[5] that "when a controlling number of the decision makers on a state licensing board are active marketplace participants in the occupation the board regulates, the board can invoke state-action immunity only if it is subject to active supervision by the state." The FTC has recently filed a complaint[6] against the Louisiana Real Estate Appraisers Board for violating the Supreme Court's ruling in the North Carolina Board of Dental Examiners decision.

PCMA strongly believes, given the FTC's comments in Mississippi, their recent complaint against the Louisiana Real Estate Appraisers Board, *and the guidance found in North Carolina Board of Dental Examiners* the Louisiana Board of Pharmacy regulating PBMs without the appropriate active supervision of the state could run afoul of the FTC. It is foreseeable that a situation could arise where the Board of Pharmacy, ostensibly acting in the best interests of the consumers of this state, promulgates a regulation perceived by the FTC as favoring pharmacists at the expense of PBMs.

The Louisiana Pharmacy Practice Act Does Not Give the Board of Pharmacy Regulatory Authority of PBMs

The Louisiana Revised Statutes, Title 37, Chapter 14 – Pharmacy Practice Act (Act), Part A. General Provisions, commences with the legislative declaration and the statement of purpose that provide guidance to the entirety of the Act and the stated purpose and role of the Board of Pharmacy.

> **§1162. Legislative declaration**
>
> The practice of pharmacy in the state of Louisiana is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. Therefore, ***any rule or regulation adopted relative to pharmacists and the operations of pharmacies,*** including any amendment, modification, or repeal thereof, shall be adopted as provided by the Administrative Procedure Act and shall be effective only upon approval by the respective oversight committees ***having jurisdiction over matters relative to pharmacists and the operation of pharmacies***. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this Chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy. This Chapter shall be liberally construed to carry out these objectives and purposes.
>
> **§1163. Statement of purpose**
>
> It is the purpose of this Chapter to promote, preserve, and protect the public health, safety, and welfare by and through the ***effective control and regulation of the practice of pharmacy; the licensure of pharmacists; and the licensure, permitting, certification, registration, control, and regulation of all persons or sites, in or out of this state that sell drugs or devices to consumers and/or patients or assist in the practice of pharmacy, within the state***.

[4] *Ibid*
[5] *North Carolina Board of Dental Examiners v. FTC* available at https://www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf
[6] United States of America Before the Federal Trade Commission in the matter of Louisiana Real Estate Appraisers Board, Respondent, Docket No. 9374

These provisions specifies that the Board of Pharmacy is limited to regulating pharmacists and pharmacies, and specifically limits in the "Statement of Purpose" the areas of regulation to include the licensure of pharmacists, pharmacies and other pharmacy personnel that sell drugs or devices to consumers or patients. PBMs are not involved in the practice of pharmacy, with the exception of mail-service pharmacies or specialty pharmacies operated by PBMs which are already licensed as out-of-state pharmacies. The legislature has not deemed it in the public interest to bestow upon this Board this regulatory authority. Furthermore, in light of the guidance in North Carolina Board of Dental Examiners v FTC the legislature has not made the findings and created the framework to displace competition or provide the "active supervision" that governing federal law requires in this area.

Board of Pharmacy Regulation of PBMs is Inappropriate and Unnecessary

- **PBMs are not acting as pharmacies with respect to their benefits management functions.** PBMs are standing in the place of employers and health plans – *payers* of pharmacy services – when they determine an enrollee's eligibility and cost-sharing, process claims, conduct prior authorization and utilization review, and negotiate rates with pharmacies. PBMs clearly are not providing pharmacy services when they undertake these benefits management functions.

- **Health plan subcontractors are regulated by state insurance departments.** Health plans and employers contract with a variety of vendors for carved-out services, which, in addition to prescription drug management, may include behavioral health, imaging, and disease management. The services PBMs provide for prescription drug benefits are the same types of services health plans contract for with PPOs, utilization review companies, and third party administrators with respect to medical benefits.

- **State insurance departments are best situated to protect consumers.** Oversight of health plan subcontractors is best undertaken by the state agency tasked with ensuring that consumers receive the benefits they have been promised, which is the insurance department. State boards of pharmacy oversee the practice of pharmacy, which involves delivery of care. The insurance commissioner oversees delivery of promised coverage.

- **PBMs comply with state laws applicable to health insurance.** As subcontractors, PBMs in their benefit management capacity must comply with the same state laws – designed to protect consumers rather than health care service providers – as their health plan clients.

In conclusion, the regulation of PBMs by the Board of Pharmacy is akin to the Board of Medicine regulating health insurance plans. PCMA respectfully requests that the Office of the Attorney General offer an opinion that the Board of Pharmacy does not have the authority, under the Pharmacy Practice Act, to regulate PBMs. We appreciate your consideration of our concerns and if you have any questions, please feel free to contact me at lrowley@pcmanet.org, or Rob Rieger, Esq., Adams and Reese, LLP at Robert.Rieger@arlaw.com.

Sincerely,

Lauren Rowley
Vice President, State Affairs

May 24, 2018

The Honorable John Bel Edwards
Office of the Governor
900 N 3rd St. #4
Baton Rouge, LA 70802

Re: Request for Veto on SB 108: Provides relative to Medicaid managed care annual reporting

Dear Governor Edwards:

On behalf of the Pharmaceutical Care Management Association (PCMA) I am submitting this letter to express our concerns regarding SB 108, a bill requiring reporting of proprietary information. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PBMs exist to make drug coverage more affordable by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help health care consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Though unions, large employers, and public programs are not *required* to use PBMs, most *choose* to because PBMs help lower the costs of prescription drug coverage.

While we agree that the rising cost of pharmaceuticals in this country is a serious problem, we believe that parts SB 108 are counterproductive because they present significant legal problems and could actually *raise* drug prices.

The Employee Retirement Income Security Act of 1974 (ERISA) preempts state reporting and disclosure requirements such as the ones included in SB 108. ERISA is the federal law that governs all employer-based health plans, including both fully-insured and self-insured plans, and Louisiana residents who work for private sector employers are for the most part enrolled in ERISA plans. PBMs provide administrative services to those ERISA plans. ERISA provides a "comprehensive system for the federal regulation of employee benefit plans,"[1] and as the Supreme Court recently noted, there must be a "single uniform national scheme for the administration of ERISA plans without interference from the laws of several states."[2] No state mandate can directly or indirectly interfere with key matters of plan administration. As the Supreme Court noted in *Gobeille*, ERISA's "reporting, disclosure, and recording requirements for welfare benefit plans are extensive," and states cannot impose differing or parallel regulations on administrators.

[1] District of Columbia v. Greater Was. Bd of Trade, 606 U.S. 125. 127 (1992)
[2] Gobeille v. Liberty Mutual Ins. Co., 577 US _____(2016)

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SB 108 requires PBMs to report to the Louisiana Department of Health pharmaceutical rebate data; administrative fees; and any other monies retained by a PBM that are not reimbursed to a pharmacy. Requiring reporting and disclosures to a state official or agency about the economic basis for a plan's provision of prescription drug benefits in Louisiana intrudes on what the federal courts have called "a matter central to plan administration," and further "interferes with nationally uniform plan administration."[3] Because PBMs are performing key administrative functions for ERISA plans, states cannot impose mandates—either directly or indirectly—that interfere with that administration, or that result in the imposition of a patchwork of differing regulatory requirements on PBMs.

SB 108's call for revealing rebate amounts while the state is likely under the mistaken belief that this type of information would benefit consumers. We believe that it is important that there be a competitive marketplace among drug manufacturers in order to drive down the cost of prescription medications. Though SB 108 directs the commissioner to keep the data confidential, the risk of accidental public disclosure still exists. Any public disclosure of rebate information would allow manufacturers to learn what type of price concessions other manufacturers are giving, thus establishing a disincentive from offering deeper discounts. The Federal Trade Commission (FTC) has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and "[w]henever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely."[4]

The FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[5] Finally, the Department of Justice and the FTC issued a report noting that "states should consider the potential costs and benefits of regulating pharmacy benefit transparency" while pointing out that "vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."[6]

It is for these reasons that PCMA respectfully requests for your veto of SB 108.

Sincerely,

Lauren Rowley
Vice President, State Affairs

[3] Gobeille, 577 US_____(2016),136 S.Ct at 945.
[4] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).
[5] Id.
[6] US Federal Trade Commission & US Department of Justice Antitrust Division, "Improving Health Care: A Dose of Competition," July 2004.

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May 24, 2018

The Honorable John Bel Edwards
Office of the Governor
900 N 3rd St. #4
Baton Rouge, LA 70802

Re: Request for Veto on SB 283: Provides relative to pharmacy benefit managers

Dear Governor Edwards:

On behalf of the Pharmaceutical Care Management Association (PCMA) I am submitting this letter to express our concerns regarding SB 283, a bill requiring reporting of proprietary information. PCMA is the national trade association for pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

PBMs exist to make drug coverage more affordable by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help health care consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Though unions, large employers, and public programs are not *required* to use PBMs, most *choose* to because PBMs help lower the costs of prescription drug coverage.

While we agree that the rising cost of pharmaceuticals in this country is a serious problem, we believe that parts SB 283 are counterproductive because they present significant legal problems and could actually *raise* drug prices.

The Employee Retirement Income Security Act of 1974 (ERISA) preempts state reporting and disclosure requirements such as the ones included in SB 283. ERISA is the federal law that governs all employer-based health plans, including both fully-insured and self-insured plans, and Louisiana residents who work for private sector employers are for the most part enrolled in ERISA plans. PBMs provide administrative services to those ERISA plans. ERISA provides a "comprehensive system for the federal regulation of employee benefit plans,"[1] and as the Supreme Court recently noted, there must be a "single uniform national scheme for the administration of ERISA plans without interference from the laws of several states."[2] No state mandate can directly or indirectly interfere with key matters of plan administration. As the Supreme Court noted in *Gobeille*, ERISA's "reporting, disclosure, and recording requirements for welfare benefit plans are extensive," and states cannot impose differing or parallel regulations on administrators.

[1] District of Columbia v. Greater Was. Bd of Trade, 606 U.S. 125. 127 (1992)
[2] Gobeille v. Liberty Mutual Ins. Co., 577 US _____(2016)

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SB 283 requires PBMs to report to the insurance commissioner pharmaceutical rebate data; administrative fees; rebates that are passed through to clients and amounts retained by the PBM; and, the "highest, lowest, and mean aggregate retained rebate percentage. Requiring reporting and disclosures to a state official or agency about the economic basis for a plan's provision of prescription drug benefits in Louisiana intrudes on what the federal courts have called "a matter central to plan administration," and further "interferes with nationally uniform plan administration."[3] Because PBMs are performing key administrative functions for ERISA plans, states cannot impose mandates—either directly or indirectly—that interfere with that administration, or that result in the imposition of a patchwork of differing regulatory requirements on PBMs.

SB 283's call for revealing rebate amounts while the state is likely under the mistaken belief that this type of information would benefit consumers. We believe that it is important that there be a competitive marketplace among drug manufacturers in order to drive down the cost of prescription medications. Though SB 283 directs the commissioner to keep the data confidential, the risk of accidental public disclosure still exists. Any public disclosure of rebate information would allow manufacturers to learn what type of price concessions other manufacturers are giving, thus establishing a disincentive from offering deeper discounts. The Federal Trade Commission (FTC) has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and "[w]henever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely."[4]

The FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[5] Finally, the Department of Justice and the FTC issued a report noting that "states should consider the potential costs and benefits of regulating pharmacy benefit transparency" while pointing out that "vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."[6]

It is for these reasons that PCMA respectfully requests for your veto of SB 283.

Sincerely,

Lauren Rowley
Vice President, State Affairs

[3] Gobeille, 577 US_____(2016),136 S.Ct at 945.
[4] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).
[5] Id.
[6] US Federal Trade Commission & US Department of Justice Antitrust Division, "Improving Health Care: A Dose of Competition," July 2004.

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PCMA LAHP LOUISIANA ASSOCIATION OF HEALTH PLANS LBGH Louisiana Business Group on Health

May 21, 2018

The Honorable John Bel Edwards
Governor, State of Louisiana
4th Floor, 900 N 3rd Street
Baton Rouge, LA 70802

Re: Veto Request for S.B. 29: Provides relative to a single uniform prescription drug prior authorization form

Dear Governor Edwards:

On behalf of the Pharmaceutical Care Management Association ("PCMA"), the Louisiana Association of Health Plans ("LAHP"), and the Louisiana Business Group on Health ("LGBH"), (collectively "Requesters"), we must respectfully request your veto on S.B. 29. While Requesters did not have objection to the underlying bill as it moved through the legislative process, we have serious objections and concerns with an amendment regarding pharmacy credentialing and accreditation that was attached to the bill upon final consideration and passage. Specifically, this language found on Page 2, Lines 29-30 and Page 3, Lines 1-9 on the Enrolled bill, would amend and re-enact La. R.S. 22:1651 by adding a new subsection J. Also of concern is the fact that this legislation possesses a Governor's signature effective date, and therefore, would apply immediately to extant contracts. We are aware of no other state that has enacted similar legislation under these terms.

PCMA is the national trade association representing America's pharmacy benefit managers ("PBMs"), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. LAHP is the voice for health plans and other organizations that comprise Louisiana's health benefits industry. As the state trade association for the industry, LAHP is committed to its broad-based membership, including all models of health benefits management and other organizations that embrace the provision of quality, cost-effective health care benefits. LBGH which represents over 200 Louisiana employers, consist entirely of stakeholders whose focus is to develop and sustain a purchaser, payer and provider partnership that will improve the quality and value of health care in Louisiana. LBGH is the only unified voice representing employers solely on health care issues in Louisiana.

S.B. 29 prohibits insurers and PBMs from requiring further licensure, accreditation, affiliation, registration, or credentialing, other than those required by federal or state government, of any pharmacy that wishes to

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Louisiana Business Group on Health
12046 Justice Ave., Suite B
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participate in a pharmacy network. Requesters are deeply concerned that this bill will risk the health and safety of patients, in particular Louisiana's most vulnerable patients taking specialty or compounded prescription drugs. If an underqualified pharmacy dispenses a specialty or compounded drug without proper logistical and clinical support, patients will suffer. Within the medical industry, credentialing of medical professionals is widely accepted as a 'gold standard' for patient safety as well as promoting the best clinical outcome. The State of Louisiana implicitly recognizes the importance of provider credentialing in R.S. 22:1009, creating a standardized process and providing for standard forms for provider credentialing. Exempting pharmacies from this process would put Louisiana patients at risk of being treated by unqualified or underqualified providers or even defrauded. An insurer or PBM's ability to require additional accreditation or credentialing of pharmacies participating in their networks is vital to protecting patients and consumers from harm. Additional accreditation or credentialing, beyond the state's requirements, demonstrates insurers' and PBMs' commitment to meet the highest standards of patient safety. Purchasers of health insurance and related pharmacy benefits get the peace of mind that the networks are populated only by the best qualified providers for the particular prescription medication or drug therapy.

PBMs Create High Quality Pharmacy Networks in Louisiana

PBMs ensure that patients, health insurance purchasers, and payers receive exceptional and affordable care through the practice of credentialing potential pharmacies within a network. The function of credentialing is to establish a high quality pharmacy network beyond a standard pharmacy license requirement. Credentialing is essential for PBMs to validate pharmacy providers prior to enrollment and network contracting. State licensure evaluations do not include measures to validate a pharmacy's ability to comply with contractual provisions and regulatory requirements (e.g. inventory control for pharmacy audits, compliance with Centers for Medicare and Medicaid Services (CMS), regulations for Medicare Part D plan sponsors). To protect patients from inferior services, pharmacies must meet the standards of credentialing as part of the terms and conditions for enrollment into a client's network. The Board of Pharmacy is charged with overseeing pharmacy practice and does not have expertise or visibility in managing a pharmacy benefit or creating provider networks. Consequently, a pharmacy being licensed by the Louisiana Board of Pharmacy is not a thorough and comprehensive assessment of pharmacy performance or patient safety.

Accreditation of Specialty Pharmacy and Credentialing of Compound Pharmacies Protect Patients and Payers

Louisiana is an 'any willing pharmacy' state allowing pharmacies that agree to the terms and conditions of a contract to participate in-network. Nevertheless, S.B. 29 prohibits insurers and PBMs from assessing the

quality and competency of pharmacies wishing to dispense delicate, complex and expensive specialty medications. URAC, a third-party commission that accredits specialty pharmacies, explained that, 'because complex therapies and medications are expensive and require intense patient management strategies, insurance purchasers, payers rely on PBMs to manage utilization and reimbursement of specialty drugs. Many PBMs, in turn, seek out accredited specialty pharmacies to provide an elevated degree of competency—one that focuses on medication adherence and patient outcomes.'[1] Importantly, PBMs, health insurance purchasers like LBGH and health insurers do not financially benefit from pharmacies being accredited by third-parties such as URAC.

Accredited specialty pharmacies demonstrate to PBMs their ability to safely dispense specialty medications that are made to treat a very small segment of the population, which requires expert knowledge and ability. For example, the average specialty drug costs $2,500 per prescription to treat conditions such as multiple sclerosis, rheumatoid arthritis or hemophilia. In addition to the extreme cost, these medications are often refrigerated at specific temperatures, involve careful storage, handling and delivery to patients and often have a very short shelf life. Since most of these drugs are made in limited supply, many specialty drug manufacturers will only distribute their drugs to accredited pharmacies. Of the 64,000 pharmacies in the U.S., only 378 have achieved specialty pharmacy accreditation from either URAC or the Accreditation Commission for Health Care (ACHC).[2] One-quarter of these pharmacy locations are accredited by both organizations.

PBMs use accreditation and credentialing to select pharmacies of good quality and standing. A pharmacy being licensed by the Board of Pharmacy simply demonstrates a basic compliance rather than overall excellence in the pharmacy services delivered. Credentialing and accrediting pharmacies, particularly compounding and specialty pharmacies, ensures the highest level of patient and consumer safety.[3] Allowing for additional accreditation and credentialing of pharmacies promotes best practices for evaluating and maintaining quality and safety controls within networks. Allowing health insurance carriers to enforce high standards for patients can go far in avoiding harmful outcomes to patients, such as the New England Compounding Center (NECC) disaster in 2012 that resulted in 76 people dying and more than 800 becoming ill with fungal meningitis. This type of disaster could befall LBGH's members, their employees, and covered loved ones should this legislation become law.

PCMA, LAHP, and LBGH would have testified to these issues during the legislative process, but the language was added on final passage on the House Floor. Consequently, Requesters had no ability to bring these issues

[1] URAC, *Competing in the Specialty Pharmacy Markey: Achieving Success in Value-Based Healthcare*, Industry Insight Report [http://info.urac.org/specialtypharmacyreport] 2017, p. 4.
[2] sPCMA, "The Management of Specialty Drugs", [http://spcma.org/wp content/uploads/2016/06/sPCMA_The_Management_of_Specialty_Drugs.pdf], 2016.
[3] Health carriers or PBMs use the term "credentialing" to define their process of admitting a pharmacy into their pharmacy network through their contracted terms and conditions of participation. At the same time, an additional use of the term "credentialing" may refer to the practice of third party credentialing of compounding pharmacies and their ability to meet safety standards, among other criteria.

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for consideration to the legislature. Therefore, PCMA, LAHP, and LBGH respectfully request your veto of S.B.29. This bill unnecessarily risks the safety of the sickest patients as well as forces PBMs, health insurers, and Louisiana businesses to contract with underqualified pharmacies leading to potentially dangerous outcomes to Louisiana citizens.

Sincerely,

Lauren Rowley
Vice President, State Affairs
PCMA

Jeff Drozda
CEO
LAHP

Cheryl D. Tolbert
President & CEO
LBGH

Enclosure: Enrolled SB 29

CC: Matthew Block, Executive Counsel (by hand and email)
Nick Albares, Health Policy Director (by hand and email)

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PCMA

February 6, 2018

The Honorable Lisa Keim & The Honorable Matthew W. Moonen
Chairs, Joint Standing Committee on Judiciary
Maine State Legislature
13 State House Station
Augusta ME 04333

Via email: margaret.reinsch@legislature.maine.gov

Re: Proposed Committee Amendment to LD 1406 (Prescription Drug Price Transparency)

Dear Senator Keim and Representative Moonen:

The Pharmaceutical Care Management Association (PCMA) submits the following comment as the Committee considers the proposed amendment to LD 1406 (Prescription Drug Price Transparency). PCMA is the national trade association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, state governments, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide feedback on the issue of drug price transparency. PCMA appreciates the Committee's intent to understand the causes of rising pharmaceutical list prices and its acknowledgement that public disclosure of certain disaggregated price information ultimately may be counterproductive to the goal of reducing consumer prices.

As the Federal Trade Commission and U.S. Department of Justice have warned:

> *"[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors…then tacit collusion among manufacturers is more feasible…Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely.*[1]

PCMA shares the concern that if sensitive price information collected by the state—such as the information described in section (4)(F) of LD 1406—is inadvertently disclosed publicly, competitive forces in the pharmaceutical market could be negatively impacted and health care payers and consumers could see increased costs. We believe that this result would be counterproductive to the Committee's goal.

[1] FTC and U.S. Department of Justice, Improving Health Care: A Dose of Competition (July 2004).

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PCMA

We appreciate the opportunity to provide comments on this proposed amendment and we welcome the opportunity to speak with you about our concerns. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

cc: Margaret Reinsch, Esq., Legislative Analyst

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June 15, 2018

The Honorable Hank Vaupel
Michigan House of Representatives
N-896 House Office Building
PO Box 30014
Lansing MI 48909

RE: Drug Price Transparency Workgroup Draft Bills

Dear Representative Vaupel:

On behalf of the Pharmaceutical Care Management Association (PCMA), I am writing you to provide feedback on the drug price transparency workgroup draft bills discussed at the June 5 workgroup. PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, health plans, labor unions, state and federal employee-benefit plans, and government programs.

PCMA appreciates the opportunity to be part of the discussion on the rising costs of prescription drugs. PBMs' primary focus is creating solutions for payers to improve the quality and continuity of care patients receive while managing ever-growing costs. Over the next ten years, PBMs and specialty pharmacies will save payers and patients an estimated total of $650 billion nationally when compared to expenditures with limited use of PBM tools.[1]

At the outset it is important to note that it is always the drug manufacturer who decides what the price of a given drug will be. PBMs do not set drug prices—rather, PBMs evolved as a means to lower the cost of drug benefits by negotiating price concessions with manufacturers and pharmacies on behalf of plan sponsors. In addition, PBMs lower costs by encouraging use of generics, offering specialty pharmacy services, and helping patients with drug adherence. Payers would not choose to use PBMs if PBMs did not bring down costs. Quite simply, the easiest and most effective way to decrease the price of drugs is for manufacturers to reduce the prices they set for drugs.

We understand that Michigan policymakers want deeply to be part of the solution to the problem of rising drug costs, and we share this concern. However, some provisions in the draft PBM bill threaten to have the opposite effect, creating an environment where tacit collusion among manufacturers can take place, which as the Federal Trade Commission has highlighted multiple times, could result in *higher* prescription drug prices, and thus negatively impact consumers.

[1] Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, Visante, (February 2016), available at https://www.pcmanet.org/pbms-generating-savings-for-plan-sponsors-and-consumers/.

However, one important, consumer-focused transparency concept incorporated in this draft is the provision that prohibits so-called “gag clauses” in PBM–pharmacy contracts. PCMA supports the patient paying the lower of the cash price or the copay, and believes that pharmacists should have the ability to discuss lower cost alternatives with patients, even if they are outside of the health plan benefit. This is the type of common sense transparency that both benefits consumers and encourages important pharmacist-patient discussions.

The concerning provisions in the draft are those that would threaten to publicly expose the amount of rebates that PBMs collect and share with payers. Rebates are used as a tool to help reduce the cost to third party payers who are arranging patient access, and indirectly patients, through lower premiums and copays. Drug price negotiations operate like sealed-bid auctions where bidders (in this case, the manufacturers) offer the lowest price they can in hopes of winning business. If rebates were made public, the companies giving the biggest rebates would likely stop giving them and costs would rise. Though the draft refers to the rebate reporting as in the “aggregate,” the definition of “aggregate retained rebate percentage” appears to establish a formula where drug-specific rebates could be calculated. Without any protections from backing into drug-specific rebate amounts, if this information were to be in the public sphere, using basic enrollment and coverage market information, manufacturers could easily figure out what price concessions their competitors are providing.

It is with this concern that the FTC has said, “"[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors … then tacit collusion among manufacturers is more feasible … Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely."[2] The FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and “undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford.”[3] Additionally, the Department of Justice and the FTC issued a report noting that “states should consider the potential costs and benefits of regulating pharmacy benefit transparency” while pointing out that “vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms.”[4]

This draft bill requires an unprecedented level of disclosure of confidential pricing information that exists between private businesses. Rebate sharing arrangements are simply an element in pricing a contract between a payer and PBM, and PBMs are transparent to clients on rebates in accordance with contractual requirements. Nearly half of employer plan sponsors negotiating to receive manufacturer rebates elect to receive 100% of the rebate amounts[5] and pay administrative fees to the PBM. Other payers negotiate for their PBMs to receive a portion of the rebates. Payers may also negotiate to put drug inflation risk on the PBM by locking in a specific

[2] U.S. Federal Trade Commission and the U.S. Department of Justice, Improving Health Care: A Dose of Competition (July 2004).
[3] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).
[4] US Federal Trade Commission & US Department of Justice Antitrust Division, “Improving Health Care: A Dose of Competition,” July 2004
[5] Pharmacy Benefit Management Institute, “PBMI Research Report: Trends in Drug Benefit Design,” 2016.

rate for their drugs. Plan sponsors may negotiate any combination of these payment methods and other provisions, and always have the right to audit their PBMs' performance under their contracts. On average, PBMs pass back 90 percent of negotiated rebates from drug manufacturers, which payers use to lower enrollees' and their own health spending.[6] Because of the variety of types of payer-PBM contracting and rebate sharing arrangements, the information reported would be out of context and would have no value to the state. However, the potential *cost* of public disclosure of those private contracts on payers and health care consumers would be great.

In addition, PCMA believes the disclosure requirements in the draft PBM bill would be preempted by the federal Employee Retirement Income Security Act (ERISA), to the extent those disclosures contain information on rebates collected for employer-provided coverage. Michiganders who work for private sector employers (whether large or small) are for the most part enrolled in ERISA plans. Many of those plans choose PBMs directly to serve as administrators to those plans, or work with health plans that choose PBMs as administrators.

ERISA provides a "comprehensive system for the federal regulation of employee benefit plans."[7] As the Supreme Court recently noted, there must be a "single uniform national scheme for the administration of ERISA plans without interference from the laws of several states."[8] No state mandate can directly or indirectly interfere with key matters of plan administration, such as interfering with PBM contracts with their clients by requiring reporting to state entities.

As the Supreme Court noted in Gobeille v. Liberty Mutual*,* "ERISA's reporting, disclosure, and recording requirements for welfare benefit plans are extensive," and states cannot impose differing or parallel regulations on administrators like PBMs. Only one entity—the U.S. Department of Labor—has the authority to require such reporting and disclosures. For these reasons, we believe the PBM reporting provisions in the draft bill are preempted by ERISA as they relate to employer-provided coverage, and would be struck down by a federal court if challenged.

On the PBM registration provisions in the draft, PCMA has no comment. As was discussed in the workgroup meeting, PBMs already register as TPAs with the Department of Insurance and Financial Services (DIFS) and provide business and financial information to the state in accordance with those requirements. We believe these long-standing protections are sufficient.

We appreciate the opportunity to provide comments on the drafts and look forward to future discussions. Thank you for your consideration.

[6] Written Testimony of Joanna Shepherd, Ph.D, Emory University for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure, June 19, 2014, Citing J. P. Morgan, "Pharmacy Benefit Management, Takeaways from Our Proprietary PBM Survey," May 21, 2014.
[7] District of Columbia v. Greater Was. Bd. Of Trade, 606 U.S. 125, 127 (1992).
[8] Gobeille v. Liberty Mutual Ins. Co., 577 U.S. ___ (2016).

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

cc: Ms. Cindy Denby, Legislative Aide

PCMA

July 19, 2018

Andrew Stolfi, Co-Chair
Dana Hargunani, Co-Chair
Interim Joint Interim Task Force On Fair Pricing of Prescription Drugs

Mr. Stolfi and Ms. Hargunani,

On behalf of the Pharmaceutical Care Management Association (PCMA), I would like to address comments previously made before the Task Force regarding the "lack of transparency for patients' co-insurance" and how that creates financial challenges for patients.

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans and operate mail-order and specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and other programs.

The financial unpredictability of the price of prescription drugs is a concern faced by many patients. As noted by several Task Force members, patient access to affordable medications should be the overarching objective of the Task Force. In serving that goal, it's important to understand that while a co-insurance is what the patient sees, it simply reflects the cost of a medication or, more importantly, any increase to the cost of that medication. A member's benefit design will remain constant throughout the plan year. For example – a member may have a coinsurance of 20% for specialty drugs throughout their plan year that will remain unchanged. However, manufacturers can and do increase the price of a drug without notice and at any time, causing patients with coinsurance to face increases in their out-of-pocket costs.

However, because the cost of a medication can increase without notice and at any time patients with coinsurance will have corresponding increases in their out of pocket spending when the manufacturer raises their price. Consequently, what a patient sees as only an increase in the amount due at the counter is, in fact, the manufacturer's increase in the price of the medication. No one can control these changes except the manufacturers.

One example is Gleevac which was launched in 2001 with a list price of $26,400 per year. As of 2016, the list price is $120,000 per year. For Medicare beneficiaries, Gleevac is on the specialty tier of a plan's formulary with a corresponding co-insurance amount. The Centers for Medicaid and Medicare Services (CMS) sets the maximum co-insurance amount allowed for drugs on specialty tiers in Part D Plan's formularies, which is currently 33%, and this has remained unchanged since 2013.CMS requires Part D plans to inform beneficiaries, before and after they enroll, of both the co-insurance percentage and equivalent dollar amount for all drugs listed on the specialty tier of the plan's formulary. Part D plans are prohibited from changing the co-insurance amount during the plan year, ensuring full transparency to the beneficiary. What is not provided, or predictable, are increases to the manufacturer's list price.

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It's worth noting Gleevac is one of CMS's protected classes of drugs and thus mandated to be covered by Part D plans. As a result, the manufacturer has no incentive or requirement to offer a rebate to ensure formulary coverage since it's already required to be on the formulary. As a result, the list price is what beneficiaries and tax payers pay. In 2014, Medicare spending for Gleevac reached $1 billion.

Examining a manufacturer's list price is essential to better understand the underlying causes of increases in prescription drugs. How the list price is established and what causes it to increase, often quite suddenly and sharply, will help the Task Force develop solutions benefiting all Oregonians.

Please let me know if you have any questions or if I can provide any additional information.

Sincerely,

Bill Head
Sr. Director, State Affairs

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December 5, 2017

VIA EMAIL – karen.j.winkel@oregon.gov

Karen Winkel, Rulemaking Coordinator
Division of Financial Regulation
Department of Consumer and Business Services
Insurance Regulation

Re: Notice of Proposed Rulemaking filed October 23, 2017 (Pharmacy Benefit Managers)

Dear Ms. Winkel:

On behalf of the Pharmaceutical Care Management Association ("PCMA"), we are providing the following comments on the Department of Consumer and Business Services ("DCBS") Notice of Proposed Rulemaking filed October 23, 2017 ("October Draft Rules"). PCMA is the national trade association representing America's pharmacy benefit managers ("PBMs"), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, state governments, health insurance plans, labor unions, and Medicare Part D.

Thank you for the opportunity to provide comments on the draft rules. Several of our member companies participated in the August stakeholder discussions and we appreciate the Department's willingness to hear differing perspectives on the issues. PCMA submitted comments on August 30, 2017 ("August Comments") to identify and explain two categories of concern: (1) proposed rules that exceed the scope of the Director of DCBS' authority, and (2) proposed rules that represent policies that are likely to impair, not improve, the relationship between pharmacies and pharmacy benefit managers. PCMA appreciates many of the changes reflected in the October Draft Rules. Nevertheless, some of the October Draft Rules continue to raise concerns, as discussed in more detail below. We urge DCBS to revise the proposed rules before adoption and have suggested revisions to assist DCBS in that process.

Legal Standard

PCMA appreciates that, as stated in the rulemaking materials, DCBS considers the proposed rules "necessary for or as an aid to the effectuation of the Insurance Code." Being an aid for effectuation of the Insurance Code, however, does not by itself mean the rules are within the

authority of DCBS to adopt. Under ORS 731.244, the rules must also not "extend, modify or conflict with the Insurance Code[.]"

The statutory requirement that rules may not extend or change the Legislative Assembly's policy choices is reinforced by the judicial rule that an administrative rule is invalid "if the rule exceeds * * * the express or implied authority granted to the agency in the statutes that the rule purports to implement[.]" *Ore. Soc. of Enrolled Agents v. Bd. of Tax Practitioners*, 283 Or App 558, 561, 389 P3d 1153 (2017); *State v. Newell*, 238 Or App 385, 392, 242 P3d 709 (2010) ("when an administrative rule cannot be reconciled with a statute, it is the statute that controls").

Terms the rules define are not "delegative" terms of the kind that "call[] for completing a value judgment that the legislature itself has only indicated." *Springfield Educ. Ass'n v. Springfield School Dist. No. 19*, 290 Or 217, 228, 621 P2d 547 (1980) (internal quotation and citation omitted). Delegative terms include "good cause," "fair," "unfair," and "reasonable." 290 Or at 228 – 29. As explained below, terms in ORS 735.530 to 735.552, such as "net amount," embody specific policy decisions by the Legislative Assembly that are not left for DCBS to complete.

An agency's refraining from "extend[ing] or modify[ing]" the Legislative Assembly's policy choices is necessary where, as here, the legislative history shows the Legislative Assembly's policy choices reflect a compromise between competing interests. *See Coday v. Willamette Tug & Barge Co*., 250 Or 39, 44, 440 P2d 224 (1968) ("The legislative history shows that the present statute was a compromise between * * * two extreme views").

The bare words of a statute are also not the touchstone for the validity of rules. Determining the validity of a rule requires "discern[ing] the legislature's intentions by examining the text and context of the relevant statutes and, if useful to the analysis, pertinent legislative history." *Ore. Soc. of Enrolled Agents*, 283 Or App at 561 (relying on legislative history to determine meaning of statute agency implemented through rules).

The proposed rules "extend, modify or conflict with the Insurance Code" in the same way the rules at issue in *Ore. Soc. of Enrolled Agents* exceeded the rulemaking authority the Legislative Assembly granted to the State Board of Tax Practitioners ("Board"). There, the Board adopted rules that added licensure requirements beyond the requirements the Legislative Assembly had prescribed—an addition the Court of Appeals found beyond the authority of the Board to adopt. 283 Or App at 564.

PCMA has the following legal and policy concerns:

1. Definition of "Net Amount"

Proposed Rule OAR 836-200-0426 defines "net amount":

> (5) The ***net amount*** that the network pharmacy paid to the supplier of the drug is the ***net*** cost of the drug to the pharmacy as reflected on the invoice from the supplier of the drug." (Emphasis added.)

ORS 735.534(3) states, in part, "[a] network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the ***net amount*** that the network pharmacy paid to the supplier of the drug." (Emphasis added.)

Although the October Draft Rules added the term "net cost" to the definition, the practical effect is that the definition was not changed and it therefore continues to exceed the scope of DCBS' authority and modifies the Legislative Assembly's policy choice.

One of the compromises in drafting HB 2123 was to use the term "net amount" rather than the term "amount." *See* May 2013 Oregon House Bill 2123 Negotiation & Amendment Summary. The legislative history is clear—the use of the term "net amount" ***not*** "amount" in the statute was negotiated language and reflected the understanding that the amount a pharmacy pays is influenced by reductions that do not appear on the invoice the pharmacy receives. *See* May 2013 Oregon House Bill 2123 Negotiation & Amendment Summary ("Negotiated language that defines what figure a MAC appeal would be determined from. (*i.e.* "amount" to "net amount.")." Although the proposed rule uses the term "net amount" and "net cost" the proposed rule defines net amount by the cost on the invoice (*i.e.* there is nothing to "net" out). This has the effect of nullifying the legislative compromise and conflicting with the statute. When the Legislative Assembly intends to use an invoice as an information point or basis for action, the Legislative Assembly does so expressly. *E.g.*, ORS 650.300(13) ("net invoice cost"). The absence of a reference to an invoice price reinforces the Legislative Assembly's intent for the term "net amount" to be determined without reference to a particular document.

An example illustrates the issue: when the state of Washington defined "net amount" for purposes of its PBM statute, the state adopted the following rule: "(3) "Net amount" means the invoice price that the pharmacy paid to the supplier for a prescription drug that it dispensed, ***plus any taxes, fees or other costs, minus the amount of all discounts and other cost reductions attributable to the drug***." WAC 284-180-130(3) (emphasis added). This Washington regulation acknowledges that the invoice price is the starting place for determining cost, but it is only a starting place—to determine the cost, other discounts and reductions must be considered.

The proposed definition here fails to take into account any off-invoice discounts and incentives that a pharmacy receives from the wholesaler. These discounts and incentives reduce the net cost of the drug to the pharmacy, which is why the Oregon Legislature chose to use the modifier "net" when referring to "amount." PCMA believes that off-invoice discounts and incentives should be considered (and were considered by the Oregon Legislature) as part of the ultimate cost of the drug to the pharmacy.

Using invoice price as the benchmark and failing to account for off-invoice rebates, discounts, and other incentives that pharmacies obtain from wholesalers will only encourage wholesalers and others in the pharmacy supply chain to increase prices and offer additional off-invoice discounts, further inflating the cost of drugs to health care payers and consumers. The "inflationary consequences of these cost-based reimbursement systems" will be increased overall spending on pharmaceuticals; guaranteed profits for pharmacies, irrespective of their actual efficiency; and an additional cost burden on consumers.[1]

We understand, that for ease of administration, the Department desires a reference to the invoice in the calculation of "net amount."

For these reasons, PCMA therefore suggests the following **amendment**:

> Proposed Rule OAR 836-200-0426: (5) The net amount that the network pharmacy paid to the supplier of the drug is the ~~*net*~~ cost of the drug to the pharmacy as reflected on the invoice from the supplier of the drug, **net of all discounts and other cost reductions attributable to the drug**.

2. Definition of "Generally Available for Purchase" and its Use in the Proposed Rule

Proposed Rule OAR 836-200-0426 defines "generally available for purchase":

> (1) A drug is generally available for purchase if the drug is available for purchase by ***similarly situated pharmacies*** in this state from a national or regional wholesaler at the time of claim

[1] *The Adverse Consequences of Mandating Reimbursements of Pharmacies Based on Their Invoiced Drug Acquisition Costs*, David A. Hyman, H. Ross & Helen Workman Chair in Law, Professor of Medicine, University of Illinois, January 2016, available at: https://www.pcmanet.org/wp-content/uploads/2016/08/hyman-pharmacy-reimbursement-january-2016.pdf.

> submission. A drug is not generally available for purchase if the drug is:
>
> (a) Restricted to hospital or institutional dispensing;
> (b) Only available at or below the maximum allowable cost price if purchased in quantities that materially exceed the dispensing needs of ***similarly situated pharmacies***;
> (c) Only available at or below the maximum allowable cost price if purchased at a discount due to being short-dated; or,
> (d) Subject to a notice of drug recall. (Emphasis added.)

ORS 735.534(2) states: A pharmacy benefit manager:

> (b) Shall ensure that all drugs on a list are generally available for purchase by ***pharmacies*** in this state from national or regional wholesalers. (Emphasis added.)

In the October Draft Rules, DCBS updated the definition to replace the terms "the pharmacy" and "by the pharmacy" with the term "similarly situated pharmacies." The use of the terms "the pharmacy" "by the pharmacy" and now "similarly situated pharmacies" is inconsistent with the statute, which uses the term "pharmacies." For the reasons discussed below, PCMA recommends that the proposed definition of "generally available for purchase" be stricken.

The proposed rule is written in two parts and the term "similarly situated pharmacies" is used once in each part, raising separate, but related concerns. The first part of the proposed rule conflicts with the law by narrowing the concept of "generally available for purchase" to a specific subgroup of pharmacies. The second part of the proposed rule conflicts with the law by defining "generally available for purchase" as a financial concept rather than about a drug's availability in the marketplace, contrary to the legislative intent. The proposed rule does not address the problems PCMA identified in the August Comments. The definition continues to raise significant concerns not only because it is inconsistent with the statute and legislative intent, but also because by breaking with the statute and legislative intent, Oregon will substantially deviate from other states by inappropriately creating a regulatory framework that controls price.

First, the proposed rule states a drug is generally available for purchase if certain conditions are met (*i.e.* "A drug is generally available for purchase if the drug is available for purchase by ***similarly situated pharmacies*** in this state from a national or regional wholesaler at the time of claim submission.")(emphasis added.). This part of the proposed rule conflicts with the law by

narrowing the concept of "generally available for purchase" to a specific subgroup of pharmacies (*i.e.* similarly situated pharmacies), when the statute applied the concept to pharmacies *as a group.* ORS 735.534(2) ("Shall ensure that all drugs on a list are generally available for purchase by ***pharmacies*** in this state from national or regional wholesalers.")

Based on the negotiations between PBMs, pharmacies, and the legislators involved, the intent of the term "generally available for purchase" was to mean simply that the wholesaler has a license to operate and to sell the drugs in the state of Oregon. For example, the law would prohibit a PBM from putting on a MAC list a drug that is only available from one wholesaler that only sells drugs in the state of Florida.

Representative Bailey, who convened and supervised the work group that arrived at Oregon's compromise legislation, noted that HB 2123 was consistent with other state laws including North Dakota, Oklahoma, and Kentucky.[2] Thus, the Legislative Assembly's concept of "generally available for purchase" is the concept expressed in those other states' laws. Each of these states adopted laws in which the concept of generally available for purchase applies to pharmacies as a group, but none has defined this term in the way that DCBS has proposed, and none has elaborated on the term to contemplate the specific needs of a subgroup of pharmacies or pharmacies in a specific class or trade. Most importantly, none of the laws on which the Legislative Assembly based Oregon's law includes price as a component of availability.

> **North Dakota Century Code Annotated §19-02.1-14.2. Maximum allowable cost lists for pharmaceuticals—Pharmacy benefits managers—Penalty**
>
> (3) "A pharmacy benefits manager may not place a prescription drug on a maximum allowable price list unless: (a) The drug has at least two nationally available, therapeutically equivalent, multiple source drugs or a generic drug is available only from one manufacturer; (b) The drug is listed as therapeutically equivalent and pharmaceutically equivalent or "A" or "B" rated in the United States food and drug administration's most recent version of the "Orange Book" or the drug is "Z" rated; and (c) The drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and not obsolete.
>
> **Oklahoma Statutes Annotated. 59 Okl St Ann §360. Pharmacy benefits manager—Contractual duties to provider**.

[2] HB 2123 hearing on March 15, 2013 at 14:05; *see also* meeting material of Matthew DiLoreto of the National Community Pharmacies Association, House Committee on Health Care, March 15, 2013.

> (B) "The pharmacy benefits manager may not place a drug on a MAC list, unless there are at least two therapeutically equivalent, multiple-source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers."
>
> **Kentucky Revised Statutes Annotated §304.174-162. Identification of sources used to calculate drug product reimbursement; process to appeal disputes over maximum allowable cost pricing; adjustment of maximum allowable cost and drug product reimbursement; duties of pharmacy benefit manager**
>
> (8) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that drugs subject to maximum allowable costs are: (a) Generally available for purchase by pharmacists and pharmacies in Kentucky from a national or regional wholesaler licensed in Kentucky by the Kentucky Board of Pharmacy; (b) Not obsolete, temporarily unavailable, or listed on a drug shortage list; and (c) 1. Drugs that have an "A" or "B" rating in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or 2. Drugs rated "NR" or "NA" or have a similar rating by a nationally recognized reference.

The second part of the proposed rule provides a definition to further explain when a drug is ***not*** "generally available for purchase." Pursuant to the proposed rule, a drug is not "generally available for purchase" if the drug is * * * (b) Only available at or below the maximum allowable cost price if purchased in quantities that materially exceed the dispensing needs of ***similarly situated pharmacies*** * * *."

Such a definition conflicts with the text of the statute, exceeds DCBS' statutory authority, and is inconsistent with the legislature's intent. The concept of "generally available for purchase" is not related to price. The statute addresses the ***availability of drugs for purchase***, not the ***accessibility of a drug at a specific price***. Pursuant to the proposed rule, if a drug could not be purchased at or below the MAC price at certain quantities, the drug is not considered "generally available for purchase," making that drug ineligible for inclusion on the MAC list.

During the negotiations of HB 2123, legislators acknowledged and understood that MAC reimbursement methodology could result in net positives and net negatives. The legislature did not intend to guarantee profit for every pharmacy on every drug. No other private business enjoys this type of financial protection.

The proposed rule exceeds the intent of the law and requires PBMs to have insight into the individual purchasing practices of the pharmacies with which it contracts. The definition appears to prohibit a PBM from including a drug on the MAC list unless it somehow knew the dispensing needs of various subgroups of pharmacies, knew how to reconcile their various dispensing needs, and knew what it would mean to materially exceed such reconciled dispensing needs. This is an unworkable standard.

A pharmacy's purchasing and dispensing needs depends upon a variety of factors including but not limited to their size, patient population, geographic location, and inventory management practices. To ensure compliance, it appears the proposed rule would require a PBM to *essentially guarantee that each and every pharmacy in the network could purchase the drug, on any given day, at or below the MAC price*, and to know this at the time the MAC list is developed.

The statute was thoughtfully crafted after significant debate and compromise and was not intended to impose such obligations. It establishes protections for pharmacies that limit the drugs that PBMs may place on the MAC lists—to establish standards regarding availability, not price.

For these reasons, PCMA suggests **deleting** the definition of "generally available for purchase":

> Proposed Rule OAR 836-200-0426: ~~*(1) A drug is generally available for purchase if the drug is available for purchase by similarly situated pharmacies in this state from a national or regional wholesaler at the time of claim submission. A drug is not generally available for purchase if the drug is:*~~
>
> ~~*(a) Restricted to hospital or institutional dispensing;*~~
> ~~*(b) Only available at or below the maximum allowable cost price if purchased in quantities that materially exceed the dispensing needs of similarly situated pharmacies;*~~
> ~~*(c) Only available at or below the maximum allowable cost price if purchased at a discount due to being short dated; or,*~~
> ~~*(d) Subject to a notice of drug recall.*~~

3. Definition of "readily accessible to and usable" and "readily accessible and useable"

Proposed Rule OAR 836-200-0426 defines "readily accessible to and usable" and "readily accessible and usable":

> (2) A list is readily accessible to and usable and readily accessible and usable if the list is provided in an electronic, computer accessible and searchable format that identifies all drugs for which maximum allowable costs have been established, and for each drug specifies:
>
> (a) The national drug code;
> (b) The maximum allowable cost price; and,
> (c) The effective date and time for maximum allowable cost price.

First, as PCMA noted in its August Comments, the previous version of the rule *requiring* a PBM to provide the generic product identifier ("GPI") would require some PBMs to breach contracts with the owner of the GPI, Medi-Span. However, the October Draft Rules eliminate the ability of a PBM to comply by providing GPI; to comply, a PBM must provide the national drug code ("NDC"). Although many PBMs use a publicly-available NDC as the drug identifier, some PBMs use GPI as the drug identifier and are authorized to share the GPI under some circumstances. PCMA requests the rule be amended (consistent with PCMA's original proposal) to provide the flexibility of providing either GPI or NDC.

Second, PCMA is concerned regarding the requirement to provide the "effective date and time" of a MAC reimbursement amount. It is unnecessary and unclear how a PBM would comply. The statute already requires that the MAC list be updated in a specific time frame: "[A PBM s]hall update each list maintained by the pharmacy benefit manager ***every seven business days*** and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format." ORS 735.534(2)(f) (emphasis added). Moreover, the statute requires the PBM to make the list available "upon request," which the proposed rule fails to consider. ORS 735.534(2)(e). There should be no concern that relevant information would not be available and updated appropriately.

For these reasons, PCMA suggests the following **amendment**:

> Proposed Rule OAR 836-200-0426: (2) A list is readily accessible to and usable and readily accessible and usable if the list is provided**, upon request,** in an electronic, computer accessible and searchable format that identifies all drugs for which maximum allowable costs have been established, and for each drug specifies:
>
> (a) The national drug code **or generic product identifier**; **and**
> (b) The maximum allowable cost price**.**~~*; and,*~~
> ~~*(c) The effective date and time for maximum allowable cost price.*~~

4. Definition of "Similarly Situated" Pharmacies

Proposed Rule OAR 836-200-0426(3) states that "Pharmacies are similarly situated in this state if they are: (a) Of like size and class of trade, including independent, chain, supermarket, mass merchandizer, mail order or specialty; and, (b) Contracted with a pharmacy benefit manger under the same network agreement."

PCMA is concerned that this definition does not take into consideration the varying nature of the types of pharmacies that are listed. Not all pharmacies within a class of trade as defined here have similar patient populations or needs, and thus would not necessarily have similar purchasing practices or arrangements with wholesalers. For example, a pharmacy that serves a specialized patient population would stock different types of drugs than a more general practice pharmacy. Furthermore, it is unclear what defines a "chain" (e.g., is a group of pharmacies owned by one person considered a chain?).

For these reasons, PCMA recommends striking this definition.

> Proposed Rule OAR 836-200-0426 ~~(3) Pharmacies are similarly situated in this state if they are: (a) Of like size and class of trade, including independent, chain, supermarket, mass merchandizer, mail order or specialty; and, (b) Contracted with a pharmacy benefit manger under the same network agreement.~~

5. Submission of Complaints

PCMA appreciates that DCBS developed a complaint form that indicates "[a] complaint submitted against a PBM shall be deemed confidential under ORS 731.264." Nevertheless, PCMA remains concerned that information included on a form may be publicly disclosed. PCMA requests that a clear statement be made in the *rule* to protect propriety information from public disclosure.

For these reasons, PCMA suggests the following **amendment**, to add a subsection:

> Proposed Rule OAR 836-200-0436. **(3) A complaint submitted under this rule is confidential under ORS 731.264 and subject to ORS 731.264. The Department shall treat all pricing, contract terms, or other proprietary information obtained from any person or entity through the complaint process as trade secrets under ORS 192.501(2).**

6. Appeals Provisions

Proposed Rule OAR 836-200-0431 describes the appeal of reimbursement for a drug subject to maximum allowable cost pricing:

> (1) A pharmacy benefit manager shall allow a pharmacy to submit an appeal, and the documentation in support of an appeal, in paper or electronic form.
> (2) A pharmacy benefit manager may not:
> (a) Refuse to accept an appeal submitted by a person or entity acting on behalf of a pharmacy;
> (b) Refuse to accept an appeal for reason that it is submitted with multiple claims or within a batch of like appeals; or
> (c) Impose procedures or restrictions that have the effect of unduly obstructing or delaying the appeals process.
> (3) If an appeal is upheld, the pharmacy benefit manager shall allow the claim, or allow resubmission of the claim, by the pharmacy and shall make adjustment without additional charge.
> (4) If an appeal is denied for reason that the drug was generally available for purchase in this state at a price equal to or less than the maximum allowable cost at the time of claim submission, the pharmacy benefit manager shall specify where the drug was so available.

PCMA is concerned about a number of requirements in this section: (1) accepting paper appeals; (2) accepting appeals from a pharmacy's representative; (3) accepting batch appeals; and (4) notifying the pharmacy of where a specific drug may be purchased upon an appeal denial.

First, given the high volume of reimbursements and appeals in the generic drug space, it is impractical, inefficient, and burdensome for companies to accept appeals on paper. Modern-day pharmacies are equipped to submit claims and appeals electronically. As noted below, PCMA suggests striking the requirement that paper appeals be accepted.

Second, PCMA is concerned that if there is not a contract between the PBM and the appealing entity, proprietary price information may be revealed inappropriately. Pharmacy services administrative organizations ("PSAOs") contract with multiple PBMs and some own PBMs that are competitors to the PBMs they would be submitting appeals to. Without a contract to require a PSAO or other entity to hold PBM reimbursement information confidential, there is nothing protecting the price information from being shared with that competitor PBM or with other parties, such as pharmacies that should not have insight into the PBM's pricing. PSAOs or other

entities could use the appeals process to obtain pricing information to which the PSAOs would not otherwise be entitled. Requiring a contract that would hold the parties to confidentiality commitments for the appeal is a reasonable, simple solution to this problem. Contracts for this purpose are common in the industry today. Accordingly, as noted below, PCMA requests an amendment that clarifies that the "person or entity acting on behalf of a pharmacy" is the "entity that has entered into a contract with the pharmacy benefit manager on behalf of the pharmacy."

In addition, PCMA is concerned that subsection 2(b) of the proposed rule is an expansion of the statute that encourages frivolous appeals or appeals of reimbursements that are not covered by the statute. There is precedent for this problem. DCBS is aware that a single pharmacy representative filed tens of thousands of complaints that had to be individually investigated by PBMs and more than 1/3 of those complaints were related to claims that were not covered by the statute. As the proposed rule is written, it is exceedingly easy for a pharmacy or its representative to file thousands of appeals without doing the work of determining whether those claims are actually covered by the terms of the statute, and shifts that significant burden onto the PBM. The pharmacy or its representative should be required to look at each reimbursement, determine whether appeal is appropriate, and then submit supporting documentation specific to that particular appeal. Additionally, under the proposed rule, PBMs would be required to accept batch appeals from any "person or entity acting on behalf of a pharmacy," which only encourages appeals without analyzing the individual cases of the drug, reimbursement, and need for appeal. To address these issues, PCMA requests that this requirement be stricken.

Fourth, Proposed Rule OAR 836-200-0431 requires PBMs to notify a pharmacy *where* a drug was available for purchase upon denying an appeal. The proposed rule exceeds DCBS' statutory authority and creates a series of legal challenges, described in detail below.

ORS 735.534(4)(c) states "If the appeal is denied, the reason for the denial ***and the national drug code of a drug that may be purchased by similarly situated pharmacies*** at a price that is equal to or less than the maximum allowable cost." (Emphasis added.) Accordingly, for a PBM to comply with the *statute*, the PBM must provide the reason for the denial and the NDC of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost. In contrast, to comply with the proposed *rule*, a PBM must also specify ***where*** the drug can be purchased at the MAC price.

DCBS appears to interpret ORS 735.534(4)(c) to include a location requirement. That interpretation, however, reads ORS 735.534(4)(c) too broadly, and, therefore, inappropriately "expands" the statute's requirements. Instead, the statute requires only a statement of availability—not "where the drug was so available." The statute, thus, contrasts with statutes in which the Legislative Assembly intends to express the location of a particular item.

E.g., ORS 353.070(5) ("provided the product or service * * * is available at the location and within the period required[.]").

The Legislative Assembly cannot have intended to require the disclosure of the availability of a drug at a particular price because the Legislative Assembly is deemed to have known a PBM would be highly unlikely to know the location of a specifically-priced drug, and, if the PBM did know the price, would run a risk of incurring liability for anti-competitive conduct.

To "specify where the drug was so available," the PBMs would need to know the cost of a drug to a specific pharmacy (or subgroup of pharmacies) at the time of claim submission. It would be very difficult for PBMs to know the applicable pricing information without all the other parties involved sharing their competitive pricing and purchasing information. PCMA is also concerned that there are anti-kickback and antitrust concerns with a PBM having knowledge of (1) why a wholesaler sets a specific price (*e.g.* unique discounts due to confidential contracts) and (2) which specific pharmacies' wholesalers are selling the drug to whom at a particular price (*e.g.* as the rule suggests, taking into account drugs being bought according to the "business needs" of certain pharmacies). However, PCMA does not dispute that DCBS has the authority to enforce the law and may request information from a PBM in the context of reviewing a complaint. Although the statute clearly does not require PBMs to provide to pharmacies information on where a drug was available at a particular price, PBMs may choose to provide this type of information to DCBS to assist DCBS with resolving a complaint and determining compliance with the statute.

For these reasons, PCMA recommends the following **amendment**:

> Proposed Rule OAR 836-200-0431.
> (1) A pharmacy benefit manager shall allow a pharmacy to submit an appeal, and the documentation in support of an appeal, in ~~*paper or*~~ electronic form.
> (2) A pharmacy benefit manager may not:
> (a) Refuse to accept an appeal ~~*submitted by a person or entity acting on behalf of a pharmacy*~~ **from a pharmacy's designated representative. A designated representative shall be the entity that has entered into a contract with the pharmacy benefit manager on behalf of the pharmacy; or**
> ~~(b) Refuse to accept an appeal for reason that it is submitted with multiple claims or within a batch of like appeals; or~~

> (c) Impose procedures or restrictions that have the effect of unduly obstructing or delaying the appeals process.
>
> (3) If an appeal is upheld, the pharmacy benefit manager shall allow the claim, or allow resubmission of the claim, by the pharmacy and shall make adjustment without additional charge.
>
> (4) If an appeal is denied ~~*for reason that the drug was generally available for purchase in this state*~~ **, the pharmacy benefit manager shall provide the pharmacy with the reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies** at a price equal to or less than the maximum allowable cost ~~*at the time of claim submission, the pharmacy benefit manager shall specify where the drug was so available*~~.

7. Application Requirements

Proposed Rule OAR 836-200-0406 describes the application requirements for Pharmacy Benefit Managers:

> (3) A pharmacy benefit manager shall provide the Department with written notification of any change to its registration information not later than 30 days after the date of change.

PCMA acknowledges that it is common to notify the state of a change in officers or directors within a certain time period. PCMA requests that the timeframe be extended to 60 days from 30 days. In addition, for the elements of the application form that require knowledge of a specific finding or action of a director or officer (e.g., falsified application, dishonesty, etc.), the person filling out the application will only know if there was a formal finding or adjudication of one of these things. PCMA requests that the notification timeframe be triggered upon a final disposition of the matter.

For these reasons, PCMA suggests the following **amendment**:

> Proposed Rule OAR 836-200-0406(3): A pharmacy benefit manager shall provide the Department with written notification of any change to its registration information not later than **60** ~~*30*~~ days after the **final disposition of the matter or the** date of change.

8. Application Form

PCMA would like to bring your attention to an issue regarding the registration application form. The registration application form contains the following questions:

Has Applicant or any person with control of Applicant:

1. Ever falsified an application for registration or for the renewal of a registration or engaged in any dishonest act in relation to the application?

2. Ever engaged in dishonesty, fraud or gross negligence in the conduct of business as a pharmacy benefit manager?

9. Ever violated any rule or order of the department or any provision of the Insurance Code?

The Applicant is an entity, not a person. These questions are not tied to a finding, legal adjudication, government action, or conviction that would provide notice. In the absence of requiring a legal finding, it would be appropriate only to have the person filling out the form to the best of the Applicant's knowledge.

PCMA acknowledges that pursuant to 2017 HB 2388, DCBS may deny an application for registration as a pharmacy benefit manager or an application for renewal of a registration as a pharmacy benefit manager, and may suspend or revoke a registration as a pharmacy benefit manager, if DCBS were to make findings related to the conduct at issue in the questions above. In addition, PCMA acknowledges that the representations made on the application form will greatly assist DCBS in carrying out its authority. Nevertheless, HB 2388 does not require PBMs to make such representations and, because the broad questions listed above that are not tied to a finding, legal adjudication, government action, or conviction that provides notice to the person completing the application , it may be impossible for the PBM entity to answer accurately.

For these reasons, PCMA suggests the following amendment:

> Applicant shall respond "Yes" or "No" to each of the following questions **to the best of the Applicant's knowledge**, and shall explain any "Yes" response in the Supplemental Information space provided below. Has Applicant or any person with control of the Applicant **knowingly and intentionally (where applicable)**: …

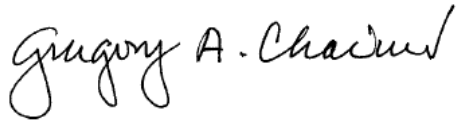
Conclusion

In the Budget Note to Senate Bill 5701 (2016), the Oregon Legislative Assembly directed DCBS to convene a workgroup with a specific charge: to develop recommendations for "a notification system for informing PBMs of new regulations and informing PBMs of complaints, investigations, and possible sanctions; investigation procedures; and [a] fees, fines, and resolution process ." This Budget Note was adopted when earlier 2016 legislation that expanded the scope of PBM regulation failed during the legislative process. During the several meetings held over 2016, the workgroup's scope increased dramatically—to areas significantly outside the Budget Note's charge—and the resulting rule proposals reflect this improper expanded scope. The proposed rule's preamble also misstates the direction of the Budget Note by saying the scope of the workgroup was to "improve the PBM regulatory framework." This is simply not accurate. PCMA does not dispute DCBS's authority to draft regulations that clarify the statutes under its purview. However, it is essential that the rules adopted fall within the limited scope of those provisions.

PCMA encourages DCBS to amend the proposed rules so they do not exceed the authority of DCBS and adopt the amendments to the proposed rules described above to avoid the implementation of policies that are likely to impair relationships between pharmacies and PBMs and raise costs in the health care system.

Very truly yours,

Davis Wright Tremaine LLP



Gregory A. Chaimov

GAC/jan

cc: Richard Y. Blackwell, Division of Financial Regulation, DCBS
Van Pounds, Division of Financial Regulation, DCBS

PCMA

February 13, 2018

Veronica Sheldon, Management Analyst
Department of Health and Human Services
4126 Technology Way, Suite 100
Carson City NV 89706

Via email: drugtransparency@health.nv.gov

Re: Proposed Amendments to the Nevada Administrative Code Chapter 439: Drug Transparency Reporting

Dear Ms. Sheldon:

The Pharmaceutical Care Management Association (PCMA) submits the following comment in response to the Department's proposed rules to implement SB 539 (2017) relating to drug price transparency. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, state governments, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide feedback on the proposed rules. First, PCMA appreciates the Department's acknowledgment that certain proprietary price information is protected by the federal Defend Trade Secrets Act and appreciates that the Department has outlined a process to address those protections as the issues arise.

PCMA has two comments on the draft regulation and the PBM data collection form.

1. Section 3(2)(b) of the proposed rule states "The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the manufacturer a copy of the written request for those records." We believe that the use of "manufacturer" was inadvertently used in place of "pharmacy benefit manager." PCMA requests that this language be clarified in the following way:

   The Department will notify the pharmacy benefit manager of any request for data elements marked as confidential and will provide the ~~manufacturer~~ pharmacy benefit manager a copy of the written request for those records.

2. The proposed data collection form includes a box to report rebates negotiated for the purchase of drugs for use by recipients of Medicare. However, Medicare is a federal program, and any state law "with respect to" a Part D plan offered by a Part D sponsoring organization is preempted. No requirement for a finding that a state law is *inconsistent* with a Part D standard is needed. All standards established under the Part D program "shall supersede any State law or regulation…with respect to [Part D] plans

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www.pcmanet.org

which are offered by [Part D plan sponsors]."[1] Only state laws governing licensure and solvency are saved from preemption.[2] In its final rules implementing the Medicare Advantage and Part D programs, the Centers for Medicare and Medicaid Services (CMS) noted that Congress had clearly enacted broad preemption language in the Medicare Modernization Act (MMA), and that state requirements that derive from case law are also preempted.[3] The courts have also recognized the broad scope of preemption under the MMA, looking at whether there is an established federal standard (i.e., a statute or rule codified in the Code of Federal Regulations), and whether the state statute is a law with respect to that standard (and therefore preempted unless it is a law of general applicability or a minimum plan licensure or solvency).[4]

Under the Medicare Part D (prescription drug program) statute, the Part D plans are required to provide the Centers for Medicare and Medicaid Services with information about prescription drug price concessions and rebates.[5] The terms of SB 539 "relate to" this federal requirement because it requires similar reporting by the same, federally-regulated entities (Part D plans). SB 539 is not a state licensure or solvency standard that is saved from preemption, and its terms are not generally applicable to any type of business in the state—it is the very fact that rebates are negotiated and purchased for Medicare recipients that triggers this provision of the state statute. Thus, federal Medicare law preempts the state law and the proposed data collection form, as they relate to rebates negotiated for the purchase of drugs for used by Medicare recipients. PCMA requests that this data element be stricken from the form.

We appreciate the opportunity to provide comments on this proposed rule and we welcome the opportunity to speak with you about our concerns. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

cc: Margot Chappel, MS, Manager, Primary Care and Health Workforce Development Office, Department of Health and Human Services

[1] Social Security Act § 1856(b)(3), 42 U.S.C. § 1395w-26(b)(3). *See also*, Social Security Act § 1860D-12(g), applying Medicare Advantage preemption standards to Part D.
[2] Id. *See also*, 70 Fed. Reg. 4588, 4663-66 (Jan. 28, 2005). CMS cites, as an example, a state requirement that a plan file Articles of Incorporation with the Secretary of State's office as a permissible state regulation.
[3] 70 Fed. Reg. 4588, 4663-66.
[4] *Pacificare v. Rogers*, 127 Nev. Adv. Rep. 71 (2011); *Uhm v. Humana*, 620 F.3d 1134, 1149, n.20 (9th Cir. 2010)
[5] 42 USC § 1395w-102(d)(2).

May 31, 2018

Nevada Department of Health and Human Services
4150 Technology Way, Suite 300
Carson City NV 89703

Via email: drugtransparency@dhhs.nv.gov

Re: LCB File No. R042-18. Revises provisions related to drug transparency.

To Whom it May Concern:

The Pharmaceutical Care Management Association (PCMA) submits the following comment letter in response to the Department's proposed rules in LCB File No. R042-18, implementing sections of SB 539 (2017) relating to drug price transparency. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through large and small employers, state governments, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit Programs, and other public programs.

Thank you for the opportunity to provide feedback on the proposed rules. First, PCMA appreciates the Department's acknowledgment that certain proprietary price information is protected by the federal Defend Trade Secrets Act and appreciates that the Department has outlined a process to address those protections as the issues arise. PCMA remains concerned about the sensitive nature of the data required to be reported to the state, but believes that the Department intends to protect the data to the extent allowed under federal and state law. We have some concerns about the implementation of the language in the context of the Defend Trade Secrets Act and suggest amendments and provide rationale below that address these concerns.

1. In several sections[1] of the proposed rule, the language allows a PBM to submit a request to the Department to keep certain information confidential and not subject to public disclosure. PCMA strongly supports the Department's goal to provide a pathway to utilize the federal protections in the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836 (DTSA), and we appreciate the Department acknowledging this in the draft rule. We are concerned, however, that the standard for seeking relief outlined in the proposal is inconsistent with the DTSA. The DTSA's pathway for seeking relief is designed to protect against the disclosure of information that qualifies as a trade secret. Although we understand that the federal law uses "misappropriation" as the trigger to determine when a remedy is in order, using the term "misappropriation" in the state rule implies that the *Department* would need to act inappropriately or commit some sort of malfeasance for the ability of a PBM to initiate the procedure to protect the information from disclosure. Because the Department would be releasing information in accordance with its state statute, we believe the standard of

[1] Sections 3(1), 3(2), 3(3), and 3(4).

"misappropriation" is not the appropriate standard for seeking relief under the DTSA. Instead, we suggest that the standard for seeking relief for PBMs to meet under the DTSA that would allow for the protection against disclosure should be any information that could cause competitive harm or information that qualifies as disclosure of a trade secret under the DTSA.

PCMA suggests the following amendments:

Sections 3(1), 3(2)(b), 3(3)(b), and 3(4): Delete "~~would constitute misappropriation~~" **from all of these sections and replace with** "could cause competitive harm or qualifies as a disclosure"

Section 3(5): Delete "~~constitute misappropriation~~" **and replace with** "cause competitive harm or does not qualify as a disclosure"

Section 3(6)(a) & (b): Delete from both (a) and (b) ~~"the federal Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836, as amended~~" **and replace with** "this regulation"

2. Section 3(3)(b) provides for the Department to perform an initial review of the potential public disclosure, and consider the interpretation and application given to the term "trade secrets" in Exemption 4 of the federal Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), as amended. We are concerned that this section would have no effect because neither Exemption 4 of FOIA, nor the DTSA define the term "trade secret." In addition, this section references "misappropriation of a trade secret," which we believe, as described above, is not an appropriate standard for seeking relief.

   PCMA suggests deleting Section 3(3)(b).

3. Section 3(5)(b) provides for the Department to provide notice to the PBM that sensitive information may be disclosed "as soon as reasonably practicable after" notifying the requester of information. PCMA is concerned that the 30-day clock begins running as soon as the notice has been provided to the requester, so the PBM would always be at a time disadvantage and may not have sufficient time to defend against disclosure when it is appropriate. We believe that the notice to the requester and the PBM should be concurrent.

   PCMA suggests the following amendment:

   Section 3(5)(b): Delete "~~As soon as reasonably practicable after~~" **and replace with** "Concurrent with"

4. Section 4(1) calls for any data that is released to be aggregated so that the identity of a drug, manufacturer, or PBM is not disclosed. PCMA is concerned that under this language, the Department may disclose the data separately by PBM. Even if those individual PBMs are not identified, it would not be difficult for a person with knowledge of the PBM market share, volume of sales, and formularies to figure out the names of the PBMs and separate total numbers. If drug manufacturers were to learn the rebate amounts and be able to identify the specific PBMs that were associated with those amounts, there is a significant

risk that competition in the marketplace among drug manufacturers would be impeded, which has the potential to lead to increased costs for Nevada consumers. On this point, the Federal Trade Commission has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors…then tacit collusion among manufacturers is more feasible…Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely."[2] The FTC has also warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[3] Because we share these concerns, we are requesting that the report compiled by the Department only include combined data from all reporting PBMs.

PCMA suggests the following amendment:

Section 4(1): Only aggregated data of all manufacturers combined or all pharmacy benefit managers combined, as applicable, and that does not disclose or allow for the determination of the identity of any drug, manufacturer, plan or pharmacy benefit manager; and"

5. PCMA is concerned that there is no clear statement in the proposed rule that requires the Department to hold information in confidence and release data only as required by statute and this regulation.

PCMA suggests the inclusion of a following new subsection (c):

Section 2(c) The Department shall hold all data in confidence and will release such data only as provided pursuant to these regulations."

We appreciate the opportunity to provide comments on this proposed rule and we welcome the opportunity to speak with you about our concerns. Please do not hesitate to contact me at 202-756-5743 if you have any questions.

Sincerely,

April C. Alexander
Assistant Vice President, State Affairs

[2] U.S. Federal Trade Commission and the U.S. Department of Justice, Improving Health Care: A Dose of Competition (July 2004).
[3] Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).

cc: Margot Chappel, MS, Manager, Primary Care and Health Workforce Development Office, Department of Health and Human Services

AMERICANS for TAX REFORM

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March 13, 2018

To: Members of the Arkansas Senate

From: Americans for Tax Reform

Re: SB2 (Arkansas Pharmacy Benefits Manager Licensure Act)

Dear Senator,

On behalf of Americans for Tax Reform (ATR) and our supporters across Arkansas, **I urge you to reject SB2, AKA the Arkansas Pharmacy Benefits Manager Licensure Act,** which is a misguided piece of legislation that would unnecessarily insert state government into certain business-to-business transactions. At a time when other states that Arkansas competes with are enacting regulatory reforms that remove red tape and rein in costly rules, SB2 represents a step in the opposite and wrong direction, imposing punitive new regulations that will lead to higher costs for your constituents.

SB2 seeks to regulate and license Pharmacy Benefit Managers (PBMs). If implemented, SB2 would restrict many of the practices PBMs use to negotiate for lower drug prices, force them to hand their proprietary information over to the Insurance Commissioner, and allow state agencies to dictate the pricing terms of their contracts.

Making matters worse for Arkansas taxpayers, the bill is vague, complex, and seems to be preempted by the Employee Retirement Income Security Act of 1974 (ERISA). As such, it is reasonable to assume that enactment of this legislation would result in Arkansas taxpayers being forced to foot the bill for costly legal challenges.

Your constituents have already been hit with 20 federal Obamacare tax increases over the last decade. The last thing individuals, families, and employers across Arkansas need is to have lawmakers in Little Rock pass legislation to impose costly new regulations that will lead to higher costs for employers and consumers across the state.

The sponsor or this bill recently touted that it "has all the regulatory language in it" so that the Insurance Commissioner can, in the author's own words, "be punitive." Imposing punitive and unnecessary regulations that will result in higher costs for consumers and employers sends the wrong message about Arkansas to site selectors, investors, and job creators.

The recently passed federal tax code overhaul is expected to precipitate an influx of investment in the United States that will yield significant economic growth and job creation. If Arkansas is to be seen as an attractive destination for this increased investment, state lawmakers need to implement the necessary reforms to make Arkansas's tax code and regulatory burden as competitive as possible. SB2 represents a step in the wrong direction toward that effort. As such, **I urge you to oppose and vote NO on SB2**. I thank you for your leadership and public service. If you have any questions regarding ATR's position on this issue, please contact Margaret Mire, ATR's state affairs manager, at 202-785-0266 or mmire@atr.org.

Sincerely,

Grover G. Norquist
President
Americans for Tax Reform

PCMA Legal Resources

PCMA v. Gerhart (852 F.3d 722 (8th Cir. 2017))
Background and Implications

Background

- In 2014 Iowa enacted a "MAC/transparency" law that narrowly limited the types of drugs that pharmacy benefit managers (PBMs) could reimburse using maximum allowable cost (MAC) lists, allowed pharmacy appeals and retroactive payment if MAC pricing was "applied incorrectly," and required PBMs to disclose certain information about MAC lists to both contracting pharmacies and to the Iowa Insurance Division.

- PCMA sued the State of Iowa after the law was enacted, asking the Court to find the statute unconstitutional under a federal law called ERISA (Employee Retirement Income Security Act of 1974), because it establishes restrictions and requirements on PBMs that the state has no authority to establish, and dictates terms of PBM contracts with ERISA plans.

- ERISA makes unconstitutional any state law that *relates to* an employee benefit plan, unless another federal statute has established an exception to ERISA's preemption. "Relates to" means the statute (1) makes "reference to" an ERISA plan, or (2) has an "impermissible connection with" an ERISA plan. Both fully insured and self-insured plans are considered "ERISA plans." The only category of state statutes that are excepted (saved) from ERISA's preemption are those that regulate "the business of insurance."

- In 40-plus years of court interpretations of this highly technical statute, what has emerged consistently is the principle that ERISA preemption is *very* broad, even in matters of health and safety, an area traditionally governed by the states.

PCMA v. Gerhart Decision

- On January 11, 2017 a three-judge panel of the 8th Circuit Court of Appeals struck down Iowa's 2014 MAC/transparency law in its entirety, in an opinion that essentially precludes ***any*** state regulation of MAC. In its opinion the Court said that under ERISA, states cannot dictate how plans structure and pay for plan benefits, including prescription drugs.

- Specifically, it held that the Iowa law was preempted by federal ERISA for two reasons:

    1) It had made "reference to" ERISA because it acted immediately and exclusively on ERISA plans and the existence of ERISA plans was essential to the law's operation.

    2) It had an impermissible "connection with" ERISA plans because it interfered with "uniform plan administration," by (1) compelling PBMs as third party administrators (TPAs) to report to the state insurance commissioner and to network pharmacies, (2) restricting classes of drugs that can be allowed on a MAC list and sources of pricing/reimbursement

methodologies, and (3) allowing appeals by and retroactive reimbursements to pharmacies. These restrictions ultimately removed the benefit plans' control over "calculation and distribution of benefits."

- On February 16, 2017, the 8th Circuit Court of Appeals denied the State of Iowa's request for rehearing en banc (a request for the full 8th Circuit to review the three-judge panel decision). The State did not file a Petition for a Writ of Certiorari in the U.S. Supreme Court.

What This Means for PBMs

- Iowa's MAC law is overturned, and regulations crafted based on the overturned statute should not be enforced.

- States can't impose requirements on health plans or their TPAs (such as PBMs) that impact the management and administration of ERISA plans.

- States can't dictate how plans or their PBMs structure and pay for benefits, meaning attempts to regulate PBM tools like MAC and incentives to use mail-order after *Gerhart* are likely invalid. In addition, any state law or regulation that interferes with uniform reporting and disclosure rules, standards and remedies—or creates the possibility of a patchwork of multiple regulatory requirements—is preempted. Other state laws on MAC and other areas of PBM concern may be unconstitutional as well. Each statute requires its own analysis.

- Though ERISA's preemption is very broad, states do have the power to regulate insurance, and whether a statute regulates "insurance" requires analysis. State statutes that have been found to fall within states' authority and thus not preempted are: benefit mandates, "any willing provider" laws applying to insured plans, and independent review of coverage decisions. Again, each statute requires its own analysis.

- *PCMA v. Gerhart* is precedential in the 8th Circuit, meaning lower courts in that circuit must follow the opinion as binding law. PCMA's later challenge of the 2015 Arkansas anti-MAC law, also in the 8th Circuit, was successful in 2018. The 8th Circuit found the Arkansas law to be preempted by both ERISA and Medicare Part D (See *PCMA v. Rutledge*, 8th Circuit 2018 Slip Op. 17-1609).

- Though *PCMA v. Gerhart* does not serve as a legal precedent in other circuits, the opinion is consistent with and based upon longstanding ERISA preemption law. The decision relied heavily on *Gobeille v. Liberty Mutual*, a 2016 U.S. Supreme Court case that found unconstitutional a Vermont law that required reporting of claims information by TPAs on behalf of ERISA-covered entities, since reporting is a "core ERISA administrative function." The Supreme Court's decision in *Gobeille* is precedential across the country.

PCMA v. Rutledge (891 F.3d 1109 (8th Cir. 2018))
Background and Implications

Background

- In 2015 Arkansas enacted a "MAC/transparency" law (SB 688 – Act 900) that imposed onerous regulations on PBMs and their relationships with pharmacies. Specifically, the law:

    - Required **PBMs** reimburse pharmacies at or above their acquisition costs;
    - Required PBMs to update MAC lists within 7 days of an increase in the pharmacy's acquisition cost;
    - Required PBMs to establish a pharmacy reimbursement appeals process;
    - Allowed pharmacies to reverse and rebill claims for which the pharmacy could not purchase the drug below the MAC list price; and
    - Allowed pharmacies to decline to dispense if they would lose money on a transaction.

- PCMA filed suit challenging the Arkansas statute as preempted by ERISA (Employee Retirement Income Security Act of 1974) and Medicare Part D. PCMA asked the Court to find the statute unconstitutional because Act 900 establishes requirements on PBMs that the state has no authority to establish, and dictates terms of PBM contracts with ERISA plans and Medicare Part D plans.

- ERISA makes unconstitutional any state law that *relates to* an employee benefit plan, unless another federal statute has established an exception to ERISA's preemption. "Relates to" means the statute (1) makes "reference to," or (2) has an "impermissible connection with," an ERISA plan. Both fully insured and self-insured plans are considered "ERISA plans." The only state statutes that are excepted ("saved") from ERISA's preemption are those that regulate "the business of insurance." In 40-plus years of court interpretations of this highly technical statute, what has emerged consistently is the principle that ERISA preemption is *very* broad, even in matters of health and safety, an area traditionally governed by the states.

- Medicare similarly has broad preemption provisions. Medicare law preempts all state laws except those that require insurer licensing and set financial solvency standards.

PCMA v. Rutledge Decision

- On June 8, 2018 the U.S. Court of Appeals for the 8th Circuit ruled in PCMA's favor, holding that the Arkansas statute regarding the pricing relationship between pharmacies and PBMs was preempted by both ERISA and Medicare Part D. The ruling affirmed the district court ruling with respect to the ERISA claim, and reversed the lower court's decision on the Medicare Part D claim.

- Regarding ERISA preemption, the Court reaffirmed and extended its holding in *PCMA v. Gerhart* (852 F.3d 722 (8th Cir. 2017)), finding that *Gerhart* controlled the outcome of the case and

compelled the conclusion that Act 900 was preempted because it "relates to" and "has a connection with" an employee benefit plan.

- ❖ *Gerhart* overruled Iowa's 2014 MAC/transparency law, in an opinion that essentially precludes any state regulation of MAC. In *Gerhart*, the Court said that under ERISA, states cannot dictate how plans structure and pay for plan benefits, including prescription drugs. (See *PCMA v. Gerhart* Summary for further information)

- ❖ *Rutledge* rejected an argument that an express reference was required for preemption to take effect and that *Gerhart's* "implicit reference" analysis is dicta.

- ❖ *Rutledge* reaffirmed that the presumption *against* preemption does not apply where a state law relates to and has a connection with employee benefit plans.

- Regarding Medicare Part D preemption, the Court found that Act 900 is a state law that acts "with respect to" Medicare D standards and is therefore preempted. Specifically, *Rutledge* held that:

  - ❖ The state's effort to change the pricing model from PBMs negotiating with pharmacies to pharmacies negotiating with wholesalers easily acts "with respect to" Medicare Part D standards governing negotiated prices.

  - ❖ The statute's decline-to-dispense provision "acts with respect to" the Medicare Part D's pharmacy access standard. The Court said that allowing a pharmacy to refuse service could "lead to a beneficiary being unable to fill a prescription in his or her geographical location," and could conflict with the Medicare Part D's standard, which was "more than enough for preemption." A pharmacy that refuses to dispense "becomes, in effect, an out-of-network pharmacy."

- *Rutledge* refused to consider the state's argument for the need to protect local pharmacies. Rutledge once again reaffirms that the federal policies embodied in ERISA and Medicare Part D governs notwithstanding states' professed need to protect local pharmacies.

What This Means for PBMs

- Arkansas' Act 900 is overturned for ERISA-governed plans and Medicare Part D, and regulations impacting these plans should not be developed or enforced. Act 900 continues to have effect on non-ERISA governed plans (individual, church, state employees).

- As after *Gerhart*, states can't impose requirements on health plans or their TPAs (such as PBMs) that impact the management and administration of ERISA plans.

- States can't dictate how plans or their PBMs structure and pay for benefits, meaning attempts to regulate PBM tools like MAC and incentives to use mail-order after *Gerhart* and *Rutledge* are likely invalid. In addition, any state law or regulation that interferes with uniform reporting and disclosure

rules, standards and remedies—or creates the possibility of a patchwork of multiple regulatory requirements—is preempted. Other state laws on MAC and other areas of PBM concern may be unconstitutional as well. Each statute requires its own analysis.

- Though ERISA's preemption is very broad, states do have the power to regulate insurance, and whether a statute regulates "insurance" requires analysis. Statutes that have been found to fall within states' authority are: benefit mandates, "any willing provider" laws applying to insured plans, and independent review of coverage decisions. Again, each state statute requires its own analysis.

- *PCMA v.* Rutledge, and its predecessor *PCMA v. Gerhart*, are both precedential in the Eighth Circuit, meaning lower courts in that circuit must follow the opinion as binding law. Though *Rutledge* and *Gerhart* do not serve as binding legal precedent in other circuits, it is persuasive authority and the opinion is consistent with and based upon longstanding ERISA preemption law. The decisions relied heavily on *Gobeille v. Liberty Mutual*, a 2016 U.S. Supreme Court case that found unconstitutional a Vermont law that required reporting of claims information by TPAs on behalf of ERISA-covered entities, since reporting is a "core ERISA administrative function." The Supreme Court's decision in *Gobeille* is precedential across the country.

McDermott Will & Emery

ERISA Preempts State Regulation of PBM–Pharmacy Pricing Agreements

July 26, 2018

M. Miller Baker | Sarah P. Hogarth

Summary

ERISA broadly preempts state laws that "relate to" ERISA-governed employee benefit plans to ensure a uniform federal regulatory scheme and to relieve ERISA plans from the burdens of satisfying a patchwork of state laws. Recently, however, several states have enacted legislation designed to regulate the prices that pharmacy benefit managers, as third-party administrators for ERISA-governed plans, agree to reimburse pharmacies for dispensing prescription drugs to ERISA plan members. These regulations run afoul of ERISA, as the US Court of Appeals for the Eighth Circuit has twice held.

IN DEPTH

ERISA Background

The Employee Retirement Income Security Act of 1974 (ERISA)[1] established a federal regulatory framework that governs both insured and self-insured "employee welfare benefit plans"[2] and retirement plans sponsored by employers, labor unions, and certain other entities. Employer-sponsored health benefit plans are "welfare benefit plans" and thus subject to ERISA. ERISA does not cover governmental plans[3] or church plans.[4]

ERISA's Broad Preemption Provision

ERISA's express preemption provision—one of the broadest preemption provisions in the United States Code—preempts all state laws that "relate to" ERISA-governed employee benefit plans.[5] Congress's purpose in including this sweeping express preemption provision was to establish a uniform federal regulatory scheme and protect ERISA plans from the administrative and compliance burdens of satisfying a patchwork of different state regulations.[6]

The US Supreme Court has construed ERISA's broad preemption provision as preempting any state law that has a "reference to" or "connection with" ERISA-governed plans.[7]

Under the Supreme Court's "reference to" test, ERISA preempts state laws that impose requirements by reference to ERISA-governed plans; that act immediately and exclusively on ERISA-governed plans; or where the existence of ERISA-governed plans is essential to the law's operation.[8]

Under the Supreme Court's "connection with" test, ERISA preempts state laws that govern central matters of plan administration or that interfere with nationally uniform plan administration.[9] Matters of plan administration include calculating benefit levels, making disbursements, monitoring the availability of funds, and keeping records to comply with reporting requirements.[10] Where a state law impacts either the structure[11] or administration[12] of ERISA-governed plans, preemption occurs.[13]

Because ERISA's express preemption provision reaches both "direct[] [and] indirect[]" state regulation of ERISA plans,[14] preemption occurs even where a state's regulation is imposed on third-party administrators (TPAs) administering ERISA-governed plans.[15]

Pharmacy Benefit Managers as TPAs for ERISA Health Plans

Pharmacy benefit managers (PBMs) serve as TPAs for health benefit plans. In that capacity, PBMs perform the essential functions necessary to deliver prescription drug benefits to plan members. PBMs contract with health plans to establish pharmacy networks, pharmacy credentialing and performance requirements, and otherwise manage the prescription-drug benefits provided by plans. PBMs in turn contract with pharmacies to provide access for plan members to a plan's prescription-drug benefits. Such contracts necessarily include arrangements for how much PBMs will reimburse (on behalf of a plan) network pharmacies for any particular prescription drug covered by the plan.

PBMs' Use of MAC Pricing Lists

"Maximum Allowable Cost" or "MAC" pricing lists specify the maximum amount a health plan or its PBM will reimburse a pharmacy for a particular generic drug. By limiting a pharmacy's reimbursement for a given generic drug, MAC pricing encourages pharmacies to acquire generic drugs at the lowest available price. MAC lists represent a carefully tailored, market-oriented balance between fairly compensating pharmacies to encourage dispensing of generic drugs and providing cost-effective prescription-drug benefits to health plans.

ERISA Preemption of State MAC Laws

Recently, several states have enacted legislation designed to regulate MAC lists in various ways. The US Court of Appeals for the Eighth Circuit, however, has already held that ERISA preempts such laws in Iowa and Arkansas.[16]

Where a state MAC law regulates PBMs and defines the scope of the law to either expressly or implicitly include those PBMs administering pharmaceutical benefits for entities that are subject to ERISA regulation, the state law impermissibly refers to ERISA-governed plans and is preempted.[17]

Further, the following specific provisions of MAC laws have an impermissible connection with ERISA and are preempted:

- Mandating particular reimbursement rates[18]
- Requiring PBMs to disclose their MAC pricing methodology to the state[19]
- Requiring PBMs to disclose MAC pricing methodology to pharmacies[20]
- Limiting the data sources used to create MAC pricing lists[21]
- Limiting the types of drugs to which MAC pricing can apply[22]
- Requiring procedures for pharmacies to comment on MAC lists or pricing[23]
- Requiring procedures for pharmacies to appeal MAC lists or pricing[24]
- Requiring updates to MAC lists within a particular time[25]
- Allowing pharmacies to reverse and re-bill claims[26]
- Requiring retroactive payment to pharmacies[27]
- Allowing pharmacies to decline to dispense covered drugs[28]

In short, ERISA preempts state MAC laws insofar as they regulate entities administering prescription drug benefits for ERISA-governed plans.

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1 29 U.S.C. § 1001 et seq.

2 *Id*. § 1002(1).

3 *Id*. § 1003(1).

4 *Id*. § 1003(2).

5 *Id*. § 1144(a).

6 *See, e.g., Fort Halifax Packing Co., Inc. v. Coyne*, 482 U.S. 1, 11–12 (1987).

7 *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016).

[8] *Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A.*, 519 U.S. 316, 324–25 (1997).

[9] *Gobeille*, 136 S. Ct. at 943.

[10] *Pharm. Care. Mgmt. Ass'n v. Gerhart*, 852 F.3d 722, 730 (8th Cir. 2017); see also Fort Halifax, 482 U.S. at 9.

[11] *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983).

[12] *Gobeille*, 136 S. Ct. at 943.

[13] *Minn. Chapter of Associated Builders & Contractors, Inc. v. Minn. Dep't of Pub. Safety*, 267 F.3d 807, 816 (8th Cir. 2001).

[14] *See* 29 U.S.C. § 1144(c)(2).

[15] *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 659 (1995); *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018); *Gerhart*, 852 F.3d 722; *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179 (D.C. Cir. 2010).

[16] *See Rutledge*, 891 F.3d 1109; Gerhart, 852 F.3d 722.

[17] *Rutledge*, 891 F.3d at 1112; Gerhart, 852 F.3d at 729.

[18] *Rutledge*, 891 F.3d at 1111.

[19] *Gerhart*, 852 F.3d at 727.

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Rutledge*, 891 F.3d at 1111; Gerhart, 852 F.3d at 727.

[25] *Rutledge*, 891 F.3d at 1111.

[26] *Id.*

[27] *Rutledge*, 891 F.3d at 1111; Gerhart, 852 F.3d at 727.

[28] *Rutledge*, 891 F.3d at 1111.

State PBM Legislation Preempted by ERISA
PBM Duty of Care Requirements
Requiring PBMs to owe a fiduciary duty to health plans or to perform their duties to a fiduciary standard
Health-Plan Reimbursement Requirements
Requiring PBMs to pass drug manufacturer benefits on to health plans
Requiring PBMs to transfer payment received due to drug substitution
Pharmacy-Reimbursement Requirements
Mandating particular pharmacy reimbursement rates
Allowing pharmacies to reverse and re-bill claims
Requiring retroactive payment to pharmacies for claims not in accord with the state law's rates
Prohibiting PBMs from imposing fees not apparent at the time of claim processing or after point of sale
Allowing pharmacies to retain the adjudicated cost if the patient pays a copayment
Requiring PBMs to reimburse pharmacies at the same rate used to reimburse a PBM affiliate
Pharmacy Network and Accreditation Requirements
Prohibiting PBMs from having an ownership interest in a patient assistance program or mail order pharmacy unless the PBM "agrees to not participate in a transaction that benefits" the PBM "instead of another person owed a fiduciary duty"
Requiring PBMs to provide a "reasonably adequate and accessible" pharmacy network structure
Prohibiting PBMs from imposing accreditation standards more stringent than federal and state pharmacy licensing laws
Pharmacy Performance Requirements
Requiring PBMs to use EQuIPP to measure pharmacy performance
Limiting pharmacy performance fees to the amount of the dispensing fees
MAC List Requirements
Limiting the data sources used to create MAC pricing lists
Limiting the types of drugs to which MAC pricing can apply
Requiring updates to MAC lists within a particular time
Pharmacy Comment and Appeal Requirements
Requiring procedures for pharmacies to comment on or appeal MAC lists or pricing
Pharmacy Dispensing Requirements
Allowing pharmacies to decline-to-dispense covered drugs
Allowing pharmacies to dispense any and all drugs allowed under their state license
Allowing all pharmacies to mail or deliver drugs
Prohibiting PBMs from limiting pharmacies' charging of shipping or handing fees to patients
Reporting Requirements[1]
Requiring PBMs to report their MAC pricing methodology to the state
Requiring an "adequacy" report describing the PBM's pharmacy network to the state
Allowing insurance commissioner to review and approve PBM-plan compensation structure for pharmacies

[1] "Reporting requirements" refers to state laws mandating that PBMs provide specified information to the state.

State PBM Legislation Preempted by ERISA
Disclosure Requirements[2]
Requiring PBMs to disclose MAC pricing methodology to pharmacies
Requiring PBMs to disclose conflicts of interest to plans
Requiring PBMs to disclose to plans when it dispenses a substitute drug that costs more than the prescribed drug
Requiring PBMs to disclose the quantity of drugs and net cost to plans
Requiring PBMs to disclose the terms of remuneration between PBM and manufacturer to plans
Requiring PBMs to disclose ownership interests in patient assistance programs or mail order pharmacies to plans
Allowing pharmacies to disclose "relevant information" to patients, including information about adjudicated reimbursements
Requiring PBMs to provide pharmacies with processor control numbers, bank identification numbers, and group numbers for each pharmacy network

[2] "Disclosure requirements" refers to state laws mandating that PBMs make disclosures to plans, pharmacies, and/or members.

Title: ERISA Broadly Preempts State Regulation of PBM-Pharmacy and PBM-Plan Agreements

Summary: ERISA broadly preempts state laws that "relate to" ERISA-governed employee benefit plans to ensure a uniform federal regulatory scheme and to relieve ERISA plans from the burdens of satisfying a patchwork of state laws. Recently, however, several states have enacted legislation designed to regulate the contracts between pharmacy benefit managers (PBMs) and pharmacies and between PBMs and health plans even when the PBMs serve as third-party administrators for ERISA-governed plans. These regulations run afoul of ERISA.

ERISA Background

The Employee Retirement Income Security Act of 1974 (ERISA)[1] established a federal regulatory framework that governs both insured and self-insured "employee welfare benefit plans"[2] and retirement plans sponsored by employers, labor unions, and certain other entities. Employer-sponsored health benefit plans are "welfare benefit plans" and thus subject to ERISA. ERISA does not cover governmental plans[3] or church plans.[4]

ERISA's Broad Preemption Provision

ERISA's express preemption provision—one of the broadest preemption provisions in the United States Code—preempts all state laws that "relate to" ERISA-governed employee benefit plans.[5] Congress's purpose in including this sweeping express preemption provision was to establish a uniform federal regulatory scheme and protect ERISA plans from the administrative and compliance burdens of satisfying a patchwork of different state regulations.[6]

The US Supreme Court has construed ERISA's broad preemption provision as preempting any state law that has a "reference to" or "connection with" ERISA-governed plans.[7]

Under the Supreme Court's "reference to" test, ERISA preempts state laws that impose requirements by reference to ERISA-governed plans; that act immediately and exclusively on ERISA-governed plans; or where the existence of ERISA-governed plans is essential to the law's operation.[8]

Under the Supreme Court's "connection with" test, ERISA preempts state laws that govern central matters of plan administration or that interfere with nationally uniform plan administration.[9] Matters of plan administration include calculating benefit levels, making

[1] 29 U.S.C. § 1001 *et seq.*
[2] *Id.* § 1002(1).
[3] *Id.* § 1003(1).
[4] *Id.* § 1003(2).
[5] *Id.* § 1144(a).
[6] *See, e.g.*, *Fort Halifax Packing Co., Inc. v. Coyne*, 482 U.S. 1, 11–12 (1987).
[7] *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016).
[8] *Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A.*, 519 U.S. 316, 324–25 (1997).
[9] *Gobeille*, 136 S. Ct. at 943.

disbursements, monitoring the availability of funds, and keeping records to comply with reporting requirements.[10] Where a state law impacts either the structure[11] or administration[12] of ERISA-governed plans, preemption occurs.[13]

Because ERISA's express preemption provision reaches both "direct[] [and] indirect[]" state regulation of ERISA plans,[14] preemption occurs even where a state's regulation is imposed on third-party administrators (TPAs) administering ERISA-governed plans.[15]

Pharmacy Benefit Managers as TPAs for ERISA Health Plans

Pharmacy benefit managers (PBMs) serve as TPAs for health benefit plans. In that capacity, PBMs perform the essential functions necessary to deliver prescription drug benefits to plan members. PBMs contract with health plans to establish pharmacy networks, pharmacy credentialing and performance requirements, and otherwise manage the prescription-drug benefits provided by plans. PBMs in turn contract with pharmacies to provide access for plan members to a plan's prescription-drug benefits. Such contracts necessarily include arrangements for how much PBMs will reimburse (on behalf of a plan) network pharmacies for any particular prescription drug covered by the plan.

ERISA Preemption of State PBM Regulation

Recently, several states have enacted legislation designed to regulate PBMs administering prescription-drug benefits for ERISA plans in various ways. ERISA preempts these efforts.

Where a state law regulates PBMs and defines the scope of the law to either expressly or implicitly include those PBMs administering pharmaceutical benefits for entities that are subject to ERISA regulation, the state law impermissibly refers to ERISA-governed plans and is preempted.[16]

Further, state regulation of the PBM-pharmacy relationship and/or the PBM-plan relationship has an impermissible "connection with" ERISA insofar as it regulates PBMs serving as TPAs for ERISA plans. In such circumstances, state law impermissibly dictates administrator choices pertaining to plan structure and administration. The following provides examples of state laws that ERISA preempts when imposed on PBMs serving as TPAs for ERISA plans:

[10] *Pharm. Care. Mgmt. Ass'n v. Gerhart*, 852 F.3d 722, 730 (8th Cir. 2017); *see also Fort Halifax*, 482 U.S. at 9.
[11] *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983).
[12] *Gobeille*, 136 S. Ct. at 943.
[13] *Minn. Chapter of Associated Builders & Contractors, Inc. v. Minn. Dep't of Pub. Safety*, 267 F.3d 807, 816 (8th Cir. 2001).
[14] *See* 29 U.S.C. § 1144(c)(2).
[15] *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1112–13 (8th Cir. 2018); *Gerhart*, 852 F.3d 722; *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179 (D.C. Cir. 2010).
[16] *Rutledge*, 891 F.3d at 1112; *Gerhart*, 852 F.3d at 729.

PBM Duty-of-Care Requirements

- Requiring PBMs to owe a fiduciary duty to health plans or to perform their duties to a fiduciary standard[17]

Health-Plan Reimbursement Requirements

- Requiring PBMs to pass drug manufacturer benefits on to health plans
- Requiring PBMs to transfer payment received due to drug substitution

Pharmacy-Reimbursement Requirements

- Mandating particular pharmacy reimbursement rates[18]
- Allowing pharmacies to reverse and re-bill claims[19]
- Requiring retroactive payment to pharmacies for claims not in accord with the state law's rates[20]
- Prohibiting PBMs from imposing fees not apparent at the time of claim processing or after point of sale
- Allowing pharmacies to retain the adjudicated cost if the patient pays a copayment
- Requiring PBMs to reimburse pharmacies at the same rate used to reimburse a PBM affiliate

Pharmacy Network and Accreditation Requirements

- Prohibiting PBMs from having an ownership interest in a patient assistance program or mail order pharmacy unless the PBM "agrees to not participate in a transaction that benefits" the PBM "instead of another person owed a fiduciary duty"
- Requiring PBMs to provide a "reasonably adequate and accessible" pharmacy network structure
- Prohibiting PBMs from imposing accreditation standards more stringent than federal and state pharmacy licensing laws

Pharmacy Performance Requirements

- Requiring PBMs to employ particular standards or programs to measure pharmacy performance
- Limiting pharmacy performance fees to the amount of the dispensing fees

MAC List Requirements

- Limiting the data sources used to create MAC pricing lists[21]

[17] *See, e.g.*, *Dist. of Columbia*, 613 F.3d at 183, 188.
[18] *See, e.g.*, *Rutledge*, 891 F.3d at 1111.
[19] *See, e.g.*, *id.*
[20] *See, e.g.*, *Rutledge*, 891 F.3d at 1111; *Gerhart*, 852 F.3d at 727.
[21] *See, e.g.*, *Gerhart*, 852 F.3d at 727.

- Limiting the types of drugs to which MAC pricing can apply[22]
- Requiring updates to MAC lists within a particular time[23]

Pharmacy Comment and Appeal Requirements

- Requiring procedures for pharmacies to comment on or appeal MAC lists or pricing[24]

Pharmacy Dispensing Requirements

- Allowing pharmacies to decline to dispense covered drugs[25]
- Allowing pharmacies to dispense any and all drugs allowed under their state license
- Allowing all pharmacies to mail or deliver drugs
- Prohibiting PBMs from limiting pharmacies' charging of shipping or handing fees to patients

Reporting Requirements

- Requiring PBMs to report their MAC pricing methodology to the state[26]
- Requiring an "adequacy" report describing the PBM's pharmacy network to the state
- Allowing insurance commissioner to review and approve PBM-plan compensation structure for pharmacies

Disclosure Requirements

- Requiring PBMs to disclose MAC pricing methodology to pharmacies[27]
- Requiring PBMs to disclose conflicts of interest to plans[28]
- Requiring PBMs to disclose to plans when they dispense a substitute drug that costs more than the prescribed drug[29]
- Requiring PBMs to disclose the quantity of drugs and net cost to plans
- Requiring PBMs to disclose the terms of remuneration between PBM and manufacturer to plans
- Requiring PBMs to disclose ownership interests in patient assistance programs or mail order pharmacies to plans
- Allowing pharmacies to disclose "relevant information" to patients, including information about adjudicated reimbursements
- Requiring PBMs to provide pharmacies with processor control numbers, bank identification numbers, and group numbers for each pharmacy network

[22] *See, e.g., id.*
[23] *See, e.g., Rutledge*, 891 F.3d at 1111.
[24] *See, e.g., Gerhart*, 852 F.3d at 727.
[25] *See, e.g., Rutledge*, 891 F.3d at 1111.
[26] *See, e.g., Gerhart*, 852 F.3d at 727.
[27] *See, e.g., id.*
[28] *See, e.g., Dist. of Columbia*, 613 F.3d at 183, 188.
[29] *See, e.g., id.*

In short, ERISA preempts state PBM regulation insofar as it regulates PBMs administering prescription-drug benefits for ERISA-governed plans in areas of ERISA concern.

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February 21, 2018

Ms. Barbara Levy
Vice President & General Counsel
PMCA
325 7th Street NW, 9th Floor
Washington, DC 20004

Re: Arkansas SR9

Dear Ms. Levy:

We understand that the Pharmaceutical Care Management Association (PCMA") is the national association representing the nation's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, Medicaid managed care, Medicare Part D, Federal Employees Health Benefit programs, and other public programs. You have requested our law firm to review the Arkansas Senate Resolution titled "To Authorize the Introduction of a Nonappropriation Bill Concerning the Regulation and Licensure of Pharmacy Benefit Managers."[1]

Should SR9 be enacted, it will almost certainly be deemed unconstitutional under recent rulings of the U.S. Supreme Court, the Eighth Circuit Court of Appeals, and the U.S. District Court for the Eastern District of Arkansas. SR9 improperly dictates the manner by which PBMs manage and administer prescription drug benefits on behalf of their client health plans, and hence is expressly preempted by a Federal statute, the Employee Retirement Income Security Act of 1974 (ERISA).[2] The Supreme Court has stated that ERISA provides a "comprehensive system for the federal regulation of employee benefit plans"[3] and applies to all employer-based health plans, whether insured or self-insured. Its central design "is to provide a single national scheme for the administration of ERISA plans without interference from the laws of the several

[1] An identical resolution has been filed in the House—HR1011. Our analysis of SR9 equally applies to HR1011.
[2] 29 U.S.C. §§ 1001, *et seq.*
[3] *District of Columbia v. Greater Was. Bd. of Trade*, 606 U.S. 125, 127 (1992).

States."[4] No state mandate can directly or indirectly interfere with key matters of plan administration, such as dictating terms of PBM contracts with their clients.

Just last month the Eighth Circuit heard the State of Arkansas's appeal of the Arkansas District Court's opinion striking down Arkansas Act 900 of 2015 as preempted by ERISA, because the statute interfered with key matters of plan administration.[5] Act 900 mandated that pharmacies be reimbursed for the generic pharmaceuticals they dispense at an artificial "acquisition cost." The Act also required PBMs to maintain an administrative appeal procedure to allow pharmacies to challenge reimbursements prospectively and retroactively, even to the point of declining to provide services to a patient or PBM.

SR9 goes even further than Act 900. This proposed Resolution would impose broad and unprecedented State oversight of *both* (1) how PBMs reimburse pharmacies in their networks and (2) how PBMs are compensated under contracts with their client health plans:

- The Resolution improperly gives the State Insurance Commissioner the ability to review whether a PBM is reimbursing a pharmacy in a given transaction at a "fair and sustainable reimbursement rate" (§23-92-507), regardless of the terms the parties to the contract have agreed to. It also forbids a PBM from charging a pharmacy "a fee related to the adjudication of a claim," and allows retroactive denial or reduction of a claim only in limited circumstances. (§ 23-92-509)

- The Resolution also specifically dictates how PBMs must be compensated by ERISA plan administrators for their services. Section 6, amending § 23-92-208, provides that PBM compensation must be based on fee-for-service, or "another form of pecuniary remuneration approved by the Insurance Commissioner," such as number of claims paid or processed, including allowing unfettered discretion to the Commissioner to determine whether the basis for compensation is "fair and equitable."

Both of those provisions run afoul of ERISA, which preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[6] Arkansas cannot impose requirements upon PBMs, which administer pharmaceutical benefits for employee benefit plans if those requirements effectively either directly or indirectly regulate the administration of those ERISA plans.[7] This Resolution facially interferes with the structure of ERISA plans in Arkansas by limiting plan choices, including how ERISA plan administrators

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[4] *Gobeille v. Liberty Mut. Ins. Co*, 136 S.Ct. 936, 947 (2016).
[5] *Pharm. Care Mgmt. Ass'n v. Leslie Rutledge, in her official capacity as Attorney General*, No. 17-1609/17-1629.
[6] 29 U.S.C. § 1144(a).
[7] See *Pharm. Care Mgmt. Ass'n v. District of Columbia,* 613 F.3d 179, 188 (D.C. Cir. 2010).

choose to reimburse Arkansas pharmacies for member prescription drug benefits through their PBMs, as well as how they choose to compensate PBMs for their services.

Directly on point here—and binding in Arkansas—is the Eighth Circuit's 2017 opinion striking down a similar Iowa law which regulated how PBMs establish generic drug pricing and required that certain disclosures on drug pricing methodology be made to PBMs' network pharmacies as well as the Iowa insurance commissioner.[8] In that Case, the Court found that the Iowa law impermissibly regulated prescription drug benefits for ERISA plans because –like this Resolution—it dictated the manner and terms under which PBMs and pharmacies choose to agree on reimbursements for generic drugs. It also found that the Iowa law had an impermissible "connection with" ERISA plans because it "govern[ed] a central matter of plan administration" as well as "interfer[ed] with nationally uniform plan administration," quoting the Supreme Court in *Gobeille*. States simply cannot "undermine the congressional goal of minimizing the administrative and financial burden on plan administrators—burdens ultimately borne by the beneficiaries."[9]

Like the Iowa law struck down by the Eight Circuit Court of Appeals, SR9 dictates plan choices by giving the Insurance Commissioner the last word over pharmacy reimbursement rates as well as when a claim may be denied or reduced. The plan administrator thus effectively loses "control in the calculation of drug benefits" as well as "the ability to conclusively determine final drug benefit payments and monitor funds," in the words of the Court in *Gerhart*. The losers ultimately are plan beneficiaries, namely the patients who inevitably will be paying higher prices for drugs as a result of the patchwork of differing regulatory requirements imposed on PBMs.

This Resolution perversely confers enormous powers on the Commissioner, yet contains no yardstick to measure how to evaluate whether a pharmacy reimbursement rate is "fair and sustainable," or whether a PBM measure of compensation is "fair and equitable"—thus (in the Eighth Circuit's words) "exacerbating the administrator's lack of control over the calculation and disbursement of benefits."[10] Nor is there any way that the Commissioner's review of pharmacy reimbursement rates or PBM compensation can be accomplished without the reporting, disclosure, and recordkeeping that the Eighth Circuit in *Gerhart* held to be "fundamental aspects of ERISA", necessitating Federal preemption.

The District Court in Arkansas relied heavily on this Eighth Circuit opinion in *Gerhart* in invalidating Act 900 in the *Rutledge* case, as it is binding in Arkansas. It is almost certain that the Circuit Court panel will also rely heavily on that same precedent in upholding the District Court's result sometime this spring. Given that appeal, and the close similarities of SR9 to

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[8] *Pharm. Care Mgmt. Ass'n v. Gerhart*, ____ (8th Cir. Jan. 11, 2017) *reh'g denied.*
[9] *Gobeille,* 136 S. Ct. at 944.
[10] *Gerhart* at 11.

Arkansas Act 900 as well as the Iowa statute invalidated in *Gerhart*, we believe enactment of SR9 will be counterproductive legally as well as costly to the citizens of Arkansas.

Please do not hesitate to contact me if you have any questions regarding this letter.

Sincerely,

MITCHELL, WILLIAMS, SELIG,
GATES & WOODYARD, P.L.L.C.

By Lyn P. Pruitt
Lyn P. Pruitt

NAIC and NASHP Model Acts

A MODEL ACT RELATING TO PHARMACY BENEFIT MANAGERS

Whereas: It is essential to understand the drivers and impacts of prescription drug costs, and transparency is the first step toward that understanding and can lead to better cost containment and greater consumer access to prescription drugs.

Whereas: Pharmacy benefit managers are companies that contract with health plans to administer the health plan prescription drug benefit.

Whereas: Nearly all health plans require some level of cost sharing either via a fixed copayment or some percentage of the cost of care. Pharmacy benefit managers may require patient drug cost sharing that exceeds the pharmacy's actual cost of the medication.

Whereas: Pharmacy benefit manager business operations are not transparent.

Whereas: Some pharmacy benefit manager business practices appear to benefit the business at the cost of the patient, the health plan, and the pharmacist.

Therefore: The legislature finds that there is a need to ensure the health and welfare of residents who access prescription drugs managed by pharmacy benefit managers.

General Description:

The purpose of this act is to improve the business practice and transparency of pharmacy benefit managers.

Section 1. Definitions

A. *Pharmacy Benefit Manager:* "Pharmacy Benefit Manager" means a person, business, or other entity that, pursuant to a contract or under an employment relationship with a health carrier, a self-insurance plan, or other third-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the health carrier, self-insurance plan, or other third-party payer including, but not limited to, the processing and payment of claims for

prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

B. *Health Carrier:* "Health Carrier" means an entity subject to the insurance laws and regulations of this State, or subject to the jurisdiction of the commissioner, that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the cost of health care services, including a health insurance company, a health maintenance organization, a hospital and health services corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

C. *Health Benefit Plan:* "Health Benefit Plan" means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of healthcare services.

D. *Covered Person:* "Covered Person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan. A covered person includes the authorized representative of the covered person.

E. *Pharmacy:* "Pharmacy" means an established location, either physical or electronic that is licensed by the State and that has entered into a network contract with a pharmacy benefit manager and/or health carrier.

F. *Network Pharmacy:* "Network Pharmacy" means a retail or other licensed pharmacy provider that contracts with a pharmacy benefit manager.

G. *Retail Pharmacy:* "Retail Pharmacy" means a chain pharmacy, a supermarket pharmacy, a mass merchandiser pharmacy, an independent pharmacy, or a network of independent pharmacies that is licensed as a pharmacy by the State of _____ and that dispenses medications to the public.

H. *Mail Order Pharmacy:* "Mail Order Pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail, telefax or through electronic submissions and to dispense medication to covered persons through the use of the United States mail or other common or contract carrier services and that provides any consultation with patients electronically rather than face to face.

I. *Aggregate Retained Rebate Percentage:* "Aggregate Retained Rebate Percentage" means the percentage of all rebates received from a manufacturer or other entity to a Pharmacy Benefit Manager for prescription drug utilization which is not passed on to Pharmacy Benefit Mangers' health carrier clients. The percentage shall be calculated for each health carrier for rebates in

the prior calendar years as follows: a) the sum total dollar amount of rebates received from all pharmaceutical manufacturers for all utilization of covered persons of a health carrier that was not passed through to the health carrier; and b) divided by the sum total dollar amount of all rebates received from all pharmaceutical manufacturers for covered persons of a health carrier.

J. *Rebates:* "Rebates" means all price concessions paid by a manufacturer to a Pharmacy Benefit Manager or health carrier, including rebates, discounts, and other price concessions that are based on actual or estimated utilization of a prescription drug. Rebates also include price concessions based on the effectiveness a drug as in a value-based or performance-based contract.

K. *Trade Secrets:* "Trade Secrets" has the meaning found in [state law citation].

L. *Cost Share/Cost Sharing:* "Cost Share/Cost Sharing" means the amount paid by a covered person as required under the covered person's health benefit plan.

Section 2. Required Pharmacy Benefit Manager Licensure

A. A Pharmacy Benefit Manager shall be licensed by [State Agency] before conducting business in the State.
B. Licensure pursuant to this section is not transferable.
C. The license may be granted only when the [State Agency] is satisfied that the entity possesses the necessary organization, background expertise, and financial integrity to supply the services sought to be offered.
D. The [State Agency] may issue a license subject to restrictions or limitations upon the authorization, including the type of services that may be supplied or the activities in which the entity may be engaged.
E. All licenses are valid for a period of three years.
F. The [State Agency] shall develop an application for licensure that includes at least the following information:

    a. The name of the Pharmacy Benefit Manager;
    b. The address and contact telephone number for the Pharmacy Benefit Manager;
    c. The name and address of the Pharmacy Benefit Manager agent for service of process in the State;
    d. The name and address of each person beneficially interested in the Pharmacy Benefit Manager; and
    e. The name and address of each person with management or control over the Pharmacy Benefit Manager.

G. The [State Agency] may suspend, revoke, or place on probation a Pharmacy Benefit Manager license under any of the following circumstances:

a. The Pharmacy Benefit Manager has engaged in fraudulent activity that constitutes a violation of state or federal law;
b. The [State Agency] received consumer complaints that justify an action under this subdivision to protect the safety and interests of consumers;
c. The Pharmacy Benefit Manager fails to pay an application fee for the license; or
d. The Pharmacy Benefit Manager fails to comply with a requirement set forth in this section.

H. If a Pharmacy Benefit Manager acts without registering, it will be subject to a fine of $5,000 per day for the period they are found to be in violation.

Section 3. Pharmacy Benefit Manager Business Practices

A. A Pharmacy Benefit Manager has a fiduciary duty to a health carrier client and shall discharge that duty in accordance with the provisions of state and federal law.

B. A Pharmacy Benefit Manager shall perform its duties with care, skill, prudence, diligence, and professionalism.

C. A Pharmacy Benefit Manager shall notify a health carrier client in writing of any activity, policy, or practice of the Pharmacy Benefit Manager that directly or indirectly presents any conflict of interest with the duties imposed in this section.

D. A Pharmacy Benefit Manager or health carrier shall not enter into a contract with a pharmacy or pharmacist that prohibits or penalizes a pharmacy or pharmacist for disclosure of information to a covered person regarding:
I. The cost of a prescription medication to the covered person; or
II. The availability of any therapeutically-equivalent alternative medications or alternative methods of purchasing the prescription medication, including but not limited to, paying a cash price that is less expensive to the customer than the cost of the prescription under a covered person's health benefit plan.

E. A Pharmacy Benefit Manager shall not require pharmacy or other provider accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the [State] Pharmacy Board or other state or federal entity.

F. A health carrier or Pharmacy Benefit Manager may not require a covered person to make a payment at the point of sale for a covered prescription medication in an amount greater than the lesser of:
   I. The applicable copayment for the prescription medication;
   II. The allowable claim amount for the prescription medication;
   III. The amount a covered person would pay for the prescription medication if the covered person purchased the prescription medication without using a health benefit plan or any other source of prescription medication benefits or discounts; or
   IV. The amount the pharmacy will be reimbursed for the drug from Pharmacy Benefit Manager or health carrier.

G. A health carrier or Pharmacy Benefit Manager is prohibited from penalizing, requiring, or providing financial incentives, including variations in premiums, deductibles, copayments, or coinsurance, to covered persons as incentives to use specific retail, mail order pharmacy, or other network pharmacy provider in which a Pharmacy Benefit Manager has an ownership interest or that has an ownership interest in a Pharmacy Benefit Manager.

Section 4. Pharmacy Benefit Manager Transparency

A. Beginning June 1, 2020, and annually thereafter, each licensed Pharmacy Benefit Manager shall submit a transparency report containing data from the prior calendar year to the [State Agency]. The transparency report shall contain the following information:

   I. The aggregate amount of all rebates that the Pharmacy Benefit Manager received from all pharmaceutical manufacturers for all health carrier clients and for each health carrier client;
   II. The aggregate administrative fees that the Pharmacy Benefit Manager received from all manufacturers for all health carrier clients and for each health carrier client;
   III. The aggregate retained rebates that the Pharmacy Benefit Manager received from all pharmaceutical manufacturers and did not pass through to health carriers;
   IV. The aggregate retained rebate percentage as defined in Sec.(2)(I); and
   V. The highest, lowest, and mean aggregate retained rebate percentage for all health carrier clients and for each health carrier client.

B. A Pharmacy Benefit Manager r providing information under this section may designate that material as a trade secret. Disclosure, however, may be ordered by a court of this State for good cause shown or made in a court filing.

C. Within sixty (60) days of receipt, the [State Agency] shall publish the transparency report of each Pharmacy Benefit Manager on the agency's website in a way that does not violate State trade secrets law.

D. The state Attorney General may impose civil fines and penalties of not more than $1,000 per day per violation of this section.

Section 5. Severability Clause

If any provision of this act or the application of this act to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of the act are declared severable.

Except as otherwise provided, this Act is effective six months after enactment.

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

Table of Contents

Section 1. Title

This Act shall be known and may be cited as the Health Carrier Prescription Drug Benefit Management Act.

Drafting Note: In some states existing statutes may provide the commissioner with sufficient authority to promulgate the provisions of this Act in a regulation format. States should review existing authority and determine whether to adopt this model as an act or adapt it to promulgate as a regulation.

Section 2. Purpose and Intent

The purpose of this Act is to provide standards for the establishment, maintenance and management of prescription drug formularies and other pharmaceutical benefit management procedures used by health carriers that provide prescription drug benefits.

Drafting Note: This Act is not intended to address the off-label use of prescription drugs. The "off-label use" of a prescription drug occurs when a prescription drug that has been approved by the federal Food and Drug Administration (FDA) for one or more indications, but the prescription drug is used for indications or in doses other than those stated in the labeling approved by the FDA. Many states have enacted "off-label use" laws or regulations to address this situation. States that have enacted "off-label use" laws or regulations should review the provisions of this Act to determine whether any provisions of this Act should be modified or clarified in light of those laws or regulations.

Drafting Note: This Act also is not intended to address prescription drug formularies and other pharmaceutical benefit management procedures health carriers or their designees may use for purposes of workers' compensation. States typically regulate workers' compensation under an independent, standalone law, which will include provisions, if the state has determined they are appropriate, concerning prescription drug formulary criteria and other related requirements specifically related to workers' compensation.

Section 3. Definitions

For purposes of this Act:

A. "Authorized representative" means:

(1) A person to whom a covered person has given express written consent to represent the covered person for the purpose of filing a medical exceptions request under Section 7 of this Act;

(2) A person authorized by law to provide substituted consent for a covered person;

(3) The covered person's treating health care professional only when the covered person is unable to provide consent or a family member of the covered person; or

(4) For the purpose of filing a medical exceptions request under Section 7 of this Act on behalf of a covered person, the covered person's prescribing, treating or dispensing provider.

B. "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocol and practice guidelines used by the health carrier to determine the medical necessity and appropriateness of health care services.

C. "Commissioner" means the Commissioner of Insurance.

Drafting Note: Use the title of the chief insurance regulatory official wherever the term "commissioner" appears. If the jurisdiction of certain health carriers, such as health maintenance organizations, lies with some state agency other than the insurance department, or if there is dual regulation, a state should add language referencing that agency to ensure the appropriate coordination of responsibilities.

D. "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of the health benefit plan.

E. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.

F. (1) "Dose restriction" means imposing a restriction on the number of doses of a prescription drug that will be covered during a specific time period.

(2) "Dose restriction" does not include:

(a) A restriction set forth in the terms of coverage under a health carrier's health benefit plan for prescription drug benefits that limits the number of doses of a prescription drug that will be covered during a specific time period; or

(b) A restriction on the number of doses when the prescription drug that is subject to the restriction cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.

G. "Drug substitution" means:

(1) For generics, the substitution of a generic version of a brand name drug that the U.S. Food and Drug Administration (FDA) in its publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the FDA *Orange Book*, has determined to be a therapeutic equivalent; or

(2) For biologics, the substitution of an interchangeable biosimilar product, which is a biosimilar product, as that term is defined in 42 USC §262(i), the FDA has determined to be interchangeable in accordance with the standards set forth in 42 USC §262(k)(4) and listed as such in the latest edition of or supplement to the FDA *Lists of Licensed Biological Products with Reference to Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, also known as the *Purple Book*.

Drafting Note: Subsection G defines the term "drug substitution" for use in Section 6C of this Act. States should review the language of this definition and the use of this defined term in Section 6C of this Act to determine whether the language of this definition needs to be modified or clarified in light of any other existing state law regulating drug substitution. In addition, states should review whether the definition of "drug" in relevant state law includes biologics.

H. "Facility" means an institution providing [physical, mental or behavioral] health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, urgent care centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

I. "FDA" means the U.S. Food and Drug Administration.

J. "Formulary" means a list of prescription drugs that has been developed by a health carrier or its designee, which the health carrier or its designee references in determining applicable coverage and benefit levels.

K. "Grievance" means a complaint submitted by or on behalf of a covered person regarding:

(1) The availability, delivery or quality of health care services, including a complaint regarding an adverse determination made pursuant to utilization review;

(2) Claims payment, handling or reimbursement for health care services; or

(3) Matters pertaining to the contractual relationship between a covered person and a health carrier.

L. "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services.

M. "Health care professional" means a physician, pharmacist or other health care practitioner who is licensed, accredited or certified to perform specified [physical, mental or behavioral] health care services consistent with state law.

Drafting Note: States may wish to specify the health care professionals to whom this definition may apply (e.g. physicians, pharmacists, psychologists, nurse practitioners, etc.). This definition applies to individual health care professionals, not corporate "persons."

N. "Health care provider" or "provider" means a health care professional or a facility.

O. "Health care services" means services for the diagnosis, prevention, treatment, cure or relief of a physical, mental or behavioral health condition, illness, injury or disease, including mental health and substance abuse disorders.

P. "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

Drafting Note: States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

Drafting Note: Section 2791(b)(2) of the PHSA defines the term "health insurance issuer" instead of "health carrier." The definition of "health carrier" above is consistent with the definition of "health insurance issuer" in Section 2791(b)(2) of the PHSA.

Q. "Medical and scientific evidence" means evidence found in the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(2) Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline), and Elsevier Science Ltd. for indexing in Excerpta Medicus (EMBASE);

(3) Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;

(4) The following standard reference compendia:

(a) The American Hospital Formulary Service–Drug Information;

(b) Drug Facts and Comparisons;

(c) The American Dental Association Accepted Dental Therapeutics; and

(d) The United States Pharmacopoeia–National Formulary;

(5) Peer-reviewed or expert consensus findings, including the studies or research used to reach the findings, developed by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:

(a) The federal Agency for Healthcare Research and Quality;

(b) The National Institutes of Health;

(c) The National Cancer Institute;

(d) The National Academy of Sciences;

(e) The federal Centers for Medicare & Medicaid Services;

(f) The FDA;

(g) The federal Centers for Disease Control and Prevention;

(h) The U.S. Preventive Services Task Force;

(i) The U.S. Health Resources & Services Administration; and

(j) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or

(6) Any other relevant data that is comparable to the sources listed in Paragraphs (1) through (5).

Drafting Note: States should note that in some limited instances, guidelines developed by the federal government or national specialty medical organizations that are nationally recognized as setting the standard of care for a condition (*e.g.* U.S. Department of Health and Human Services (HHS) antiretroviral treatment guidelines and the hepatitis C recommendations developed by the American Association of the Study of Liver Diseases and the Infectious Diseases Society of America) may initially lack broad expert consensus or peer-review because of an urgent need to make drugs that improve or maintain critical life functions available as they are approved and/or treatment data is released. Such information can be helpful to the P&T committee as it determines coverage updates and/or changes.

R. "Participating provider" means a provider who, under a contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care services to covered persons with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier.

S. "Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, and any entity or any combination of the foregoing.

T. "Pharmaceutical benefit management procedure" or "PBMP" includes any of the following that is used to manage prescription drug benefits:

(1) A formulary;

(2) The grouping of drugs into different categories;

(3) Dose restrictions;

(4) Prior authorization requirements; or

(5) Step therapy requirements.

Drafting Note: The definition of "pharmaceutical benefit management procedure" refers to commonly used utilization management criteria. It is possible that a health benefit plan may utilize new or different utilization management criteria. States should consider whether additional utilization management criteria should be included in the definition of "pharmaceutical benefit management procedure."

U. "Pharmacy and Therapeutics committee" or "P&T committee" means an advisory committee or committees or equivalent body or bodies that have current knowledge and expertise in:

(1) Clinically appropriate prescribing, dispensing and monitoring of outpatient prescription drugs; and

(2) Drug use review, evaluation and intervention.

Drafting Note: Although this definition is broad, states should take note of the federal rules implementing the federal Affordable Care Act (ACA) effective January 1, 2017, which will require health carriers providing essential health benefits in the individual and small group markets to meet a range of requirements related to the use of a P&T committee (see Title 45 CFR – Subpart B – Essential Health Benefits, Section 156.122(a)(3).

V. "Prescriber" means any licensed, certified or otherwise legally authorized health care professional authorized by law to prescribe a prescription drug.

W. "Prescription drug" means a drug that has been approved or is regulated and for which marketing is permitted by the federal Food and Drug Administration and that can, under federal and state law, be dispensed only pursuant to a prescription drug order from a licensed, certified or otherwise legally authorized prescriber.

Drafting Note: States with laws that mandate coverage for patient costs associated with clinical trials and laws that mandate coverage for the off-label use of prescription drugs should review those laws to determine what impact, if any, this definition of "prescription drug" has on those laws. This reference was included in order to exclude coverage under this Act for treatment investigational new drugs (INDs). States should note that under Section 2709 of the Public Health Service Act, as added by the ACA, a health carrier, (1) is prohibited from denying a qualified individual from participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition; (2) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and (3) may not discriminate against the individual on the basis of the individual's participation in the trial.

X. "Prescription drug order" means an order from a prescriber or the prescriber's designated agent to a pharmacist for a prescription drug to be dispensed.

Y. "Prior authorization" means the process of obtaining prior approval for coverage of a prescription drug.

Z. "Step therapy" means a type of protocol or program the health carrier utilizes that establishes a sequence of covered prescription drugs for a given medical condition.

Section 4. Applicability and Scope

This Act shall apply to health carriers that provide benefits for outpatient prescription drugs under a health benefit plan issued by the health carrier where the health carrier or its designee administers coverage for this benefit through the use of a formulary or through the application of any other pharmaceutical benefit management procedure.

Drafting Note: The provisions of Section 4 above should not be construed to have this Act: 1) apply to a health benefit plan that does not cover outpatient prescription drugs; 2) require coverage of a prescription drug for a medical condition that is not covered under the health benefit plan; or 3) require coverage of a prescription drug categorically excluded from coverage under a health benefit plan unless an express exception is made pursuant to Section 7 of this Act.

Drafting Note: The reference to "designee" in Section 4 is intended to be construed broadly to apply to any person or entity the health carrier contracts with to perform, or carry out on its behalf, specified activities required under this Act or applicable regulations, such as pharmacy benefit manager (PBM). Section 10 of this Act provides that the health carrier is responsible for monitoring all of activities carried out by, or on behalf, of the health carrier by a designee that the health carrier has contracted with to perform that activity and ensuring that the designee is complying with the requirements of this Act and any applicable regulations related to that activity. If a state has enacted or intends to enact a specific law or regulation directly regulating certain persons or entities that may be designees under this Act, such as PBMs, those states should review the provisions of this Act, such as Section 10 of this Act, to determine whether any provisions of this Act should be modified or clarified to encompass such persons or entities in light of that law or regulation.

Section 5. Requirements for the Development and Maintenance of Prescription Drug Formularies and Other Pharmaceutical Benefit Management Procedures

A. Each health carrier that provides coverage for prescription drugs and manages this benefit through the use of a formulary or other PBMP shall establish, or have established, one or more P&T committees meeting the requirements of this section.

B. (1) Any P&T committee established under Subsection A shall include members the health carrier considers appropriate who represent a sufficient number of clinical specialties to adequately meet the needs of covered persons, the majority of which are practicing physicians, practicing pharmacists and other practicing health care professionals licensed to prescribe prescription drugs, to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.

(2) A P&T committee established under Subsection A shall seek outside expert advice, as appropriate, to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.

(3) The health carrier shall ensure that any P&T committee established under Subsection A has the following policies and disclosure requirements in place that address potential conflicts of interest that members of a P&T committee may have with the carrier and any pharmaceutical developer or manufacturer:

(a) At least 20% of the P&T committee membership has no conflict of interest with respect to the health carrier and any pharmaceutical developer or manufacturer;

(b) Prohibits any P&T committee member with a conflict of interest with respect to the health carrier or a pharmaceutical developer or manufacturer from voting on decisions with regard to a particular prescription drug or class of prescription drugs for which the conflict exists; and

(c) Each P&T committee member, and any individual who advises the P&T committee, signs a conflict of interest statement, which reveals any economic or other relationships the P&T committee member, or other individual advising the P&T committee, has with any person affected by drug coverage decisions that could influence P&T committee decisions.

(4) (a) Each P&T committee shall establish procedures outlining its conflict of interest standards for its members and any individuals providing expert advice to the P&T committee, which, at a minimum, are consistent with Paragraph (3).

(b) The procedures shall require the P&T committee to have a system in place to maintain the signed conflict of interest statements described in Paragraph (3)(c) and to document any P&T committee member recusals from voting.

(c) The procedures and information under Subparagraph (b) of this paragraph shall be available for regulatory review and provided to the commissioner upon request.

Drafting Note: State regulators should be aware that any conflict of interest standards a P&T committee establishes might need to permit the P&T committee to receive information from a non-voting individual who may have significant conflicts of interest with the health carrier or a pharmaceutical developer or manufacturer because the individual has special information, knowledge, or expertise related to the particular prescription drug or class of prescription drugs under consideration.

(5) The P&T committee shall meet at least quarterly and shall maintain documentation of its rationale for all decisions regarding formulary drug list development or revision.

C. Each health carrier that offers coverage for prescription drugs shall ensure that it offers a formulary based on the recommendations of the carrier's P&T committee and covers at least the greater of:

(1) One drug in every United States Pharmacopeia (USP) category and class; or

(2) The same number of prescription drugs in each category and class as the essential health benefits (EHB)-benchmark plan.

Drafting Note: States should be aware the provisions of Subsection C above are a requirement under federal regulations implementing the ACA for plans providing essential health benefits (EHBs) in the individual and small group markets (Title 45 CFR – Subpart B – Essential Health Benefits Package Section 156.122(a) (Prescription Drug Benefits)).

D. (1) The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process and documents and procedures to base clinical decisions on the strength of:

(a) Medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including the FDA label indications of the prescription drug and available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to review and include on a formulary; and

Drafting Note: Any P&T committee shall base formulary decisions, in part, on whether prescription drugs included for a therapeutic category or class are effective for all populations, including racial and ethnic minorities, and shall consider whether the formulary includes prescription drugs that have proven efficacy in all patient subgroups, including racial and ethnic minority populations. In making these considerations, the P&T committee shall consider medical and scientific evidence, as well as medical treatment guidelines developed or endorsed by specialty organizations.

(b) Applicable medical and scientific evidence concerning the safety and effectiveness of prescription drugs and the therapeutic advantages of prescription drugs when developing any PBMP.

(2) In the case of rare or ultra-rare diseases, the P&T committee process under Paragraph (1) shall include the review, as the P&T committee considers appropriate and necessary, of clinically appropriate and relevant information when there is no or limited medical and scientific evidence concerning the safety and effectiveness of prescription drugs or drug classes used to treat rare and ultra-rare diseases.

Drafting Note: Paragraph (2) above is meant to require the P&T committee, when deciding what prescription drugs to review and include on a formulary or when developing any PBMP, to have as part of this review process procedures in place to review the best available and appropriate information at the time concerning a prescription drug or drugs to include on a formulary that may be used to treat rare or ultra-rare diseases. Such diseases have been described as from a population of one million people, 650 have a rare disease and fewer than 20 have an ultra-rare disease.

(3) The health carrier shall ensure that any P&T committee maintains documentation of the process required under Paragraph (1) to ensure appropriate prescription drug review and inclusion and makes any records and documents relating to the process available, upon request, to the health carrier for record keeping purposes under Section 9 of this Act.

E. (1) The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process to enable it, in a timely manner, but at least annually, to consider the need for and implement appropriate updates and changes to the formulary or other PBMPs based on:

(a) Newly available scientific and medical evidence or other information concerning prescription drugs currently listed on the formulary or subject to any other PBMP and scientific and medical evidence or other information on new FDA-approved prescription drugs and other prescription drugs not currently listed on the formulary or subject to any other PBMP to determine whether a change to the formulary or PBMP should be made;

(b) The strength of medical and scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data and other such information the P&T committee considers appropriate;

(c) Information received from the health carrier with respect to medical exception requests made under Section 7 of this Act to enable the P&T committee to evaluate whether the prescription drugs currently listed on the formulary or subject to any other PBMP are meeting the health care service needs of covered persons; and

(d) Information relating to the safety and effectiveness of a prescription drug currently listed on the formulary or subject to any other PBMP or relating to clinically similar prescription drugs not currently listed on the formulary or subject to any other PBMP from the health carrier's quality assurance activities or claims data that was received since the date of the P&T committee's most recent review of that prescription drug.

(2) The P&T committee also shall:

(a) Review and approve appropriate updates and guidance related to the medical exceptions process under Section 7 of this Act and other utilization management processes, including any PBMP requirements such as drug utilization review, quantity limits and therapeutic interchange;

(b) Review and approve appropriate updates and changes to all clinical prior authorization criteria, step therapy protocols and quantity limit restrictions applied to each covered prescription drug; and

(c) Review new FDA-approved prescription drugs and new uses for existing prescription drugs.

Drafting Note: A health carrier's P&T committee also should ensure the health carrier's formulary drug list covers a range of prescription drugs across a broad distribution of therapeutic categories and classes and recommend prescription drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of covered persons, and provides appropriate access to prescription drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

F. (1) A health carrier shall allow covered persons to access outpatient prescription drug benefits at in-network retail or mail order pharmacies, unless:

(a) The drug is subject to restricted distribution by the FDA; or

(b) The drug requires special handling, provider coordination or patient education that a retail pharmacy cannot provide.

(2) The health carrier may charge covered persons different cost-sharing amounts based on the distribution method used to obtain the covered prescription drug. All in-network cost-sharing amounts paid shall count towards the health benefit plan's annual limit on cost-sharing paid by the covered person and shall be included in the actuarial value calculated for that plan.

G. Subject to Section 10 of this Act, a health carrier may contract with another person to perform the functions of a P&T committee as described in this section.

Section 6. Information to Prescribers, Pharmacies, Covered Persons and Prospective Covered Persons

A. (1) (a) Except as provided in Paragraph (6), a health carrier shall display on its website in plain language the prescription drug benefit information required in this subsection.

(b) For a health benefit plan providing group market health insurance coverage, a health carrier may require:

(i) A covered person to create or access an account or enter a plan or contract number to access the plan's formulary list and other prescription drug benefit information; and

(ii) A prospective covered person to access a plan's formulary list and other prescription drug benefit information by searching by plan name or contract number.

(c) For a health benefit plan providing individual market health insurance coverage, a health carrier may not require a covered person or prospective covered person to create or access an account or enter a plan or policy number to access a plan's formulary list or other prescription drug benefit information, but may require a covered person or prospective covered person to access a plan's formulary list and other prescription drug benefit information by searching, as appropriate, by plan name.

(2) (a) (i) The health carrier's formulary list(s) shall include each prescription drug covered under the carrier's plan(s) prescription drug benefit and outpatient medical benefit, which are prescription drugs administered by a health care professional or under the professional's direct supervision in an outpatient setting.

(ii) The health carrier may provide the information pertaining to prescription drugs covered under a plan's outpatient medical benefit as an addendum or link to the formulary, if applicable, provided the information is prominently displayed.

(b) The formulary shall be electronically searchable by drug name and any other means required by the commissioner.

Drafting Note: States should be aware that organizing formularies also by major therapeutic class can be helpful to consumers when determining whether the formulary offered under the health benefit plan is robust with respect to a specific disease or medical condition.

(c) The prescription drug benefit information shall include a notice for any individual reviewing the information that the inclusion of a prescription drug on a health benefit plan's formulary does not mean that a prescriber will prescribe that drug for the individual's specific medical condition.

(d) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, a health carrier shall include in the prescription drug benefit information how and what written documentation is required to be submitted in order for a covered person or the covered person's authorized representative to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this Act.

(3) The health carrier shall include in the prescription drug benefit information a description in plain language of how an individual can access the following benefit information:

(a) An indication of whether the drug is preferred, if applicable, under the plan;

(b) A disclosure of any prior authorization, step therapy, quantity limits, pharmacy restrictions or other PBMP requirement; and

(c) The specific tier the drug falls under, if the plan uses a tiered formulary.

(4) (a) The health carrier shall include in the prescription drug benefit information a description in plain language of how an individual may find the benefit cost-sharing information for the prescription drugs on a formulary list that includes:

(i) Whether the prescription drug is subject to a deductible, and if so, the amount of the deductible;

(ii) The amount of the prescription drug copayment;

(iii) The amount of the prescription drug coinsurance; and

(iv) The amount of any cost-sharing difference between the days' supply of the prescription drug.

(b) For a health benefit plan providing individual market health insurance coverage, a health carrier may meet the requirements set forth in Subparagraph (a) of this paragraph by referring the individual to a summary of the plan's benefits and coverage displayed or linked to a place elsewhere on the carrier's website, provided that a covered person or prospective covered person is not required to create or access an account or enter a policy or plan number to access this information.

Drafting Note: States may want to look at the prescription drug benefit information that is to be provided to consumers in accordance with the requirements of this paragraph to see if that information can be easily found and is clear and understandable.

(5) A health carrier shall provide, upon request, a print copy of specifically requested prescription drug benefit information of a carrier's current, accurate and complete formulary.

(6) A health carrier may make available the prescription drug benefit information required in this subsection using electronic links associated with the specific health benefit plan for which the information applies.

(7) A health carrier shall ensure a formulary list(s), whether in electronic or print format, shall accommodate individuals with disabilities, and include a link to or information regarding available assistance for persons with limited English proficiency.

(8) A health carrier shall ensure the formulary list itself:

(a) Is accurate;

(b) Updated, as needed, to reflect changes in a health benefit plan's covered prescription drugs; and

(c) Includes the date it was last updated.

Drafting Note: Health carriers are required to maintain accurate formulary lists for their health benefit plans. State insurance regulators may want to closely monitor consumer complaints received to determine if there is a problem or pattern of complaints that might indicate a problem with the formulary list.

B. Whenever the health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a new or revised dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a particular prescription drug not to be covered until the requirements of that PBMP have been met, unless the change is being made for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer, the health carrier or its designee shall provide notice of that change to:

(1) Prescribers at least sixty (60) days prior to the effective date of the change; and

(2) Pharmacies participating in the health carrier's network prior to the effective date of the change.

C. (1) Whenever a health carrier makes or approves a change in a formulary impacting prescription drug benefit coverage or PBMP administration, including, but not limited to, co-payment amounts, co-insurance percentage level, step therapy, drug substitution and mandatory generics, the health carrier or its designee shall do one of the following:

(a) At least sixty (60) days prior to its effective date, the health carrier or its designee shall notify covered persons impacted by the change currently receiving benefits for the drug of the change; or

(b) The health carrier or its designee shall cover a refill of a drug impacted by the change for any covered person currently receiving benefits for the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person and notify the covered person or the covered person's authorized representative at the time of the refill of the change.

Drafting Note: State insurance regulators should keep in mind that under certain circumstances notices to covered persons under this paragraph may not be needed if the health carrier decides to continue coverage of the prescription drug on the same terms and conditions as covered previously for covered persons currently receiving coverage for that drug as long as the drug continues to be prescribed for the covered person and the covered person is covered under the health benefit plan.

Drafting Note: State insurance regulators should be aware Paragraph (1) above does not obviate the requirement that the carrier or its designee provide a minimum 60-day advance notice before the effective date of a formulary change to consumers in order to provide sufficient time for consumers to discuss alternatives to the prescription drug impacted by the change with their physician or prescriber or file a request for approval of an exception under the health carrier's medical exceptions process.

(2) (a) As part of the information to be provided in a notice pursuant to Paragraph (1)(a) or Paragraph (1)(b), the health carrier or its designee shall include information on any available alternatives to the prescription drug impacted by the formulary change and direct the covered person to speak with the prescriber.

(b) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, the notice provided pursuant to Paragraph (1)(a) or Paragraph (1)(b) shall include information on how and what written documentation is required to be submitted for the covered person or the covered person's authorized representative to file a medical exceptions request in accordance with the health carrier's medical exceptions process set forth in Section 7 of this Act.

(3) A health carrier or its designee shall not be required to cover a refill of a prescription drug pursuant to Paragraph (1)(b) whenever:

(a) The prescription drug is being discontinued from coverage on the formulary for safety reasons;

(b) The prescription drug is not available because the drug's manufacturer no longer supplies the drug or has withdrawn the drug from the market; or

(c) The change in or a new PBMP for the prescription drug is for safety reasons.

D. In addition to the information to be provided under Subsection A, a health carrier or its designee electronically or in writing, upon request, shall include in any notice provided under Subsection C information explaining in plain language that:

(1) Any formulary change impacting prescription drug benefit coverage or PBMP administration could impact the covered person's out-of-pocket costs and the covered person may want to consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug impacted by the change is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition;

(2) The covered person may want to review the health benefit plan's formulary from time-to-time or contact the health carrier or its designee to obtain any updated formulary information prior to obtaining a refill for a particular prescription drug the covered person is currently using to find out if there has been any change in the requirements for obtaining coverage for the drug or if there has been a change in the covered person's out-of-pocket costs for the drug and include the telephone number or electronic link that covered persons can use to contact the health carrier or its designee to obtain this information; and

(3) The amount the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time.

Section 7. Medical Exceptions Approval Process Requirements and Procedures

A. Each health carrier that provides prescription drug benefits and manages this benefit through the use of a formulary or through the application of a dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met shall establish and maintain a medical exceptions process that allows covered persons or covered persons' authorized representatives to request approval for:

(1) Coverage of a prescription drug that is not covered based on the health carrier's formulary;

(2) Continued coverage of a particular prescription drug that the health carrier is discontinuing coverage on the formulary except when coverage for the drug is being discontinued for safety reasons or because the drug's manufacturer is no longer supplying the prescription drug or the drug's manufacturer has withdrawn the prescription drug from the market; or

(3) An exception to a PBMP that causes a prescription drug to not be covered until the step therapy requirement is satisfied or not be covered at the prescribed number of doses.

Drafting Note: States should ensure that health benefit plans have a process in place to address issues that may not fall under this section as a formulary exception, but would be considered a benefit exception.

Drafting Note: This section is not intended to apply to requests for an exception to a pharmaceutical benefit management procedure (PBMP) involving a prior authorization requirement. Those types of requests for benefits for which a health carrier requires prior authorization are to be resolved under a health carrier's utilization review process.

Drafting Note: This section also is not intended to apply to situations where the consumer may have issues with pharmacy access, such as an in-network pharmacy being too far from a covered person's home address or when a prescription drug a covered person is currently using changes from being available through a range of pharmacy options to mail order pharmacy only. In these situations, states should review the network access requirements in state law or regulation similar to the requirements in the *Health Benefit Plan Network Access and Adequacy Model Act* (#74).

B. (1) A covered person or the covered person's authorized representative may file, and the health carrier shall review, a request under Subsection A only if the covered person's prescribing provider has determined that the requested prescription drug is medically necessary to treat the covered person's disease or medical condition because:

(a) There is not a prescription drug listed on the formulary to treat the covered person's disease or medical condition that is an acceptable clinical alternative;

(b) The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:

(i) Has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance;

(ii) Is contraindicated; or

(iii) Has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the covered person in the prescriber's clinical judgment;

Drafting Note: States should be aware that this Act does not contemplate covered persons using the medical exceptions process established under this section to request a change in benefits, which, in some cases, could impact potential medical exception requests involving step therapy requirements. This Act contemplates benefit exception requests would be handled under a different state law or regulations related to utilization review or grievance processes. Given this, states should review their existing state laws for consistency when considering adoption of this section.

(c) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(d) The covered person's condition and function are stable and based on the covered person's medical history a change in prescription drug would have the potential for adverse consequences or other risks.

(2) (a) A health carrier may require the covered person or the covered person's authorized representative upon request to provide a written certification from the covered person's prescribing provider of the determination made under Paragraph (1).

(b) The health carrier may require the written certification to include any of, but no more than, the following information:

(i) The patient's name, group or contract number, subscriber number or other information necessary to identify the covered person;

(ii) Patient history;

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the medical exceptions request;

(iv) Based on Paragraph (1)(a), (b) or (c), the reason:

(I) Why the formulary drug is not acceptable for the individual patient;

(II) If the medical exceptions request involves a step therapy requirement, why the prescription drug required to be used is not acceptable for the individual patient; or

(III) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the individual patient;

(v) The reason why the prescription drug that is the subject of the medical exceptions request is needed for the individual patient or, if the medical exceptions request involves a dose restriction, why an exception to the dose restriction is needed for the individual patient; and

(vi) Any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request.

(c) A prescriber may submit additional information the prescriber deems necessary to establish medical necessity for purposes of the medical exceptions request.

(3) Participation by a provider on behalf of a covered person in the medical exceptions process established under this section shall be construed as being the same as a provider's advocating on behalf of a covered person within the utilization review process established by the health carrier for purposes of [insert reference to state law equivalent to Section 6J of the *Health Benefit Plan Network Access and Adequacy Model Act* (#74)].

Drafting Note: Section 6J of the NAIC *Health Benefit Plan Network Access and Adequacy Model Act* (#74) provides that a health carrier may not prohibit a participating provider from advocating on behalf of covered persons within the utilization review or grievance or appeals processes established by the carrier or a person contracting with the carrier. The medical exceptions process established under this section for the review of requests for approval for exceptions to a formulary or being subject to a dose restriction or step therapy requirement is similar to the expedited utilization review process that health carriers may be required to establish for the review of health care service benefit requests. Paragraph (3) is intended to ensure that providers participating in the medical exceptions process established under this section have the same protections given to participating providers under Section 6J of the NAIC *Health Benefit Plan Network Access and Adequacy Model Act* (#74).

C. (1) Upon receipt of a request made pursuant to Subsection A, the health carrier shall ensure that the request is reviewed by appropriate health care professionals who, in reaching a decision on the request, shall take into account the specific facts and circumstances that apply to the covered person for whom the request has been made using documented clinical review criteria that:

(a) Are based on sound clinical evidence and medical and scientific evidence; and

(b) If available, appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, practice guidelines developed by the health carrier's P&T committee or any other practice guidelines developed by the federal government, national or professional medical or pharmacist societies, boards and associations.

(2) The health care professional or professionals designated by the health carrier to review the request under Paragraph (1) shall ensure that the decision reached on the request is consistent with the benefits and exclusions under the covered person's health benefit plan with the health carrier.

D. (1) (a) Except as provided in Subparagraph (b) of this paragraph, the medical exceptions process under this section shall require the health carrier to make a decision on a request made pursuant to Subsection A and provide notice of the decision to the covered person or the covered person's authorized representative as quickly as the covered person's particular medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health carrier, the date of receipt of the certification under Subsection B(2).

(b) (i) A health carrier shall include in its medical exceptions process required under Subsection A an expedited medical exceptions review based on exigent circumstances.

(ii) Exigent circumstances exist when a covered person is suffering from a health condition that may seriously jeopardize the covered person's life, health, or ability to regain maximum function.

Drafting Note: Item (ii) above also is intended to apply when an infant's or a child's health condition may seriously jeopardize their ability to develop maximum function.

(iii) A health carrier shall make a decision on an expedited medical exceptions review request based on exigent circumstances made pursuant to Subsection A and notify the covered person or the covered person's authorized representative of its coverage decision no later than [24] hours following receipt of the request.

(2) (a) If the health carrier fails to make a decision on the request and provide notice of the decision within the time frame required under Paragraph (1)(a) or Paragraph (1)(b):

(i) The covered person shall be entitled to have coverage for, up to one month's supply of the prescription drug that is the subject of the request; and

(ii) The health carrier shall make a decision on the request prior to the covered person's completion of the supply provided in Item (i).

(b) If the health carrier fails to make a decision on the request and provide notice of the decision prior to the covered person's completion of the supply provided for in Subparagraph (a) of this paragraph, the health carrier shall maintain coverage, as specified in Subparagraph (a) of this paragraph, on the same terms on an ongoing basis, as long as the prescription drug continues to be prescribed for that covered person and is considered safe for the treatment of the covered person's disease or medical condition until a decision is made on the request and notice of that decision is provided, unless there is a material change in the covered person's terms of coverage or the applicable benefit limits have been exhausted.

E. (1) Whenever a request made under this section is approved, the health carrier shall not require the covered person to request approval under this section for a refill, or a new prescription to continue using the prescription drug after the refills for the initial prescription have been exhausted, for the same prescription drug that was previously approved under this section for coverage or continued coverage or that was previously approved under this section as an exception to the health carrier's PBMP for that drug, subject to the terms of coverage under the health carrier's health benefit plan for prescription drug benefits as long as:

(a) The covered person's prescribing provider continues to prescribe the prescription drug to treat the same disease or medical condition of the covered person; and

(b) The prescription drug continues to be considered safe for treating the covered person's disease or medical condition.

(2) In addition to Paragraph (1), whenever a request made under this section is approved, the health carrier shall provide coverage for the approved prescription drug [and count the covered person's in-network cost-sharing for the drug toward the covered person's annual limitation on cost-sharing].

Drafting Note: States should be aware that the bracketed language above is a requirement under federal regulations implementing the ACA for plans providing essential health benefits (EHBs) in the individual and small group markets (see Title 45 CFR – Subpart B – Essential Health Benefits Package Section 156.122(c) (Prescription Drug Benefits)). As such, states will need to consider whether to include the bracketed language where it could have a broader application.

(3) A health carrier shall not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

Drafting Note: A state that requires health carriers to establish specific formulary tiers with specific cost-sharing requirements for each tier should modify the language in Paragraph (3) to take into account the requirements of its law.

F. (1) Any denial by a health carrier of a request made under Subsection A:

(a) Shall be provided to the covered person or, if applicable, the covered person's authorized representative in writing or, if the covered person has agreed to receive information in this manner, electronically;

(b) Shall be provided electronically to the covered person's prescribing provider or, upon request, in writing; and

(c) May be appealed by filing a grievance pursuant to [insert reference in state law equivalent to the *Health Carrier Grievance Procedure Model Act* (#72)].

(2) The denial shall, in plain language, set forth:

(a) The specific reason or reasons for the denial;

(b) A reference to the evidence or documentation, including the clinical review criteria, including practice guidelines, and clinical evidence and medical and scientific evidence considered in reaching the decision to deny the request;

(c) Instructions for requesting, a written statement of the clinical and medical or scientific rationale for the denial; and

(d) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to [insert reference in state law equivalent to the *Health Carrier Grievance Procedure Model Act* (#72)], including any time limits applicable to those procedures.

G. A health carrier that permits a covered person's prescriber to make formulary and other PBMP exceptions without having to obtain authorization from the carrier and that maintains on an ongoing basis in its administrative systems information about the exception status of a particular prescription drug for a particular covered person shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F with respect to the prescription drug orders of these prescribing participating providers.

Drafting Note: Subsection G above is intended to apply to carriers that are organized and operated as integrated care systems, such as a staff model HMO, where health care providers manage and provide covered health care services to covered persons without having to seek specific authorization from the carrier for the provision of those specific services.

H. A health carrier shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F if the health carrier:

(1) Has an expedited utilization review process as set forth in [insert reference in state law equivalent to Section 10 of the *Utilization Review and Benefit Determination Model Act* (#73)]; and

(2) Allows covered persons or their authorized representatives to use this process to seek approval for coverage of a prescription drug that is not otherwise covered because of the health carrier's formulary or because of any other PBMP requirement that restricts coverage of the prescription drug until the PBMP requirement has been met.

I. A covered person may not use the process established under this section to request coverage for: (1) an investigational or a non-FDA-approved prescription drug; or (2) a prescription drug for a specifically excluded benefit under the covered person's health benefit plan.

Drafting Note: Subsection I reflects that health benefit plans exclude certain benefits from coverage by listing non-covered benefits, but do not exclude specific medical conditions from coverage.

Drafting Note: Also, with respect to Subsection I, states should be aware that an issue could arise in situations where an application for new drug approval has been submitted to the FDA, but, at the time a covered person submits a medical exceptions request for coverage of that prescription drug, the drug has not received FDA-approval.

Section 8. Nondiscrimination in Prescription Drug Benefit Design

A health carrier or its designee shall not adopt or implement a formulary or prescription drug benefit design that is discriminatory in violation of state or federal law.

Drafting Note: State insurance regulators should consider federal nondiscrimination laws and regulations requiring health carriers in the individual and small group health insurance markets to meet a range of requirements related to prescription drug benefit coverage, including nondiscrimination in prescription drug benefit design.

Drafting Note: State insurance regulators should consider the nondiscrimination provisions contained in state laws based on the *Individual Market Health Insurance Coverage Model Act* (#36), the *Small Group Market Health Insurance Coverage Model Act* (#106); or the *Unfair Trade Practices Act* (#880).

Drafting Note: State insurance regulators should pay particular attention to the formulary and prescription drug benefit notices and disclosures health carriers are required under this Act to provide to covered persons to ensure that these notices and disclosures, whether provided electronically or in print, accommodate individuals with disabilities and individuals with limited English proficiency.

Section 9. Record Keeping and Reporting Requirements

A. (1) Each health carrier shall maintain written or electronic records sufficient to demonstrate compliance with this Act, including records documenting the application of a process for making decisions on formularies and other PBMPs that is required under Section 5 of this Act and, except for a health carrier that satisfies the requirements of Section 7G or H of this Act, records documenting the application of the medical exceptions process that is required under Section 7 of this Act.

(2) The records shall be maintained for period of three (3) years or until the completion of the health carrier's next market conduct examination, whichever is later, and shall be made available to the commissioner upon request by the commissioner.

B. Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, each health carrier shall maintain data on and, upon request, make available to the commissioner the following information with respect to medical exceptions requests made under Section 7 of this Act:

(1) The total number of medical exceptions requests;

(2) From the total number of medical exceptions requests provided under Paragraph (1):

(a) The number of requests made for coverage of a nonformulary prescription drug;

(b) The number of requests made for continuing coverage of a prescription drug that the health carrier was discontinuing from coverage on the formulary for reasons other than safety or because the drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; and

(c) The number of requests made for an exception to being subject to a PBMP;

(3) The number of medical exceptions requests approved and denied;

[(4) The changes to its formulary or prescription drug benefit information made after the start of the plan year;] and

(5) Any other information the commissioner may request.

Section 10. Oversight and Contracting Responsibilities

A. A health carrier shall be responsible for monitoring all activities carried out by, or on behalf, of the health carrier under this Act and for ensuring that all requirements of this Act and applicable regulations are met.

B. Whenever a health carrier contracts with another person to perform activities required under this Act or applicable regulations, the commissioner shall hold the health carrier responsible for monitoring the activities of that person with which the health carrier contracts and for ensuring that the requirements of this Act and applicable regulations with respect to that activity are met.

Section 11. Disclosure Requirements

A. Each health carrier that uses a formulary or any other PBMP shall in the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons:

(1) Disclose the existence of the formulary and any other PBMP and that there may be other plan restrictions or requirements that may affect the specific prescription drugs that will be covered and where to find more specific information;

(2) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, describe the medical exceptions process that may be used to request coverage of nonformulary prescription drugs or to obtain an exception to being subject to any PBMP requirement; and

(3) If applicable, describe the process for filing a grievance as set forth in [insert reference in state law equivalent to the *Health Carrier Grievance Procedure Model Act* (#72)] to appeal a denial of a medical exceptions request.

B. (1) In addition to Subsection A, the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons shall explain in plain language information on the health carrier's formulary and other prescription drug benefit information as provided in Section 6A and state where the information is available electronically and a print copy of the formulary list and specific prescription drug information can be provided to a covered person by the health carrier or its designee on request.

(2) In addition to the information explained under Paragraph (1), a health carrier shall explain in plain language in a separate document or other attachment to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage that:

(a) Any formulary change impacting prescription drug benefit coverage or PBMP administration could impact the covered person's out-of-pocket costs and the covered person may want to consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug impacted by the change is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition;

(b) The covered person may want to review the health benefit plan's formulary from time-to-time or contact the health carrier or its designee to obtain any updated formulary information prior to obtaining a refill for a particular prescription drug the covered person is currently using to find out if there has been any change in the requirements for obtaining coverage for the drug or if there has been a change in the covered person's out-of-pocket costs for the drug and include the telephone number or electronic link that covered persons can use to contact the health carrier or its designee to obtain this information; and

(c) The amount that the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time;

Section 12. Regulations

The commissioner may promulgate regulations to carry out the provisions of this Act. The regulations shall be subject to review in accordance with [insert statutory citation providing for administrative rulemaking and review of regulations].

Section 13. Penalties

A violation of this Act shall [insert appropriate administrative penalty from state law].

Section 14. Separability

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of the Act, and the application of the provision to persons or circumstances other that those to which it is held invalid, shall not be affected.

Section 15. Effective Date

This Act shall be effective [insert date]. [If applicable:] The [insert year of adoption] amendments to this Act shall be effective [insert date].

Chronological Summary of Action (all references are to the Proceedings of the NAIC).

2002 Proc. 4th Quarter 279, 323-333 (adopted by task force).
2003 Proc. 1st Quarter 175 (adopted by parent committee).
2003 Proc. 2nd Quarter 12, 16 (adopted by Plenary).
2018 Proc. 1st Quarter (amendments adopted by Plenary).

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

This chart is intended to provide readers with additional information to more easily access state statutes, regulations, bulletins or administrative rulings related to the NAIC model. Such guidance provides readers with a starting point from which they may review how each state has addressed the model and the topic being covered. The NAIC Legal Division has reviewed each state's activity in this area and has determined whether the citation most appropriately fits in the Model Adoption column or Related State Activity column based on the definitions listed below. The NAIC's interpretation may or may not be shared by the individual states or by interested readers.

This chart does not constitute a formal legal opinion by the NAIC staff on the provisions of state law and should not be relied upon as such. Nor does this state page reflect a determination as to whether a state meets any applicable accreditation standards. Every effort has been made to provide correct and accurate summaries to assist readers in locating useful information. Readers should consult state law for further details and for the most current information.

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

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HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

KEY:

MODEL ADOPTION: States that have citations identified in this column adopted the most recent version of the NAIC model in a **substantially similar manner**. This requires states to adopt the model in its entirety but does allow for variations in style and format. States that have adopted portions of the current NAIC model will be included in this column with an explanatory note.

RELATED STATE ACTIVITY: Examples of Related State Activity include but are not limited to: older versions of the NAIC model, statutes or regulations addressing the same subject matter, or other administrative guidance such as bulletins and notices. States that have citations identified in this column **only** (and nothing listed in the Model Adoption column) have **not** adopted the most recent version of the NAIC model in a **substantially similar manner.**

NO CURRENT ACTIVITY: No state activity on the topic as of the date of the most recent update. This includes states that have repealed legislation as well as states that have never adopted legislation.

NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Alabama	NO CURRENT ACTIVITY	
Alaska	NO CURRENT ACTIVITY	
American Samoa	NO CURRENT ACTIVITY	
Arizona	NO CURRENT ACTIVITY	
Arkansas	NO CURRENT ACTIVITY	
California		2011 CAL. HEALTH & SAFETY 1367.241 (2011).
Colorado	NO CURRENT ACTIVITY	
Connecticut	NO CURRENT ACTIVITY	
Delaware	NO CURRENT ACTIVITY	
District of Columbia	NO CURRENT ACTIVITY	
Florida	NO CURRENT ACTIVITY	
Georgia	NO CURRENT ACTIVITY	
Guam	NO CURRENT ACTIVITY	
Hawaii	NO CURRENT ACTIVITY	
Idaho	NO CURRENT ACTIVITY	
Illinois	NO CURRENT ACTIVITY	

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Indiana	NO CURRENT ACTIVITY	
Iowa	NO CURRENT ACTIVITY	
Kansas	NO CURRENT ACTIVITY	
Kentucky	NO CURRENT ACTIVITY	
Louisiana	NO CURRENT ACTIVITY	
Maine	NO CURRENT ACTIVITY	
Maryland	NO CURRENT ACTIVITY	
Massachusetts	NO CURRENT ACTIVITY	
Michigan	NO CURRENT ACTIVITY	
Minnesota	NO CURRENT ACTIVITY	
Mississippi	NO CURRENT ACTIVITY	
Missouri	NO CURRENT ACTIVITY	
Montana	NO CURRENT ACTIVITY	
Nebraska	NO CURRENT ACTIVITY	
Nevada	NO CURRENT ACTIVITY	
New Hampshire	NO CURRENT ACTIVITY	
New Jersey	NO CURRENT ACTIVITY	
New Mexico	NO CURRENT ACTIVITY	
New York	NO CURRENT ACTIVITY	
North Carolina	NO CURRENT ACTIVITY	
North Dakota	NO CURRENT ACTIVITY	
Northern Marianas	NO CURRENT ACTIVITY	

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Ohio	NO CURRENT ACTIVITY	
Oklahoma	NO CURRENT ACTIVITY	
Oregon	NO CURRENT ACTIVITY	
Pennsylvania	NO CURRENT ACTIVITY	
Puerto Rico	NO CURRENT ACTIVITY	
Rhode Island		R.I. GEN. LAWS §§ 27-20.8-1 to 27-20.8-2 (2004/2008).
South Carolina	NO CURRENT ACTIVITY	
South Dakota		S.D. CODIFIED LAWS §§ 58-29E-1 to 58-29E-11 (2004).
Tennessee	NO CURRENT ACTIVITY	
Texas	NO CURRENT ACTIVITY	
Utah	NO CURRENT ACTIVITY	
Vermont	NO CURRENT ACTIVITY	
Virgin Islands	NO CURRENT ACTIVITY	
Virginia	NO CURRENT ACTIVITY	
Washington	NO CURRENT ACTIVITY	
West Virginia	NO CURRENT ACTIVITY	
Wisconsin	NO CURRENT ACTIVITY	
Wyoming	NO CURRENT ACTIVITY	

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

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PCMA Communications

Spectrum News (Kentucky): Committee studies cost of Medicaid prescriptions in relation to pharmacy benefit managers

1/11/2018

By Don Weber

The role of pharmacy benefit managers and their role in determining the cost of drugs for Medicaid patients was the subject of today's joint meeting of the Senate and House committee on Banking and Insurance.

A pharmacy benefits manager (PBM) is a health care company that contracts with insurers, employers, and government programs to administer the prescription drug portion of the health care benefit.

PBMs work with insurers and employers to perform a variety of services to ensure high-quality, cost efficient delivery or prescription drugs to consumers.

Pharmacy benefit management services include claims processing, formulary management, pharmacy networks, mail-service pharmacy, specialty pharmacy, drug utilization review, disease management and adherence services, and price, discount and rebate negotiations with pharmaceutical manufacturers and drugstores.

Officials from the Care Management Association and Express Scripts holding Company addressed concerns from lawmakers about how their organizations come to the prices that they charge for prescription medicine.

Co-chair Sen. Tom Buford, R-Nicholasville, says the aim of lawmakers is to make sure that the state's Medicaid patients are getting the lowest price on their prescriptions to save taxpayer money.

"We want to be sure that our Medicaid department, what we're dealing with ultimately, that the dollars that we spend are well used, and that are pharmaceutical managers are giving not only the best price to the clients of Medicaid, but at a cost that is affordable to our Medicaid services,

meaning the taxpayer who has to pay the cost from any benefit that comes out of a pharmacy," Buford said.

Rep. Jim DuPlessis, R-Elizabethtown, expressed his frustration that it seems that prescription medicine is not part of the traditional marketplace.

"What we have in America and subsequently in Kentucky is not a market place," DuPlessis said. "Consumers don't know what they pay, consumers, in fact; don't have a choice on what they pay because they're told what their co-pays are."

Melodie Shrader, Senior Director, State Affairs, of the Pharmaceutical Care Management Association, defended the fact that the free market is not part of purchasing prescriptions.

"Healthcare in the United States is not a free market, the way to make it a free market is to do away with insurance, and you have to pay with your own dollars," Shrader said. "I'm not going to apologize for the fact that when I walk in, or my neighbor walks in, or my loved one walks in and needs a drug that costs eighty thousand dollars, that there is insurance to cover that because that's a good thing."

Buford admits that, even after the meeting, more information is needed, especially in the area of prescription rebates and where that money goes.

Sen. Max Wise, R-Campbellsville, is currently working on legislation regarding pharmacy benefit managers and the cost of prescriptions.

KAIT/KARK (Arkansas Tv station): PBM's discussed during meeting at Capitol

2/21/18

A group of pharmacists spent their Wednesday at the state Capitol in Little Rock, battling for changes in drug reimbursement rates as lawmakers plan for a possible special session on the matter.

According to a report from Little Rock television station KARK, the pharmacists are upset over Pharmacy Benefit Managers receiving more money for prescriptions than what pharmacies receive.

PBM's are the middleman in the prescription issue between insurance companies and pharmacies.

"This is an example of blatant self-dealing," Arkansas Pharmacists Association CEO Scott Pace told the group. Pace said the group received information that the PBM for the state of Arkansas, CVS, pays itself at least $60 per prescription more than it pays pharmacies, KARK reported.

"When the fox guards the hen house, all sorts of games can be played and in Arkansas with the PBM's, they have been," Pace told KARK. "They operate behind a curtain of secrecy."

However, the Pharmaceutical Care Management Association told KARK that a proposal from lawmakers on the issue was ill-conceived.

"This resolution would raise prescription drug costs for Arkansas' patients, employers, state government, and taxpayers and do nothing to improve the quality of pharmacy benefits. The state should be encouraging market-based solutions to reduce drug costs, not giving special protections to the drugstore lobby," the group said in a statement.

Arkansas Matters: Lawmakers, Pharmacists Meet with CVS over Regulation of Pharmacy Benefit Managers

2/21/18

By Jessi Turnure

Hundreds of pharmacists and patients from every corner of the state spilled out of the Old Supreme Court Room at the capitol Wednesday to fight for change.

The nearly 750 pharmacies in Arkansas noticed cuts to their drug reimbursement rates at the beginning of the year. They have been working with lawmakers ever since to regulate who they say is to blame: pharmacy benefit managers (PBMs).

"This room is packed because this is an Arkansas issue," Lt. Gov. Tim Griffin told the crowd. "This is every household in Arkansas. We don't have a healthy market. We don't have healthy competition. What we have is dysfunction because of oversized players who are basically helping themselves at your expense."

The Arkansas Pharmacists Association obtained records of more than 270 popular drugs in the state and found CVS pays itself at least $60 per prescription more than it pays pharmacies.

"This is an example of blatant self-dealing," CEO Scott Pace told the crowd.

Pace pointed to two cases in particular. While Arkansas pharmacies received about $28 for 30 tablets of Aripiprazole, a medication to treat depression, CVS received $512. The other showed the state's pharmacists received about $909 for 20 tablets of Temozolomide, a cancer treatment. CVS received nearly $4,000.

"When the fox guards the hen house, all sorts of games can be played and in Arkansas with the PBMs, they have been," Pace said. "They operate behind a curtain of secrecy."

The CEO has been working with lawmakers on the legislation to regulate these PBMs, giving the state insurance department oversight of them.

Pace said they have trimmed the resolution from 14 to seven pages, which CVS saw for the first time Wednesday morning right before the press conference. He had another meeting scheduled with CVS representatives at 4 p.m. at the capitol.

The Pharmaceutical Care Management Association, who represents PBMs across the country, released the following statement on the proposed Arkansas legislation:

> **"This resolution would raise prescription drug costs for Arkansas's patients, employers, state government, and taxpayers and do nothing to improve the quality of pharmacy benefits. The state should be encouraging market-based solutions to reduce drug costs, not giving special protections to the drugstore lobby."**

Arkansas pharmacists argue PBMs have forced them to cut hours and jobs, even consider closures in the near future.

"They say it's proprietary, but it's affecting my business every day that I love," said Mike Smith, the owner of Rose Drugstore in Russellville. "We are the boots on the ground. We are the ones with all the customers. We have been serving families for generation after generation that we need to take care of. We would like to have a reasonable, fair reimbursement on a level playing field."

Gov. Asa Hutchinson plans to call a special session on this issue once lawmakers wrap up the fiscal session.

St. Rep. Michelle Gray, R- Melbourne, who is sponsoring the PBM legislation on the House side, is adamant about her colleagues addressing the issue immediately during the fiscal session. However, Gray said a meeting with Hutchinson Wednesday morning convinced her to back off.

"He assures me that this bill, which we are still working to finalize to make sure that there are no unintended consequences, will be on the special call," Gray told the crowd. "He looked me in the eyes, and I have to trust that. If I can't trust my governor to do what he says he'll do, I might as well just pack up and go home."

Rep. Gray and the legislation's sponsor on the Senate side, St. Sen. Ron Caldwell, R-Wynne, said they would not have been able to act this fast without the help of their colleagues, pharmacists, patients and other community members across the state.

Third-Party Ally Op-Eds

THE BUFFALO NEWS

The Buffalo News: Pharmacy benefit managers work for patients

10/2/2017

Edmund Pezalla, Op-Ed

There is so much rancor and finger-pointing these days over prescription drug prices that consumers are often left to wonder: who is fighting on their behalf? The answer: pharmacy benefit managers, or PBMs.

Companies and public programs providing prescription drug coverage hire PBMs for their expertise and ability to reduce drug costs by negotiating for rebates and discounts from big drug companies and drugstores. It would be too expensive and complicated for employers, or other payers, to match PBMs' ability to reduce drug costs while providing access.

Though drugmakers continue to raise prices out of proportion to increases in value, PBMs are doing their job by keeping drug costs down. A recent report by QuintilesIMS Institute showed that discounts, rebates and other price concessions on brand-name drugs reduced overall drug spending by an estimated 28 percent in 2016.

The report also shows that net price growth - the price payers actually pay - for prescription drugs is likely to remain in the zero to 3 percent range, largely because of the work of payers and PBMs.

Having been involved as a clinician representing insurers and PBMs for more than 25 years, I know firsthand the importance of leveraging savings while ensuring that patients have the medications they need.

One patient-friendly and cost-saving option that PBMs provide to consumers is home delivery of chronic medications. As more and more people move to a "home-delivery economy" for many of their needs, mail-service pharmacies are a natural extension that adds convenience and lowers costs.

By using home delivery, consumers can avoid multiple (and unnecessary) trips to the drugstore while receiving private counseling from trained pharmacists seven days a week, 24 hours a day.

Pharmacists, doctors and other professionals employed by PBMs review the medical evidence for every drug approved by the FDA, assist in managing drug-related side effects and provide support to create formularies so that patients stay on their drug regimens and out of the hospital. That in turn lowers costs for patients and the entire health care system.

As the health care sector moves toward payment for value rather than volume, PBMs are providing expertise in developing and executing on these types of outcomes-based contracts that are intended to

ensure that our pharmaceutical dollars are spent on drugs that provide the best outcomes.

These agreements require a high level of sophistication about drug use patterns and patient outcomes, as well as the ability to monitor and improve patient compliance and measure relevant outcomes.

As the public debate continues to unfold on health care and lawmakers are even more hungry to hear from better-informed voters, PBMs are part of the solution that lowers drug costs and improves quality.

the ct mirror

The Connecticut Mirror: These people advocate for consumers to lower prescription drug prices

10/2/2017

Edmund Pezalla, Op-Ed

There is so much rancor and finger pointing these days over prescription drug prices that consumers are often left to wonder: who is fighting on their behalf? The answer: Pharmacy Benefit Managers, or PBMs.

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Though drug makers continue to raise prices out of proportion to increases in value, PBMs are doing their job by keeping drug costs down. A recent report by QuintilesIMS Institute showed that discounts, rebates, and other price concessions on brand-name drugs reduced overall drug spending by an estimated 28 percent in 2016. The report also shows that net price growth - the price payers actually pay - for prescription drugs is likely to remain in the 0-3 percent range, largely because of the work of payers and PBMs.

Having been involved as a clinician representing insurers and PBMs for more than 25 years, I know first hand the importance of leveraging savings while ensuring that patients have the medications they need.

One patient-friendly and cost-saving option that PBMs provide to consumers is home delivery of chronic medications. As more and more people move to a "home-delivery economy" for many of their needs, mail-service pharmacies are a natural extension that adds convenience and lowers costs. By using home delivery, consumers can avoid multiple (and unnecessary) trips to the drugstore while receiving private counseling from trained pharmacists seven days a week, 24-hours a day.

Mail-service pharmacies feature cutting-edge technology that can track and improve patients' adherence to prescribed medications. Research shows that better adherence to prescribed drug regimens means that patients would not need as many trips to the doctor or hospital, lowering overall health care costs for everyone.

It is easy to see that PBMs reduce drug costs, but often overlooked is the clinical value that they provide payers and patients. PBMs work in coordination with their clients to carefully evaluate new drugs, review existing drugs, and apply sophisticated drug assessments that promote the best use of complex

medications, and the appropriate use of mainstay drugs.

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These formularies often organize medications according to their therapeutic effects and create logical sequences for their use based on clinical effectiveness, place in therapy according to national guidelines, and safety. Generic and lower cost brand medications can be incentivized before more expensive medicines because they work well for the majority of patients and have lower copays.

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Statehouse Report
South Carolina's legislative and policy forecast

Statehouse Report (South Carolina): PBMs will save $10 billion in S.C. drug costs over 10 years

10/19/2017

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Though drug makers continue to raise prices out of proportion to increases in value, PBMs are doing their job by keeping drug costs down. In fact, PBMs will save patients and payers in South Carolina $10.3 billion over 10 years.

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As the public debate continues to unfold on health care and lawmakers are even more hungry to hear from better-informed voters, PBMs are part of the solution that lowers drug costs and improves quality.

The State Journal
Frankfort, KY

The State Journal (Kentucky): PBMs will save Kentucky billions in drug costs

11/30/2017

Edmund Pezalla, Op-Ed

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Though drugmakers continue to raise prices out of proportion to increases in value, PBMs are doing their job by keeping drug costs down. In fact, PBMs will save patients and payers in Kentucky $9.4 billion over 10 years.

A recent report by QuintilesIMS Institute showed that discounts, rebates and other price concessions on name-brand drugs reduced overall drug spending by an estimated 28 percent in 2016. The report also shows that net price growth â€“ the price payers actually pay â€“ for prescription drugs is likely to remain in the 0 percent to 3 percent range, largely because of the work of payers and PBMs.

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As the public debate continues to unfold on health care and lawmakers are even more hungry to hear from better-informed voters, PBMs are part of the solution that lowers drug costs and improves quality.

THE CAPITOLIST

The Capitolist (Florida): What You Need to Know About PBMs: The Patient Advocate for High Quality, Affordable Prescription Drugs

2/6/2018

Edmund Pezalla, Op-Ed

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Specialty pharmacies dispense complex medicines, many of which are infused intravenously, or injected. They also manage patient care to optimize outcomes, reduce medication errors, manage and prevent side effects, and promote more affordable alternatives. Most drugstores simply don't have the expertise to dispense specialty medications to patients.

It is easy to see that PBMs reduce drug costs, but often overlooked is the clinical value that they provide payers and patients. PBMs and PBM-affiliated specialty pharmacies work in coordination with their clients to carefully evaluate new drugs, review existing drugs, and apply sophisticated drug assessments that promote the best use of complex medications, and the appropriate use of mainstay drugs.

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As the public debate continues to unfold on healthcare and lawmakers are even hungrier to hear from better-informed voters, PBMs are part of the solution that lowers drug costs and improves quality.

Florida Politics: PBMs: patient advocates for high quality, affordable prescription drugs

2/6/2018

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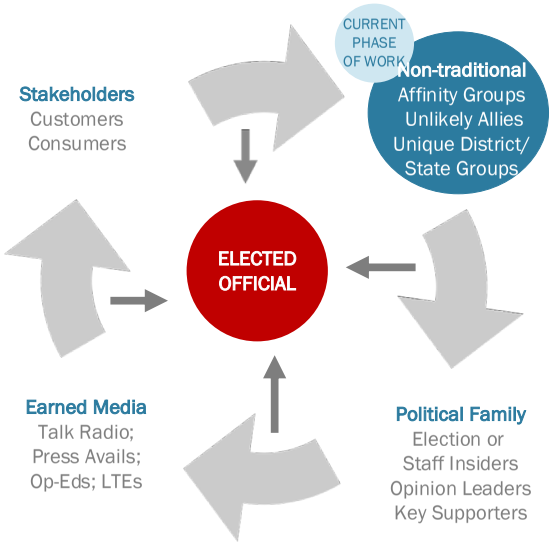
ADVOCATES DC

PCMA ADVOCACY
CALIFORNIA

SURROUND STRATEGY



MISSION CRITICAL ISSUES	CORE MESSAGES	TARGETED OPINION LEADERS	
AB315	PBMs reduce RX costs	Chambers of Commerce	Hispanic Groups
	Misguided transparency increases RX prices		
Transparency	Avoid anti-competitive transparency	Seniors	Local Elected Officials
	Giveaway to big drugmakers so they can charge more		

DISTRICT BY DISTRICT FOCUS

CURRENT FOCUS
Senator Hernandez
District 22
Chair, Senate Health Committee

CURRENT FOCUS
Senator Atkins
District 39
Senate President Pro Tempore

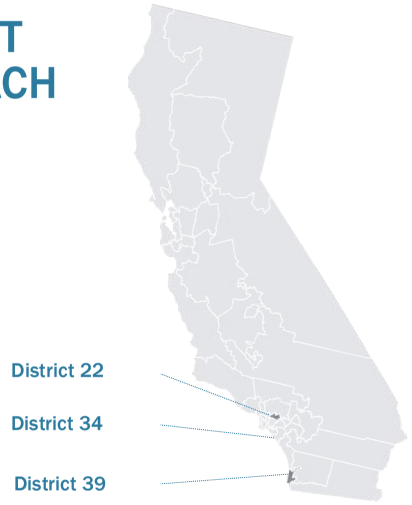
CURRENT FOCUS
Senator Nguyen
District 34
Vice-Chair Health Committee

ADVOCATES DC

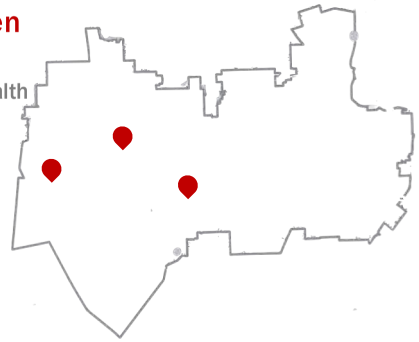
PCMA ADVOCACY ACTIVITY REPORT CALIFORNIA

YEAR-TO-DATE 2018

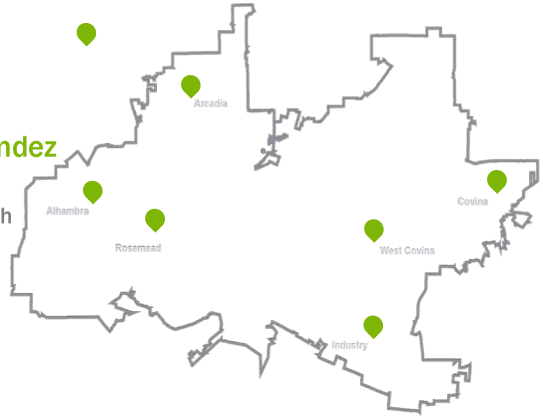
DISTRICT OUTREACH FOCUS



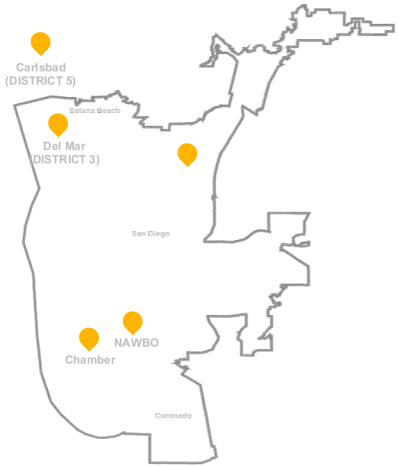
Sen. Janet Nguyen (District 34)
Vice-Chair, Senate Health Committee



Sen. Ed Hernandez (District 22)
Chair, Senate Health Committee



Sen. Toni Atkins (District 39)
Senate President Pro Tempore



HIGHLIGHTS

Sen. Ed Hernandez (District 22)

Letters to Sen. Hernandez
Signatories include Mayor of Covina and Hispanic elected officials from Rosemead

Third Party Outreach
to Chambers in Arcadia, Alhambra & Hispanic; Mayors of Industry, Rosemead and West Covina; Santa Clarita Veterans Cooperative and Santa Clarita Signal

HIGHLIGHTS

Sen. Toni Atkins (District 39)

Outreach to San Diego County Supervisors Kristin Gaspar (District 3) and Bill Horn (District 5), San Diego County Hispanic Chamber, Del Mar Chamber and National Association of Women Business Owners (NAWBO)

HIGHLIGHTS

Sen. Janet Nguyen (District 34)

Outreach to Orange County Supervisors Andrew Do (District 1) and Michelle Steel (District 2), State Senator Janet Nguyen (District 34), Veterans and Senior Citizens.

ADVOCATES DC

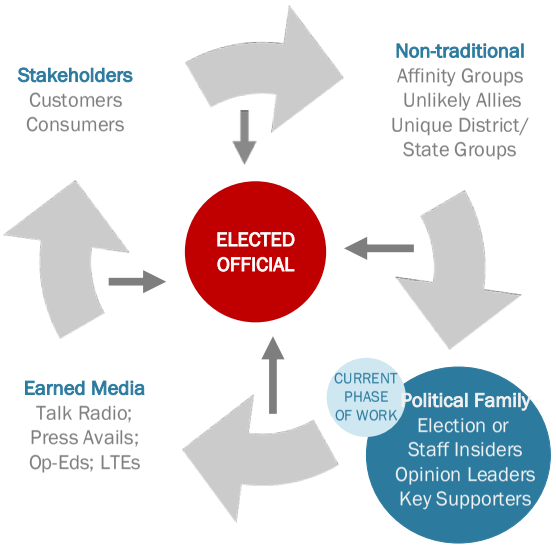
PCMA ADVOCACY KENTUCKY

EARNED MEDIA

Conservative Blog Post:

"Let the private market do what it does best"

SURROUND STRATEGY



MISSION CRITICAL ISSUES	CORE MESSAGES	TARGETED OPINION LEADERS	
SB5	Violates Republican Ideals	Free Enterprise Organizations	Chambers of Commerce
Transparency	Big Government Handout	Ideological Republican Activists	Trade Associations
	Increases Costs	Center Right Groups	Local Elected Officials

NOTABLE QUOTES

To KY Senate leadership by phone:

"What the Hell are you guys thinking?"

To KY Senator:

"KY can't afford to do this without passing the cost to taxpayers"

To Trusted Political Family Member at face-to-face meeting:

"My job description is to not raise the budget in this state by $1"

ADVOCATES for DC

PCMA ADVOCACY ACTIVITY REPORT
KENTUCKY

YEAR-TO-DATE 2018

JANUARY

3
Legislators Contacted

FEBRUARY

103+
Legislative Contacts

MARCH - MAY

178+
Legislative Contacts

65
Key Policy Leaders

Highlights

Grasstops outreach to **Governor's Office** and **Senate Leadership**

Grasstops contacts with **Senate Majority Leader** and **Key Committee Chairs**

100 emails sent (10 grasstops emails to 10 Senate targets)

138+Legislators received infographic from grasstops allies: *"Senate Bill 5-Vote 'No'-Get the Facts on SB5"* (Heartland Institute)

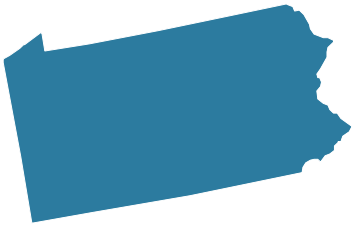
Grasstops letters to Senate leadership from: Eastern Kentucky Tea Party, Scott County GOP, Marshall County GOP, Jefferson County business owner, Jefferson County Tea Party, Montgomery County Tea Party, Fayette County GOP, Cato Institute

Association Executives: Presenting *"PBM 101"* Overviews

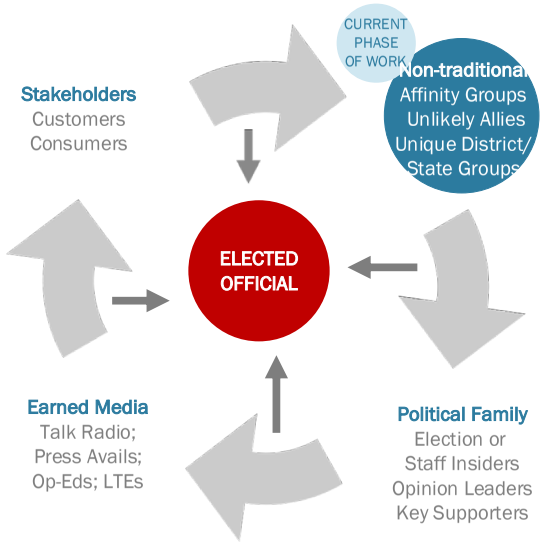
2 Kentucky Progress Blog Posts authored by David Adams: "Are Frankfort Republicans swallowing spiders?" and "Will Frankfort pit taxpayers against Amazon"

ADVOCATES DC

PCMA ADVOCACY
PENNSYLVANIA



SURROUND STRATEGY



FOCUS	CORE MESSAGES	TARGETED OPINION LEADERS	
EDUCATION	PBMs integral to Rx supply chain	Chambers of Commerce	Political Family
	PBMs increase Rx safety		
PBM 101	PBMs help improve health	Labor Unions	Non-traditional Allies
	PBMs reduce Rx costs		

TARGETED MEETINGS

PA General Assembly Leadership	PA Chamber Business & Industry	PA AARP
Chairs – Health, Banking, Policy Committees	PA Service Employees International Union (SEIU)	PA Farm Bureau
PA Department of Aging PACE/PACENET	PA Manufacturers Association	Political Family

PCMA

Affordable Pharmacy Action Network

2018
Overview

APAN
Affordable Pharmacy Action Network

2018 Overview

- APAN: Activated to oppose legislation/regulations that would reduce competition and raise Rx costs.
  - ✓ Arkansas
  - ✓ Kentucky
  - ✓ Illinois
  - ✓ California
  - ✓ Targeted Federal House/Senate Districts

- Tactical Elements:
  - ✓ Constituent phone calls
  - ✓ Strategic social media to raise awareness, drive opposition messages to key legislators.

PCMA

APAN Phone Calls to Elected Officials

- **Arkansas:** 800 phone calls from constituents to the governor and targeted legislators in opposition to the Arkansas Pharmacy Benefits Manager Licensure Act.
- **Illinois**: 1,650 calls to targeted legislators in opposition to HR 4146.
- **Louisiana:** 500 calls to Governor John Bel Edwards urging him to veto SB 29.
- **California:** Generated 901 calls to Governor Jerry Brown in opposition to AB 315.

Social Media: State Breakdown

Arkansas:

- 295,000 impressions via Facebook / Instagram / Twitter.
- 27,594 views of “Not Neighborly” video.
- 2,000 social media comments / shares.

Illinois:

- 713,841 impressions via Facebook / Instagram / Twitter.
- 2,760 social media comments / reactions / shares.

Kentucky:

- 35,000 impressions via Facebook / Instagram / Twitter.
- 899 reads of APAN blog posts.

California:

- 320,754 impressions via Facebook
- 3,071 social media commets / shares / reactions.

APAN Emails to Elected Officials

- **Illinois:** 602 emails to 101 different legislators, including 29 targeted senators and representatives.
- **Arkansas:** 605 emails to 112 different legislators, including the governor and 17 targeted senators and representatives.
- **California:** 548 emails to Governor Jerry Brown in opposition to AB 315.

PCMA Advocacy Materials

Just the Facts: A PBM-Pharmacy Snapshot

Pharmacy Benefit Managers (PBMs) work with pharmacies across the country to provide prescription drug benefits to more than 266 million Americans with health coverage through large employers, health insurers, labor unions, and federal and state-sponsored plans.

PBMs Help Reduce Drug Costs

PBMs work to keep drug costs down for consumers, increase access, and improve outcomes. Between 2016 and 2025, PBMs are positioned to save the Commonwealth of Pennsylvania $28.45 billion amongst the state Medicaid program ($1.5 billion), Medicare Part D ($12.5 billion), and Commercial Insurance ($14.3 billion).[1] PBMs reduce costs by:

- Encouraging the use of generics and affordable brand medications;
- Reducing waste while increasing adherence to improve health outcomes;
- Creating networks of affordable, high-quality pharmacies, including offering home delivery of medications and access to high-value specialty pharmacies, which will save Pennsylvania consumers, employers and other payers $14.88 billion over 10 years;[2]
- Negotiating price concessions from manufacturers and discounts from drugstores; and
- Providing clinical support services to patients who are taking specialty medications.

The Independent Pharmacy Industry in Pennsylvania Is Strong

- As of January 2018, independent pharmacies comprised 38% of the pharmacy market in Pennsylvania, **one of the highest market concentrations in the region**.[3]
- Between 2010 and 2017, the number of independent retail pharmacies in Pennsylvania grew from 932 to 1,077, **an increase of 15.5%.** Nationally, the number of independents grew 12% over the same period. During this same time period, the number of chain retail pharmacies has decreased 2.3%.[4]
- According National Community Pharmacists Association data, over the past decade, gross profits have held steady at around 23%.[5]

[1] Visante "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers" 2016, available at: https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf.
[2] Visante, analysis of savings due to the use of specialty and mail service pharmacies, prepared for PCMA. (September 2014), available at https://spcma.org/wp-content/uploads/2015/11/Visante_PCMA_Mail_and_Specialty_Savings.pdf.
[3] NCPA 2017 Digest, http://www.ncpanet.org/newsroom/news-releases/2015/10/13/ncpa-digest-adherence-diversified-revenue-critical-for-community-pharmacies. "Region" includes Delaware (18.4%), District of Columbia (31.6%), Maryland (33.5%), (Virginia (23.4%), and West Virginia (42.9%).
[4] Quest Analytics analysis of NCPDP dataQ data, 2017.
[5] NCPA Digest.

Independent Pharmacies Have Significant Bargaining Clout

Independent pharmacies are not just mom-and-pop neighborhood businesses—they garner significant bargaining clout in negotiations with health plans and PBMs by hiring powerful pharmacy services administrative organizations (PSAOs).

- PSAOs represent 80% of independent pharmacies in the U.S.;[6]
- PSAOs represented or provided other services to as many as 28,000 pharmacies in 2012;[7]
- Individual PSAOs contract on behalf of as many as 5,000 pharmacies at one time;[8]
- They negotiate and contract with third-party payers on behalf of independent pharmacies, negotiating reimbursement rates, payment, and audit terms;
- They provide access to pooled purchasing power, negotiating leverage, and contracting strategies similar to those of large, multi-location chain pharmacy corporations;
- They provide inventory and back-office functions to improve pharmacy business efficiency; and
- PSAOs enable rural pharmacies to negotiate contract terms as effectively as pharmacies operating in urban areas with many competitors.

PBMs are regulated across the country, including Pennsylvania

- In 2016, the Pennsylvania General Assembly passed HB 946, which was sweeping PBM legislation that included:
    - PBM registration with the Pennsylvania Department of Insurance;
    - Restrictions on PBM audits of pharmacy activities; and
    - Rules around the use of Maximum Allowable Cost reimbursements.
- About half of the states in the US have enacted prohibitions on gag clauses in pharmacy contracts. **PCMA supports the patient paying the lowest possible price for their prescription drugs, and supports PA HB 2211, which prohibits gag orders in PBM-pharmacy contracts**.

[6] GAO, The Number, Role, and Ownership of Pharmacy Services Administrative Organizations. (January 2013). http://www.gao.gov/assets/660/651631.pdf.
[7] Id.
[8] Id.

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Any Willing Pharmacy (AWP) Policies Undermine Competition and Raise Costs

Health plans and pharmacy benefit managers contract with independent, chain, mail-order, and specialty pharmacies to provide patients with access to a range of high-quality pharmacies, while balancing savings for patients and payers. PBMs require pharmacies to compete on service, price, convenience, and quality to be included in preferred networks. Pharmacies that agree to participate in such arrangements are designated as "preferred," and become members of a preferred pharmacy network.

How preferred pharmacy networks provide value to patients and payers:

- ***Exclusivity.*** Pharmacies participating in a preferred network can count on a predictably higher volume of sales. Increased sales mean that the pharmacy can pass savings on to patients by setting lower product prices and/or lower dispensing fees—while still meeting its bottom line.

- ***Enhanced Level of Services.*** Plan sponsors typically require preferred pharmacies to deliver higher levels of service, (e.g., enhanced clinical review and management) and access (e.g., longer operating hours).

- ***Emphasis on Quality.*** Participating pharmacies are typically required to comply with quality of care factors measured by Medicare Star Ratings or recommendations from standard-setting bodies such as the National Committee for Quality Assurance (NCQA), URAC, or the Pharmacy Quality Alliance (PQA).

- ***Value-Based Innovation.*** Preferred pharmacy networks are more likely to participate in value-based care activities, such as those with accountable care organizations and preferred provider organizations, where services are rated on quality, cost, and efficiency factors.

- ***Reduction of Fraud, Waste and Abuse.*** Preferred networks enhance a plan sponsor's ability to exclude pharmacies that pose a higher risk of engaging in fraud, waste or abuse.

The utilization of pharmacy networks is growing and effective in driving down costs.

- Preferred networks are gaining traction among employer sponsored plans. In 2013, only 18 percent of these plans were using preferred networks**. By 2017, over half of all employer-sponsored plans were utilizing these exclusive networks.**[1]

- Restrictions on pharmacy networks would cost employers and commercial health plans **$35.56 billion between 2019 and 2028**,[2] diminishing their ability to offer quality health insurance to employees.

The FTC has found that AWP laws undermine competition and raise consumer prices.

According to the Federal Trade Commission, networks and selective contracting generate significant savings that are passed on to consumers in the form of lower premiums, lower out-of-pocket costs, and better services, while AWP laws lead to higher drug prices because:

- When a retail pharmacy "faces no threat of sales losses if it fails to bid aggressively for inclusion in the payers' networks," it has no incentive to offer its most competitive terms.

- Opening networks to any willing provider reduces the volume of sales for all network participants, ultimately resulting in smaller discounts.[3]

PBMs offer their clients a choice of selective networks as a way to reduce costs.

- A selective network provides plan sponsors a great degree of economic control over prescription fulfillment, while maintaining adequate access to pharmacies for members. A pharmacy will offer deep discounts, or a lower dispensing fee to participate in a more exclusive network due to increased volume of business.

- CVS Health found that its network programs have saved payers 4 percent on retail drug costs and that narrow networks tailored to plan sponsors' beneficiaries can reduce retail drug spending by 5-8 percent.[4]

- Express Scripts' clients saved 4.5 percent on pharmacy costs using networks with 20,000 pharmacies.[5]

AWP requirements are not needed to maintain consumer access to pharmacies.

- Proponents of AWP laws claim that these policies are needed to ensure patient access to retail pharmacies. The data tell a different story:

    - Today, consumers have unprecedented levels of access to retail pharmacies. **Since 2005, the number of retail pharmacies has increased 6,000 stores and currently stands at 63,000, and of that number over 23,000 are independent pharmacies.[6]**

    - According to Medicare, **90 percent of Medicare Part D Beneficiaries live within 5 miles of a retail pharmacy and in urban areas that number drops to only 1.1 miles.[7]**

- **Put simply, there is no evidence that consumer access to pharmacies is a problem. Preferred pharmacy networks benefit both plan sponsors and patients.**

[1] Adam Fein. (2018). *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.*
[2] Visante. (2015). *Increased Costs Associated with Proposed State Legislation Impacting PBM Tools.* Available at: https://www.pcmanet.org/increased-costs-associated-with-proposed-state-legislation-impacting-pbm-tools/.
[3] Federal Trade Commission. (March 7, 2014). Letter to the Centers for Medicare and Medicaid Services, Department of Health and Human Services.
[4] CVS Health (2016). "Made-To-Order Networks". Available at: http://investors.cvshealth.com/~/media/Files/C/CVS-IR-v3/reports/cvs-health-insights-executive-briefing-made-to-order-networks-october-2016.pdf.
[5] Joanna Shepherd. (2014). "Selective Contracting in Prescription Drugs: The Benefits of Pharmacy Networks." *Minnesota Journal of Law, Science & Technology.*
[6] Quest Analytics analysis of NCPDP data, January 2018.
[7] Adam Fein. (2018). *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.*

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PBM Disclosure Mandates Increase Prescription Drug Costs for Consumers and Payers

PBMs help lower the cost of prescription drugs for payers by negotiating deep discounts with drug manufacturers and pharmacies. Private negotiation drives competition among manufacturers, yielding savings that benefit consumers and payers. If health plans and PBMs were required to publicly disclose these negotiations, the cost savings generated for consumers and payers would be at risk.

National Impact of PBM Disclosure Mandates

- Legislation requiring public disclosure of PBM price concessions with manufacturers and pharmacies would increase commercial plan drug spending by 4.3 percent, or $53 billion, over the next 10 years.[1]

- Mandatory disclosure of proprietary information would likely lead to a compression in rebates, weakening the power of large program sponsors to extract large discounts for beneficiaries.[2]

- In the current marketplace, contract negotiations between PBMs, manufacturers, and pharmacies are like sealed-bid auctions: manufacturers and pharmacies are encouraged to offer aggressive price concessions since they don't know what's being offered by their competitors.

Public Disclosure Mandates Will Curb Competition Among Manufacturers

- The Federal Trade Commission (FTC) has warned that "whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely. The FTC concluded that PBM disclosure mandates could "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[3]

- The Congressional Budget Office, in analyzing the potential effect of potential transparency rules in Medicare, said that "[f]or a range of medical conditions, drugs appropriate for treatment are available from only a few manufacturers; [and thus] disclosure of drug-by-drug rebate data in those cases would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices."[4]

PBM Disclosure Mandates Will Not Benefit Consumers or Plan Sponsors

- PBM clients—large employers, health plans, and government programs—are sophisticated purchasers. When negotiating with PBMs, clients determine the level of disclosure and reporting they desire from their PBM and whether rebates will be part of the compensation structure.

- Today, almost half of all commercial plans elect to pass through 100 percent of manufacturer rebates, while some choose to retain a certain portion in exchange for lowered administration fees.[5] On average, PBMs pass through about 90 percent of rebates to their clients.[6] PBM clients always have the final say over both the plan benefit design and compensation structure for their PBM.

[1] Visante. (2018). "Increased Costs Associated with Proposed State Legislation Impacting PBM Tools." Available at: https://www.pcmanet.org/increased-costs-associated-with-proposed-state-legislation-impacting-pbm-tools/.
[2] The Moran Company. (2017). "Assessing the Budgetary Implications of Increasing Transparency of Prices in the Pharmaceutical Sector." Available at: https://www.pcmanet.org/wp-content/uploads/2017/04/Assessing-the-Budgetary-Implications-of-Increasing-Transparency-of-Prices-in-the-Pharmaceutical-Sector-04142017.pdf.
[3] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, July 15, 2005; Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, September 3, 2004.
[4] Letter from Peter Orszag, Director, Congressional Budget Office, to Reps. Joe Barton and Jim McCrery (March 12, 2007).
[5] Pharmacy Benefit Management Institute. (2017). "PBMI Research Report: 2017 Trends in Drug Benefit Design."
[6] Adam Fein. (January 14, 2016). "Solving the Mystery of Employer-PBM Rebate Pass-Through." Available at: http://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html.

Prescription Eye Drop Refills

Prescription Eye Drop Refill Limits

Patients suffering from eye diseases (such as glaucoma or chronic dry eye syndrome) may be prescribed topical liquid ophthalmic drugs, commonly known as "eye drops." Prescribers and pharmacists may advise on the proper amount of liquid that a patient should apply, but some patients, especially those with motor function issues or sight problems, may "miss" when applying a solution to their eyes, resulting in inadvertent product waste. As with most prescriptions, eye drop scripts are subject to refill limitations to ensure patients are receiving the right medicine at the right time, but in some cases, patients may need early refills. Although health plans have procedures in place for these situations, some states are considering legislation to require that health plans cover unlimited early refills for eye drops.

Medicare's Non-Binding Early Eye Drop Refill Guidance

In 2010, the Centers for Medicare and Medicaid Services (CMS) issued non-binding guidance on early eye drop prescription refills to Medicare Part D (prescription drug) plans. CMS recommends that Part D plans override early fill limits "when appropriate and necessary to prevent unintended interruptions in drug therapy."[1] CMS recommended that Part D plans:

- Permit refills at 70 percent of the predicted days of use (21 of 30 days);
- Ensure the same refill allowances regardless of dispensing channel (retail versus mail); and
- Permit prescribers to authorize even earlier refills for beneficiaries with particular need.

Mandating Early Eye Drop Refills May Not Improve Adherence

The California Health Benefits Review Program, which reviews health benefit mandates being considered by the legislature, reviewed a proposal to apply the Medicare eye drop refill standard to all health plans in the state.[2] The study found that there is "insufficient evidence to conclude that coverage of refills for topical ophthalmic products at or after 70% of the expected days of use would affect eye health."

Broad State Mandates Are Unnecessary

The Medicare population, for whom the CMS guidance was originally developed, consists of the elderly and disabled, who typically have more problems related to motor skills and mobility. Compared with the overall population, Medicare enrollees are more likely to have issues that cause eye drop overuse and spills. Since CMS issued this non-binding guidance years ago, Part D plans have voluntarily complied and have addressed most problems for patients in need of early eye drop refills. Additionally, many plans have voluntarily applied this or similar early refill standards to non-Medicare patient groups.

Requiring plans to provide all patients early access to eye drop refills without review or limitation could decrease the care with which patients approach taking their ophthalmic medications and possibly increase waste. For this reason, PCMA opposes broad state eye drop refill mandates.

[1] CMS Guidance Memo: "Early Refill Edits of Topical Ophthalmic Products," June 2, 2010. Available at: http://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovContra/Downloads/MemoEarlyRefillOpth_060210.pdf.
[2] California Health Benefits Review Program, "Analysis of Assembly Bill 2418: Prescription Drug Refills: A Report to the 2013-2014 California Legislature," April 25, 2014.

PCMA

Formulary Management: Ensuring Patient Access to Safe, Cost-effective Drugs

What is a formulary?

A drug formulary is a continually updated list of drugs that a health plan or pharmacy benefit manager will cover under a plan sponsor's pharmacy benefit, representing the current clinical judgment of healthcare providers who are experts in the diagnosis and treatment of a wide range of conditions. There are different types of formularies—open, closed, or tiered—and each type can be customized to meet a specific payer's objectives. **The primary purpose of the formulary is to optimize patient care by ensuring access to clinically appropriate, safe, and cost-effective drugs.**

How are formularies developed and kept current?

Formularies are developed by a payer's Pharmacy and Therapeutics (P&T) Committee, made up of primary care and specialty physicians, pharmacists, and other health care professionals. P&T Committee members must disclose and appropriately handle any conflicts of interest, and their identity is usually kept confidential to avoid undue outside influence. P&T Committees evaluate available clinical evidence to select the best drugs for various conditions. This review focuses ***only*** on clinical considerations, including medical literature, FDA-approved prescribing information and safety data, and current therapeutic use guidelines—***not*** economic or cost considerations.

P&T Committees meet on a regular basis, typically quarterly, to review recent developments, such as new drugs on the market and new safety or efficacy information for existing drugs. This regular P&T Committee review process helps prescribers and patients by recommending up-to-date prescribing guidelines and promoting clinical information for high-quality, affordable care. For example, P&T Committees would review the 46 new drugs and biologics and 80 first-to-market generic drugs as those approvals cleared the U.S. Food and Drug Administration in 2017.[1]

What are the benefits of formularies?

- Only safe and effective products are covered by payers and used by patients.
- Ineffective and/or high-cost drugs with less expensive alternatives will generally not be included.
- Use of the most effective drugs leads to fewer physician office or ER visits, improved outcomes for patients, and lower overall costs for patients and payers.
- Patients experience lower out-of-pocket costs and convenient availability of drugs.

Why does formulary management matter?

- The National Academies of Sciences, Engineering, and Medicine recommends **"expand[ing] flexibility in formulary design" as a strategy to improve the affordability of prescription drugs**.[2]
- Milliman examined legislative efforts to restrict payers' ability to make mid-year formulary changes that would limit coverage of or increase out-of-pocket costs for a specific drug, estimating that such legislation would increase drug costs in the fully-insured commercial market by approximately **$4.84 billion nationwide from 2017 through 2021**.[3]

[1] U.S. Food and Drug Administration. "Novel Drug Approvals for 2017," available at: https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm537040.htm.
[2] National Academies of Sciences, Engineering, and Medicine. (2017). *Making Medicines Affordable: A National Imperative*. Available at: http://nationalacademies.org/hmd/Reports/2017/making-medicines-affordable-a-national-imperative.aspx.
[3] Milliman, Inc. (2017). Estimated Cost of Potential "Frozen Formulary" Legislation: Fully-Insured Commercial Payer Impact, 2017-2021. Available upon request.

America's Independent Pharmacies: Profitable, Stable, and Resilient

Independent pharmacies generate billions in profit, and owners often own multiple outlets.

Independent pharmacies rank among America's most profitable small businesses. With more than 23,000 stores nationwide,[1] the independent pharmacy industry generates **$80 billion in sales** and more than **$17 billion in gross profits** annually.[2]

Over the past 15 years, the number of independent pharmacies has remained relatively stable, despite significant economic headwinds in the broader economy and in health care specifically.[3] Many independent pharmacy owners operate multiple pharmacies: 29 percent of independent pharmacy owners have ownership in two or more pharmacies, and the average number of pharmacies in which each independent owner has ownership is 1.96.[4]

Decade-long trend points to stable, double-digit independent pharmacy margins.

According to the National Community Pharmacists Association (NCPA), the trade group representing independent pharmacies, **"For the last 10 years, gross margins as a percentage of sales have remained in the 22 to 24 percent range."**[5]

On par with independent pharmacies, drug manufacturers' average profit as a percentage of revenues was 23.4 percent in 2016.[6] By comparison, pharmacy benefit managers (PBMs) had net profit margins of 2.3 percent in 2015."[7]

Do policymakers need to rescue the independent pharmacy?

NCPA has said that **"[i]ndependent community pharmacists have proven throughout the years that they are resilient and will modify and reinvent their practices to adapt to economic challenges."**[8] We agree—state legislatures do not need to create an unlevel playing field in the market for independent pharmacists, especially as prescription drug costs are increasing.

PBMs, hospitals, insurers, providers, and other parts of the health care system have evolved in response to changes in patient care, developments of new technologies, the advent of generic drugs, and the rise of pay-for-performance and value-based purchasing. So too must pharmacies, especially independent pharmacies, adapt to a changing marketplace and meet the needs of the 21st century patient and payer.

[1] Quest Analytics analysis of NCPDP data, January 2018.
[2] NCPA 2017 Digest.
[3] Adam J. Fein. *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2018.
[4] NCPA 2017 Digest.
[5] *Id.*
[6] Adam J. Fein, "Profits in the 2017 Fortune 500: Manufacturers vs. Wholesalers, PBMs, and Pharmacies," available at: http://www.drugchannels.net/2017/06/profits-in-2017-fortune-500.html.
[7] Neeraj Sood et al. "The Flow of Money Through the Pharmaceutical Distribution System," available at: https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/.
[8] NCPA 2017 Digest.

Maximum Allowable Cost (MAC) Lists: Driving Value for Generic Drugs

What is a MAC list?

Identical generic drugs can be made by multiple manufacturers, which sell them at different prices to pharmacies. A MAC list specifies the most a pharmacy benefit manager (PBM) will reimburse a pharmacy for a particular generic drug. PBMs set and regularly update MAC lists to reflect a market-based average acquisition cost of a well-run independent or chain pharmacy.

MAC lists encourage pharmacies to purchase generics at the lowest possible cost—driving competition among wholesalers and generic drug manufacturers—which ultimately provides value to health plan sponsors and consumers.

Who uses MAC lists, and why?

Both public and private payers use MAC lists to determine pharmacy reimbursement for generic prescriptions, including state Medicaid programs, Medicare Part D plans, unions, and 79 percent of private employer plans.[1]

Why? MAC lists help PBMs fairly compensate both independent and chain pharmacies while providing cost-effective drug benefits to payers.

How is MAC calculated?

Independent pharmacies[2] and chains buy drugs at different prices and terms from various wholesalers. PBMs are ***not*** involved in these transactions and have no insight into the prices that pharmacies pay.

To determine a fair reimbursement for the generic drugs that pharmacies dispense, PBMs survey market data to calculate the average cost for those drugs, including information from nationally recognized pricing reference services (e.g., Medi-Span), wholesalers, and drug manufacturers.

The resulting MAC reimbursement for a given generic drug product is established using that estimated market price while balancing the contractual requirements established by each unique pharmacy and plan sponsor.

- Each PBM develops and maintains its own confidential MAC lists using its own proprietary methodologies. Market pricing is reviewed on a regular basis, and MAC lists are adjusted and made available to pharmacies, typically at least every seven days.

What happens if a MAC list price doesn't cover the cost of a drug?

Like in any business, it is possible that a pharmacy's costs on every single product may not be fully covered by a consumer or PBM payment. Some drugs will cost more than the MAC price, and some will cost less, but overall, the MAC list should balance a pharmacy's profitability on generic drugs with the payer's desire not to overpay for drugs. PBMs have appeal processes that pharmacies may access to dispute MAC reimbursements in the event the MAC list was significantly out of sync with market fluctuations in price.

Why might a PBM have multiple MAC lists?

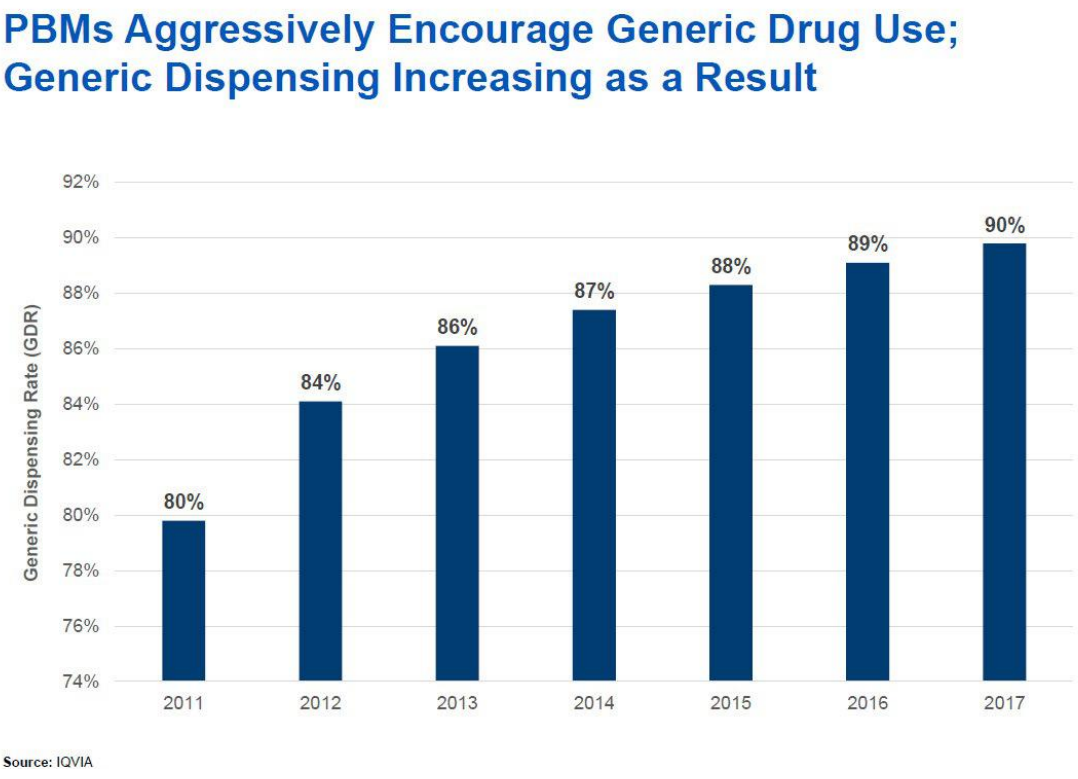
PBMs and their clients contract in different ways to meet individual plan needs, and PBMs' multiple MAC lists reflect those differences. For example, a large national employer would bring a larger volume of business to pharmacies than a small employer, and would thus have a different reimbursement list. A state employee/retiree health program may have different reimbursement objectives than commercial health programs or Medicaid. These varying objectives cannot be achieved with a single MAC list.

Why do MAC lists matter?

PBMs have helped drive generic dispensing rates to 90 percent,[3] yet generic drugs account for only 23 percent of drug expenditures, **saving U.S. consumers $265 billion**.[4] Given the volume of generic drug scripts, it is critical that generic drug prices remain low.

A 2015 analysis of more than 800 generic drugs found that legislative restrictions on MAC lists could:

- Increase costs by **31 percent to 56 percent** for affected generic prescriptions, and
- Increase drug expenditures nationally by up to **$6.2 billion** annually.[5]



[1] Express Scripts. (2016). Available at: http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx.
[2] Over 80 percent of independent pharmacies use large bargaining groups called pharmacy services administrative organizations (PSAOs), which are oftentimes owned by drug wholesalers, to provide access to pooled purchasing power, negotiating leverage, and contracting strategies similar to chain pharmacies. PSAOs negotiate and enter into contracts with third-party payers on behalf of independent pharmacies, providing independent pharmacies with significant bargaining clout in negotiations with payers.
[3] Association for Accessible Medicines. (2018). "Generic Drug Access & Savings in the U.S." Available at: https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_Access_and_savings_report.pdf.
[4] *Id.*
[5] Visante. (2015). *Proposed MAC Legislation May Increase Costs of Affected Generic Drugs By More Than 50 Percent*. Available at: https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pcma-mac-legislation-study-2015-update.pdf.

Mail-Service Pharmacies Are Safe and Provide Cost-Effective Patient Services

What Is a Mail-Service Pharmacy?

Many pharmacy benefit managers (PBMs) operate mail-service pharmacies, which are a convenient option for patients to have their prescriptions delivered safely and securely, straight to their doors. Here's how they work:

The patient goes to their local drugstore for a new prescription

The patient fills several 30-day prescriptions at the local drugstore

Once stabilized, the patient will use home delivery for maintenance drugs

Mail-Service Pharmacies Enhance Patient Access to Medications and Care Management.

- Pharmacists and customer service representatives are available to help patients 24 hours a day, seven days a week, and can counsel patients on affordable medication options and answer any questions they have concerning their prescription.
- For vulnerable populations like the homebound and elderly, mail-service pharmacies provide a convenient way to access medications. Translation services are available in many languages and accessibility options are available for the hearing impaired.
- The technological and workflow advances in mail-service pharmacies allow pharmacists to focus on clinical management, rather than basic prescription processing.

Mail-Service Pharmacies Put Patient Safety First and Improve Health Outcomes.

- Before any prescription is dispensed and shipped, mail-service pharmacies electronically screen the patient's comprehensive prescription profile to detect any potentially harmful drug reactions and interactions—even when the consumer has previously used several pharmacies or seen multiple providers.
- A seminal study by the U.S. Department of Defense found that highly automated mail-service pharmacies dispensed prescriptions **with 23-times greater accuracy than retail pharmacies.** The mail-service error rate was zero in several of the most critical areas, including dispensing the correct drug, dosage, and dosage form.[1]
- A 2014 *Health Affairs* study found that patients who received their medications through home delivery were more likely to adhere to their prescribed regimen and experience improved health outcomes, preventing extra visits to the doctor's office and unnecessary emergency room visits.[2]

The Bottom Line: Patients Benefit from Mail-Service Pharmacies.

- Mail-service pharmacies are able to generate significant savings for consumers and payers because of their unmatched efficiency compared to brick-and-mortar pharmacies. Payers choose to have mail-service pharmacies as a part of their pharmacy networks.

- Mail-service pharmacies are able to keep prescription drug costs down because they have greater efficiency and lower overhead costs than retail pharmacies. Through the use of computer-controlled quality processes, robotic dispensing machinery, and advanced workflow practices, mail-service pharmacies are able to fill large quantities of prescriptions—improving quality and reducing costs.

- The Centers for Medicare and Medicaid Services (CMS) studied drug costs at retail and mail-service pharmacies. **The CMS study showed that drug costs were 16 percent lower at mail-service pharmacies compared to brick-and-mortar drug stores.**[3]

- Health plans and PBMs often incentivize patients to use mail-service pharmacies by providing lower copayment options for 90-day supplies of maintenance medications.

- Mail-service pharmacies promote the use of generic drugs, which are equally effective as brand medications but have lower copays. **Research shows that the generic substitution rate is higher for mail-service pharmacies compared to retail drugstores, which translates into lower costs for payers and lower overall benefit costs.**[4]

- In addition to cost savings, research shows that patients who receive their medications by mail adhered to their prescribed regimen more often than those who picked up their medications from a traditional drugstore. Medication adherence leads to reductions in other healthcare spending, like extra visits to the doctor and re-hospitalizations.[5]

- Restrictions on the use of mail-service pharmacies take choices away from patients and force one-size-fits-all copayments.

[1] Office of the Inspector General, Department of Defense. (2013). *TRICARE Mail Order Pharmacy Program Was Cost Efficient and Adequate Dispensing Controls Were in Place*, available at: http://www.dodig.mil/reports.html/Article/1118953/the-tricare-mail-order-program-was-cost-efficient-and-adequate-dispensing-contr/.
[2] Niteesh K. Choudry et al. (March 2014). *Health Affairs.* "Five Features Of Value-Based Insurance Design Plans Were Associated With Higher Rates Of Medication Adherence."
[3] Centers for Medicare & Medicaid Services. (December 2013). "Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies," available at: https://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovGenIn/Downloads/Negotiated-Pricing-Between-General-Mail-Order-and-RetailPharmaciesDec92013.pdf.
[4] Visante. (2014). "Mail and Specialty Savings," available at: https://www.pcmanet.org/wp-content/uploads/2016/10/visante-pcma-ca-mail-specialty-savings.pdf.
[5] OK Duru et al. (2010). *The American Journal of Managed Care*. "Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications."

Medication Synchronization: "One Size Fits All" Doesn't Work

What is medication synchronization?

Medication synchronization allows a pharmacist to dispense all of a patient's prescription drugs on the same refill cycle. All new prescriptions are initially filled on a partial basis until they are synchronized with the existing medications, allowing all of a patient's prescription drugs to be dispensed on the same day throughout the year. For some patients suffering from chronic illnesses, medication synchronization may be a useful tool to promote long-term medication adherence.

Appointment-based medication synchronization requires patients to make an appointment each month to pick up their prescriptions, but patients can request or waive counseling with a pharmacist to review their therapies. Advocates for this approach claim that it will improve patient adherence to their drug regimens. Medication synchronization increases customer loyalty to the sponsoring pharmacy—increasing pharmacy revenues and lowering its operating costs.

Medication synchronization is not appropriate for most patients.

Medication synchronization may make sense for patients with several chronic conditions who take multiple drugs and have a high risk of medication error and overmedication. Most plans will accommodate a request for medication synchronization for a patient who needs it. It is not, however, appropriate for all patients, including those who:

- Have acute illnesses treated with short-term therapies;
- Take specialty drugs requiring more frequent monitoring;
- Are starting new therapies where medications and dosages are subject to change;
- Have interruptions in drug therapy due to hospitalization or long term care; or
- Need to spread the cost of multiple prescriptions over the course of the month.

Medication synchronization may enhance pharmacy, not customer, convenience.

- Information about these programs emphasizes the cost savings, potential for revenue enhancement, and staff convenience for participating pharmacies, not for consumers.
- Partial fills for new prescriptions may increase customer costs due to higher dispensing fees, or may disrupt patients' personal budgets if a large number of copays are due on the same day.
- Medication synchronization imposes severe limits on customer choice and convenience.
- The pharmacy benefit manager (PBM) or payer does not necessarily know how, when, or why the dispensing cycle has been adjusted, which can trigger red flags for fraud, waste, and abuse, especially without proper communication by the pharmacy.

Key principles to keep in mind when considering medication synchronization:

- Medication synchronization is a one-size-fits-all approach and has limited application in a diverse market for pharmacy services. It has not been shown to be cost-effective for consumers.
- Health insurers and PBMs need flexibility on whether to offer medication synchronization, and need to be able to make a note of the timing of medication synchronization in the event the patient needs it.
- Synchronization (and resynchronization) should be limited to once per year, unless necessitated by a change in patient health status. Frequent re-synching poses significant logistical and monitoring challenges and defeats the purpose of synchronization for patients.
- Drug therapies for chronic illnesses should be the focus of any synchronization plan.
- Prescription drugs for acute conditions and those that carry high risk for addiction and diversion, such as opioids, should be excluded from medication synchronization plans.
- Dispensing fees are part of contract negotiations between health plans, PBMs, and pharmacies and should not be part of any legislative package.
- Communication between PBMs and pharmacies is of utmost importance. The plan needs to keep a record of synchronization and understand the cycle of dispensing, so as not to raise red flags for fraud, waste, and abuse.

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How Pharmacy and Therapeutics (P&T) Committees Develop Formularies

A drug formulary is a continually updated list of drugs that a health plan or pharmacy benefit manager (PBM) will cover under a plan sponsor's pharmacy benefit. These formularies are developed, in part, by independent P&T committees, made up of physicians, pharmacists, and other clinical experts in the diagnosis and treatment of a wide range of conditions. P&T committees meet throughout the course of a year, often quarterly, to review and recommend formulary updates and consider drug coverage based on emerging scientific evidence and clinical standards of practice.

P&T committees establish and evaluate the safety, efficacy and therapeutic need for drugs.

- Selecting the right drug for the right diagnosis is the essence of efficient healthcare spending. P&T committees take on the complex task of evaluating the safety and clinical efficacy of thousands of competing drugs.

- Plan sponsors always have the final say over which drugs are included on the formularies offered to their employees or members.

Following safety and efficacy review, health plans and PBMs consider cost implications.

- After the P&T committee evaluates all drugs on the market, a health plan or PBM will then assign each covered drug to a reimbursement tier of the formulary, designing a plan that encourages the use of cost-saving generic drugs and the most cost-effective brand drugs.

- Plan sponsors hire PBMs to drive down the cost of the prescription drug benefit by aggressively negotiating price concessions with drug manufacturers. PBMs are in the best position to calculate the price differentials between competing drug therapies.

- Nearly all plan designs share some portion of drug costs with members using copayment or coinsurance. Plan designs with three or more tiers are selected by 85 percent of employers.[1]

- Plan designs often incentivize patients to using generic and lower-tier formulary drugs by requiring the patient to pay progressively higher co-payments for drugs on higher tiers. Cost-saving generic drugs on the lowest tier are the least expensive for the plan sponsor and consumer and sometimes have no copay or coinsurance.

- Health plans and PBMs have exceptions and appeals processes for patients to request coverage for non-formulary drugs where medically necessary and/or likely to create the best outcome.

Typical Configuration of Formulary Designs Selected by Plan Sponsors

Tier	Two-Tier Design	Three-Tier Design	Four-Tier Design	Five-Tier Design
First	Generic	Generic	Generic	Generic
Second	Brand	Preferred Brand	Preferred Brand	Preferred Brand
Third		Non-Preferred Brand	Non-Preferred Brand	Non-Preferred Brand
Fourth			Specialty	Specialty
Fifth				Lifestyle

[1] Pharmacy Benefit Management Institute, *2017 Trends in Drug Benefit Design Report.*

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Pharmacy Benefit Manager (PBM) Myths, Debunked

Myth: PBMs don't hold down drug costs.

PBMs work on behalf of their clients to bring down the cost of drugs by aggressively negotiating with drug manufacturers and pharmacies. While payers have faced significant headwinds—the price of brand prescription drugs increased 110 percent between 2012 and 2016[1]—**where PBM tools are used, net spending on prescription drugs declined by 2.1 percent in 2017**.[2] However, where PBM tools are not widely used, like hospitals and clinics, drug spending grew by 5.9 percent in 2017.[3]

Myth: Drug manufacturers raise their prices because of PBMs.

Drug manufacturers set drug prices. While PBMs negotiate with drugmakers to bring down the net cost of prescription drugs, manufacturers are ultimately responsible for the prices of their products. PBMs drive prices down by forcing manufacturers to compete with one another for formulary placement, but this happens only when there are competing drugs in the marketplace. A key tool in getting to the lowest net price is a rebate. There is no correlation between the prices drug manufacturers set and rebate levels. A recent study of the top 200 self-administered, patent-protected, brand-name drugs found **no correlation between the prices drugmakers set and negotiated rebates across 23 major drug categories**.[4]

Myth: PBMs contribute to waste in the drug supply chain.

Drug companies blame PBMs, employers, unions, and government programs for their high prices, but the fact is that they keep 67 percent of all prescription drug spending, while **PBMs retain less than 5 percent of prescription drug spend**.[5] For every $1 spent on PBM services, PBMs reduce costs by $6.[6] **On average, PBMs save payers and patients an average of $941 per person per year.**[7] PBMs save payers and patients 40-50 percent on their annual prescription drug and related medical costs compared to what they would have spent without PBMs.[8]

Myth: PBMs are threatening the viability of independent pharmacies.

According to the National Community Pharmacists Association (NCPA), **"For the last 10 years, [independent pharmacy] gross margins as a percentage of sales have remained in the 22 to 24 percent range."**[9] On par with independent pharmacies, drug manufacturers' average profit as a percentage of revenues was 23.4 percent in 2016. By comparison, PBMs had net profit margins of 2.3 percent in 2015.[10] NCPA has said, "Independent community pharmacists have proven throughout the years that they are resilient and will modify and reinvent their practices to adapt to economic challenges."[11] We agree—legislatures do not need to create an unlevel playing field in the market favoring independent pharmacists, especially as prescription drug costs are increasing.

Myth: PBMs aren't regulated.

Federal and state regulators have broad oversight over PBM activities. States may regulate PBMs through PBM registration or licensure, as third-party administrators, preferred provider organizations, and/or utilization review organizations. State boards of pharmacy regulate PBM-affiliated mail-order and specialty pharmacies and oversee generic substitution and biosimilar laws. State and federal governments also regulate PBMs indirectly through compliance requirements for insurers and employer-sponsored ERISA plans.

Myth: PBMs aren't transparent.

At the direction of plan sponsors, PBM contracts include disclosures and compensation models to ensure transparency. PBM contracts give clients the right to audit. Audits help ensure the integrity of the PBM contract and verify that the PBM is complying with contract terms. Auditors are able to follow claims through the system so that pricing and crediting of rebates can be confirmed. Clients determine how to use drug rebate dollars, and on average, **PBMs pass through more than 90 percent of drug manufacturer rebates back to clients**.[12]

Myth: Disclosing PBMs' confidential and proprietary information will benefit consumers.

The Federal Trade Commission (FTC) has stated that the public disclosure of pricing-related data could increase drug prices. If confidentiality protections are inadequate and "pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors…then tacit collusion among manufacturers is more feasible…**Whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely.**"[13] Publishing aggregate rebates raises the possibility that a sophisticated competitor can calculate price concessions for individualized drugs or plans even from aggregated data, which would raise the prices of drugs by distorting market dynamics.

Myth: The PBM market is anticompetitive.

As of 2017, **there are over 80 companies providing PBM services operating in the United States**, and this number has grown over the last 10 years.[14] PBMs design products and services that reach clients of varying sizes, with different patient populations and geographic reaches. In a 2012 study, the FTC found "a competitive market for PBM services characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders."[15]

Myth: PBM ownership of mail-order and/or retail pharmacies represents a conflict of interest.

The FTC examined PBM-owned pharmacies comprehensively and determined that there are not conflicts of interests between PBMs and their affiliated pharmacies.[16] PBMs disclose their ownership interests, if any, in mail-order, specialty, and retail pharmacies to their clients. These disclosures effectively manage potential conflicts of interest. Furthermore, clients have the final say on plan designs and pharmacy networks PBMs propose, which must also meet access standards set by plan sponsors and applicable state and federal laws.

[1]Health Care Cost Institute, *2016 Health Care Cost and Utilization Report*. (January 2018).
[2]IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*. (April 2018).
[3]Id.
[4]Visante. *No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories*. (April 2017).
[5]Nancy L. Yu, Preston Atteberry, Peter B. Bach. "Spending On Prescription Drugs In The US: Where Does All The Money Go?" *Health Affairs*, July 31, 2018.
[6]Visante. *The Return on Investment (ROI) on PBM Services*. (November 2016).
[7] *Id.*
[8]*Id.*
[9]NCPA 2017 Digest.
[10] Neeraj Sood et al. "The Flow of Money Through the Pharmaceutical Distribution System," available at: https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/.
[11] NCPA 2017 Digest.
[12] Fein, A.J. (2016, January 14). Solving the Mystery of Employer-PBM Rebate Pass-Through [Web log post]. Available at: http://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html.
[13] Id.
[14] Pharmacy Benefit Management Institute (PBMI) data, prepared for PCMA, 2017.
[15] Federal Trade Commission, "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc." FTC File No. 111-0210. April 2, 2012.
[16]Federal Trade Commission. *Pharmacy Benefit Managers: Ownership of Mail-order Pharmacies*, August 2005. Available at: https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.

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VOTE NO ON SB 283

SB 283 Will only Help Big PhRMA at the Expense of Louisiana Patients

- If the goal is to help Louisiana Patients, SB 283 is not the answer. Publicizing year old aggregated information on a PBMs' administrative fee for payment of services from a health plan or pharmaceutical manufacturer does not provide patients with any useful information as to what they will actually pay at the pharmacy counter. **In fact, revealing this information could adversely affect a PBMs ability to negotiate rebates with pharmaceutical manufacturers, leading to higher prescription drug benefit costs.**

- The percentage of rebates passed through from a PBM to a client is specific to the client contract. PBMs are transparent with plan sponsors on the services they receive in accordance with contractual requirements. On average, 90 percent of negotiated rebates from drug manufacturers are passed on to the plan sponsor, which is then used to lower overall health spending.[1] Some PBM clients receive 100% of the rebates collected by the PBM, but some clients choose to receive less than 100%, depending on the PBM-client contract. [2] PBM contracts also have audit clauses that ensure a client receives what they are entitled to in their contract**. The state has no business reporting information negotiated and contained in private contracts between health plans and their PBMs.**

- **Public reporting of "the highest, lowest, and mean aggregate retained rebate percentage" as required in Section C.(1)(d), could lead to tacit collusion amongst pharmaceutical manufacturers and higher prescription drug costs for patients.** The Federal Trade Commission (FTC) has stated that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and "[w]henever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely."[3] It would be fairly easy for a pharmaceutical manufacturer to back out the information. And again, how does the reporting of this information in any way protect or help consumers?

- **This special interest legislation only benefits Big PhRMA and will most likely result in higher drug benefit costs for Louisiana patients and health plans.**

[1] Written Testimony of Joanna Shepherd, Ph.D, Emory University for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure, June 19, 2014, Citing J. P. Morgan, "Pharmacy Benefit Management, Takeaways from Our Proprietary PBM Survey," May 21, 2014.
[2] Drug Channels, "Solving the Mystery of Employer-PBM Rebate Pass-Through," January 14, 2016. http://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html
[3] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).

Board of Pharmacy Regulation of PBMs

The Board of Pharmacy 'BOP' is clearly operating outside its legislatively endowed authority in attempting promulgate this rule.

- The legislature has passed no law authorizing the BOP to regulate PBMs; by contrast LDI received additional regulatory authority over PBMs in the 2018 legislation session.
- No state licensing board may regulate when the legislature hasn't specifically given it authority. Allowing the Board of Pharmacy "BOP" to regulate plan administration is akin to allowing the Board of Medicine to regulate health insurance plans.
- "Utilization management" is **NOT** the practice of pharmacy. These programs, as all "coverage decisions" in plan administration, are designed to determine which drug will be covered under the plan's benefit, not which drug is legally allowed to be dispensed to a patient pursuant to a prescription
- An Attorney General's opinion stated the BOP "might" be able to regulate.

US Supreme Court precedents differentiate "treatment decisions" made by licensed professionals from "coverage decisions" made by plan administrators.

- When a PBM administers the terms of a prescription drug benefit plan pursuant to a contract with a health plan client, its actions are contractually required and constitute "coverage decisions" and not the "practice of pharmacy." [1]

The Board invites antitrust litigation by promulgating this rule.

- The Board, as well as its individual members, are virtually assured to be subject to antitrust lawsuits by both private parties and the Federal Trade Commission 'FTC', under the Supreme Court decision in *North Carolina State Board of Dental Examiners.*[2] A private party or a government agency like the FTC can claim that any action by the Board—such as revoking a license, disciplinary action, or imposing regulations—is aimed at discouraging, deterring, or removing participants from the market.
- Pharmacists are market competitors with PBMs.
- PBMs have no representatives on the BOP.

Historically, PBMs are appropriately regulated as third party administrators by the Louisiana Dept. of Insurance (LDI).

- Consistent with the nature of the contractually-based, benefit administration functions of PBMs, the LDI has regulatory authority over PBMs. Pharmacy benefits are also reviewed for compliance with state requirements when the LDI undertakes market conduct investigations on health plans operating in the state.
- No other state BOP is attempting to exert this authority.

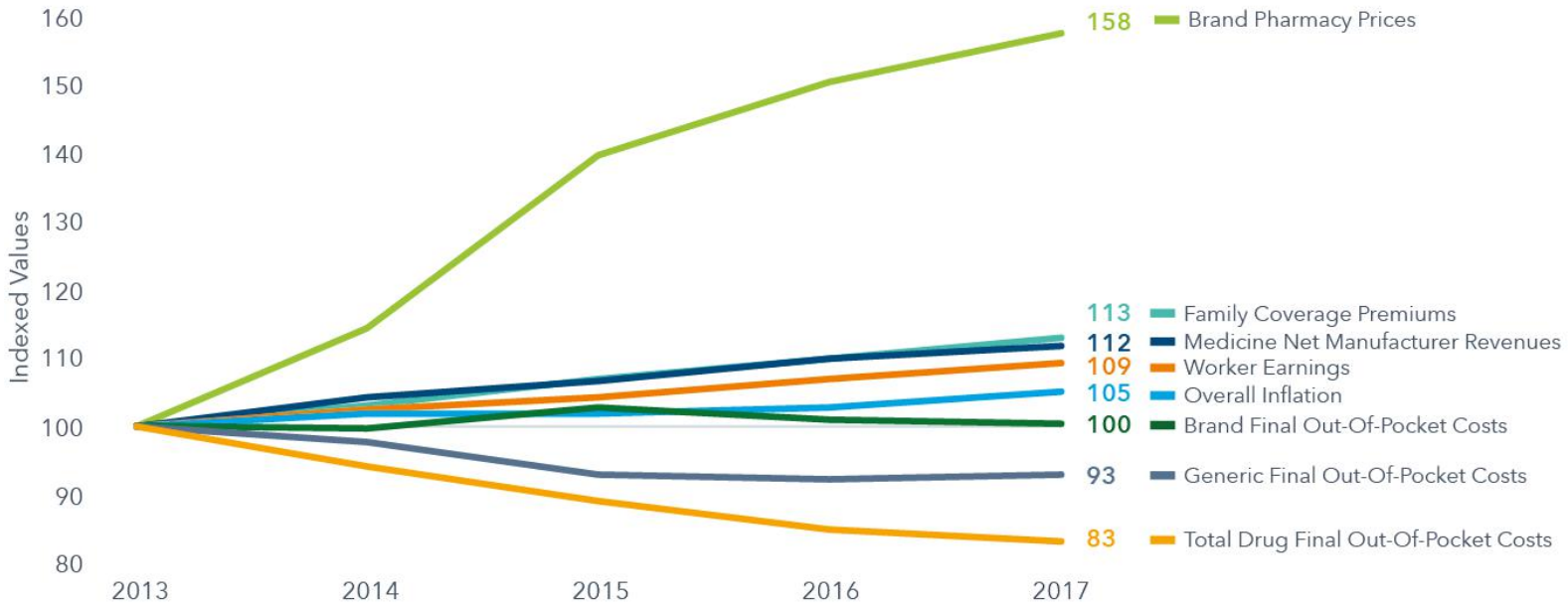
PBMs engage in pharmacy functions and are already appropriately licensed and regulated by the Board of Pharmacy.

- Mail-service pharmacies or specialty pharmacies operated by PBMs are appropriately licensed as out-of-state pharmacies and subject to BOP's enforcement protocols.

[1] *Pegram v. Herdrich*, 530 U.S. 211 (2000), in *Aetna v. Davila*, 542 U.S. 200 (2004)
[2] *North Carolina Board of Dental Examiners v. FTC* available at https://www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf

Brand Drug Prices Increased 58% 2013-2017

Changes in Healthcare Costs or Cost Drivers 2013-2017, Indexed (2013 Values + 100)



Source: IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018. Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2017; IQVIA Formulary impact Analyzer (FIA). IQVIA Institute, December 2017.

Chart notes: Indices sourced from Kaiser/HRET Employer Survey4 include: family coverage, premiums, workers earnings, overall inflation. Brand, generic and total final out-of-pocket costs and brand pharmacy prices are for commercially insured, Medicare Part D and cash payment types sourced from IQVIA Formulary Impact Analyzer. All charted values are indexed to set their 2013 value equal to 100.

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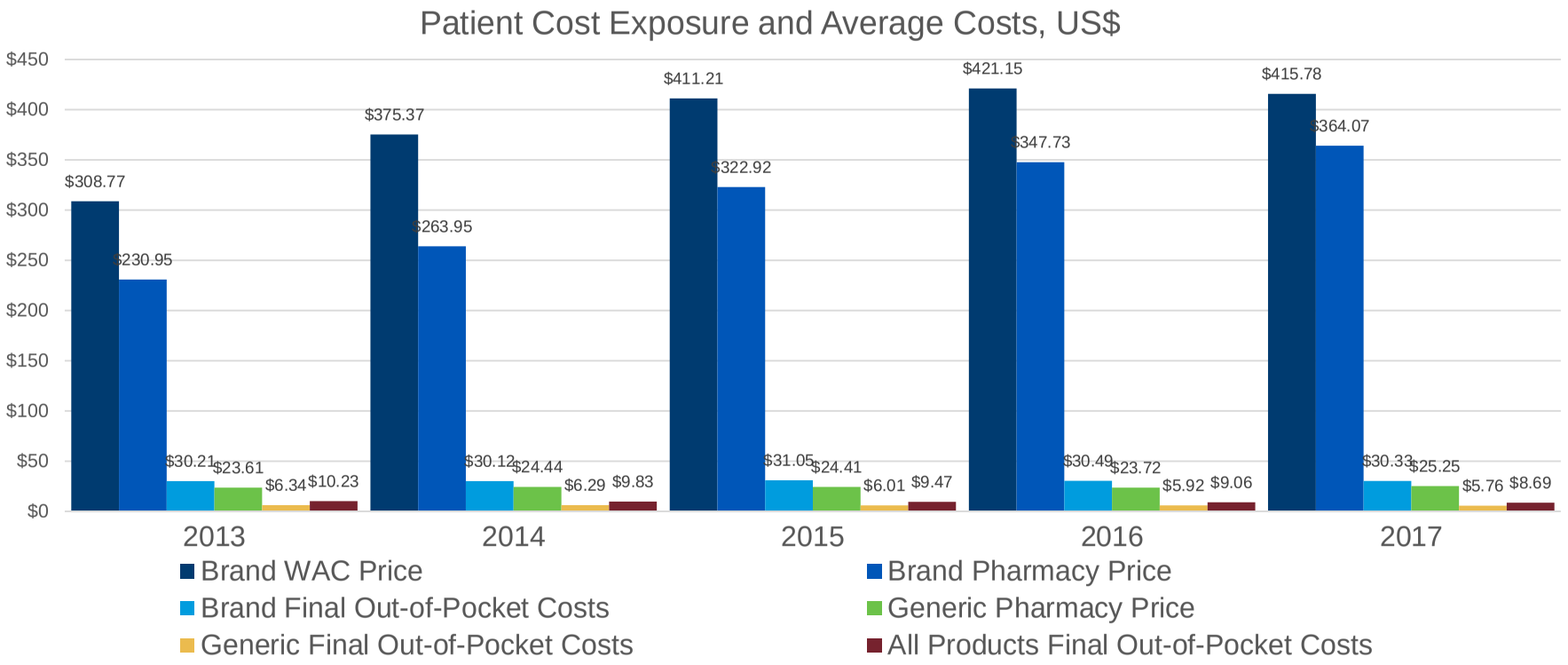
Patient OOP Rx Costs Steadily Decreasing

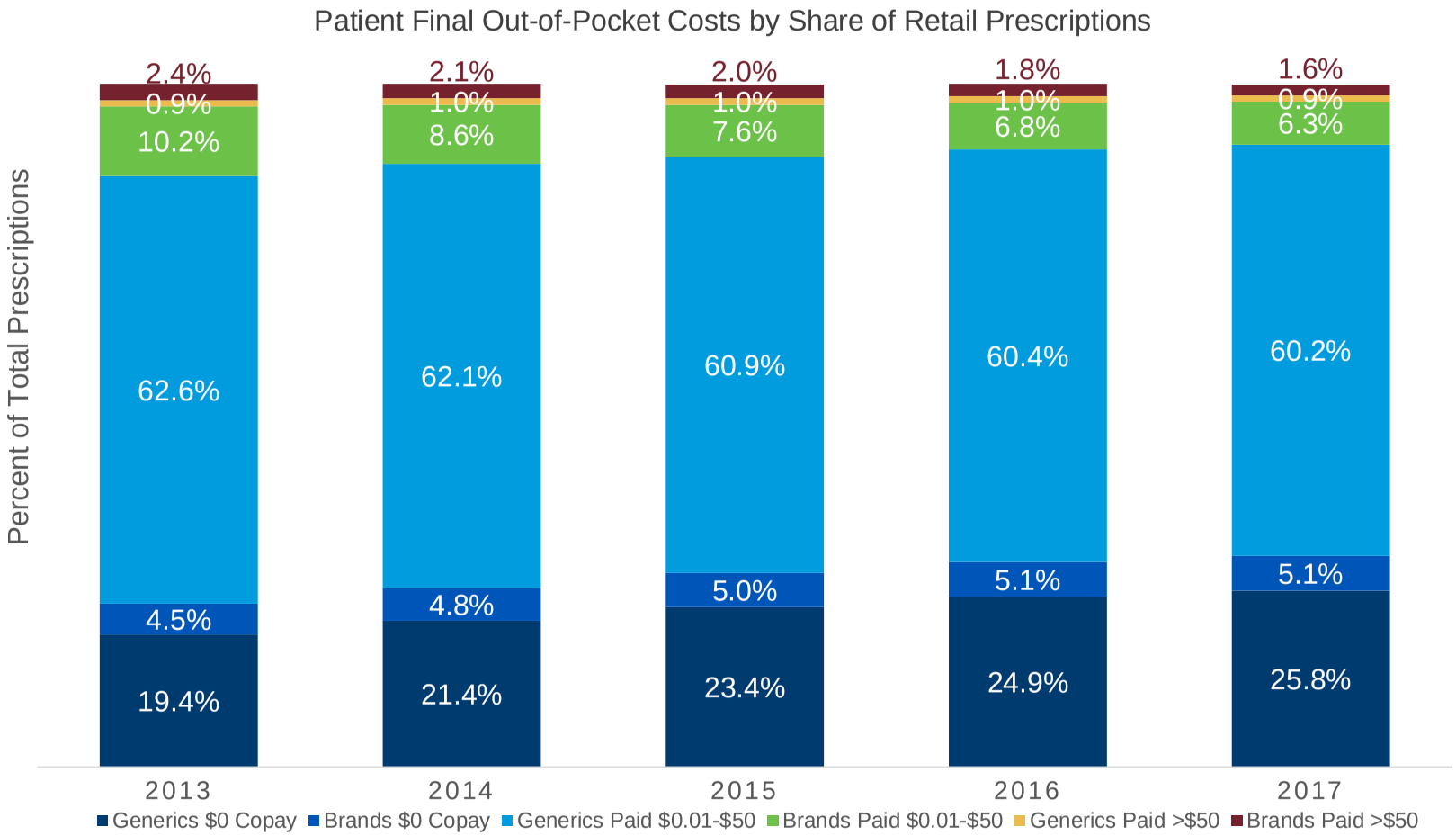


Source: IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018. Formulary Impact Analyzer (FIA). IQVIA Institute, December 2017.

Notes: Costs are normalized to 30-day prescriptions. Brand and generic pharmacy prices' cost exposure calculated using paid and reversed claims include the amount paid by the primary insurer and the amount of patient responsibility before the application of coupons. Brand WAC price is the Wholesaler Acquisition Cost and is often the most publicly available reference price. Final out-of-pocket costs are calculated as patient responsibility after the application of all applicable discounts and coupons.

PCMA

What Do Patients Pay at the Counter?

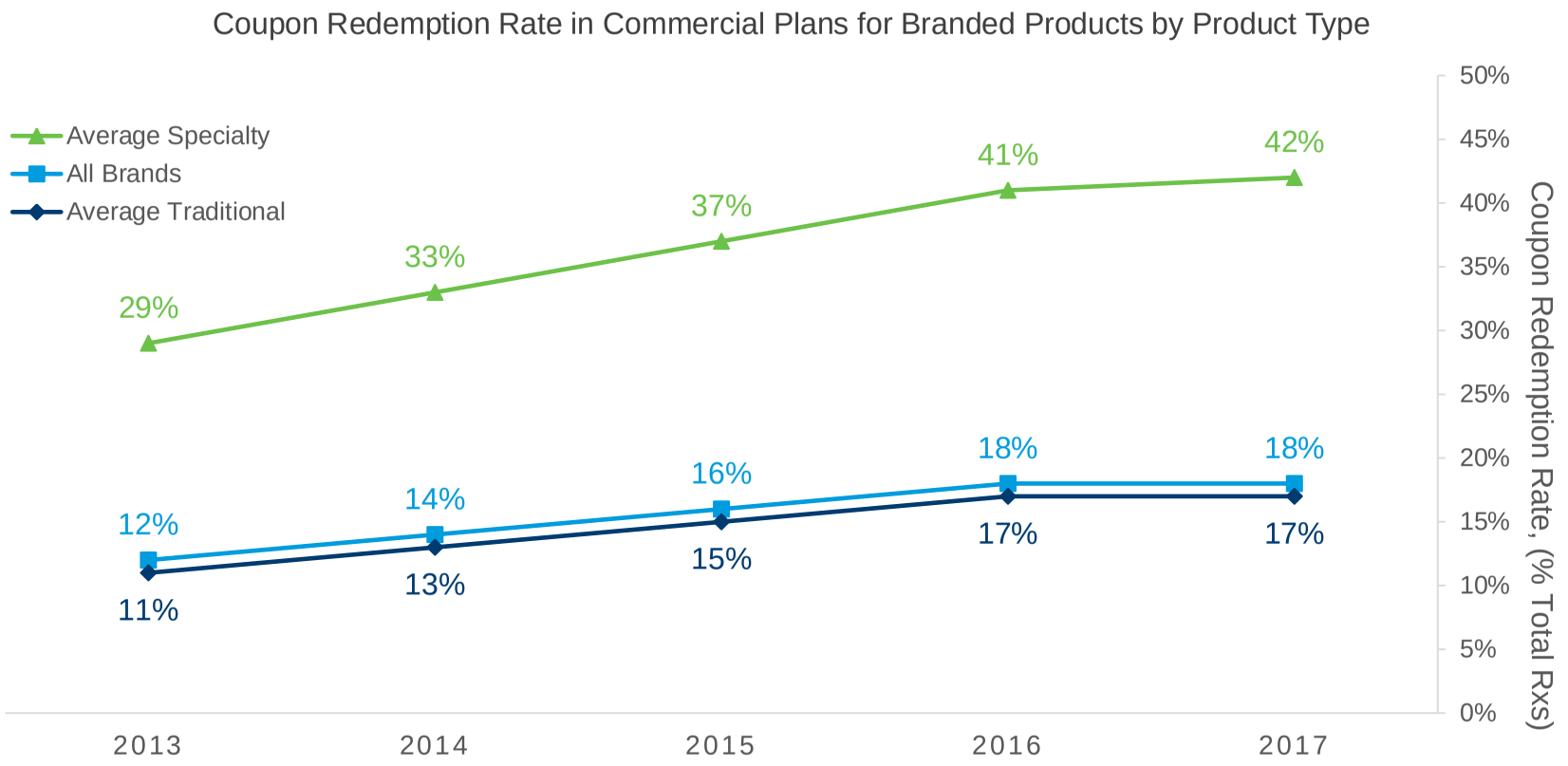


Source: IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018. IQVIA Formulary Impact Analyzer (FIA). IQVIA Institute, December 2017.

Notes: Costs exposure is calculated using paid and reversed claims, includes the impact of the coupon if applicable and is normalized to 30 days. Brand list price is calculated as the total of the primary payer paid amount plus primary copay amount.

PCMA

Drug Makers Are Flooding the Market with Copay Coupons

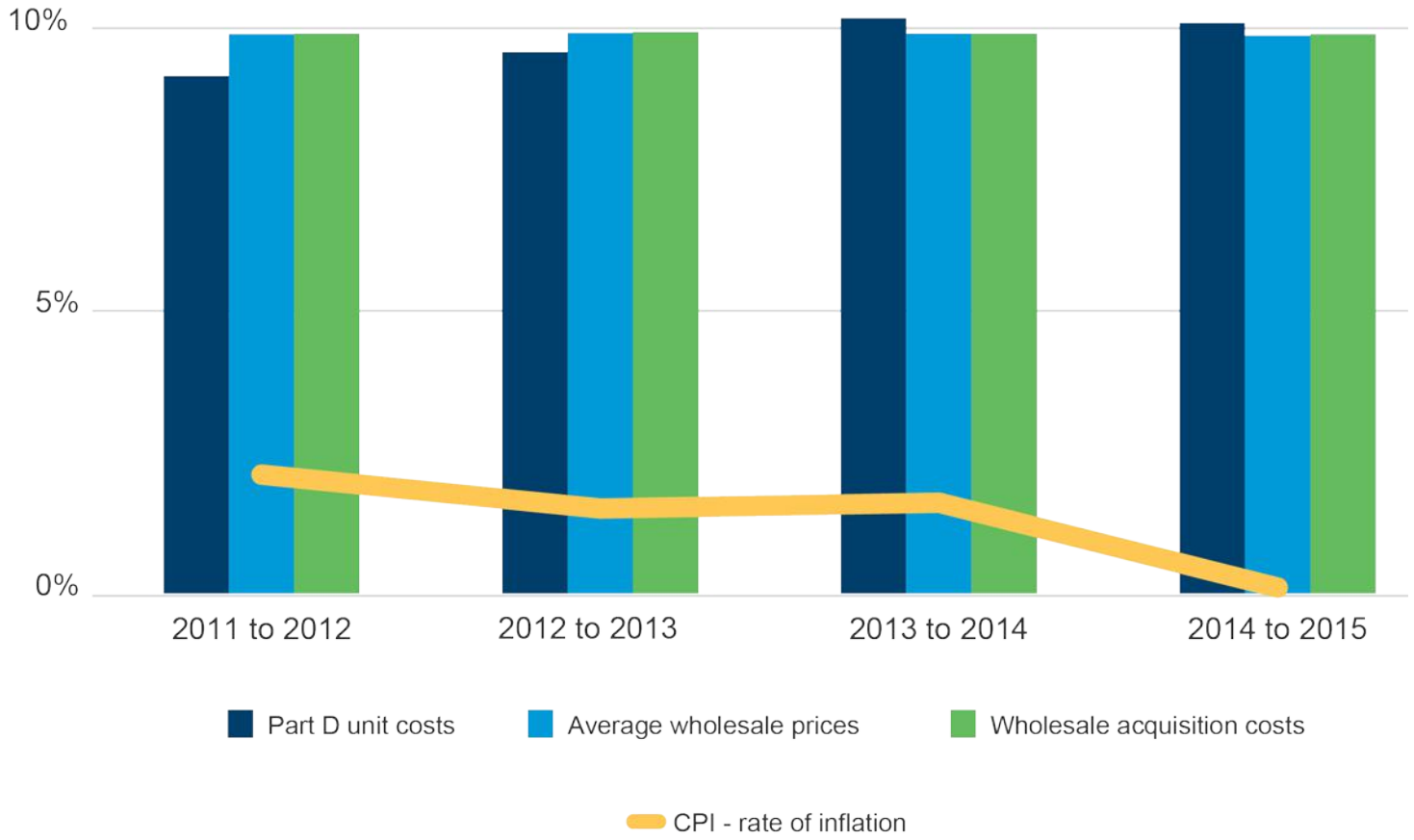


Source: IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, April 2018. IQVIA Formulary Impact Analyzer (FIA), January 2018.

Notes: Coupon penetration rate is based on commercially insured patients only, cash patients are excluded and Medicare/Medicaid are precluded by law from the use of coupons. Specialty therapy areas have significant volume through mail-order pharmacies, which are not included in this analysis.

PCMA

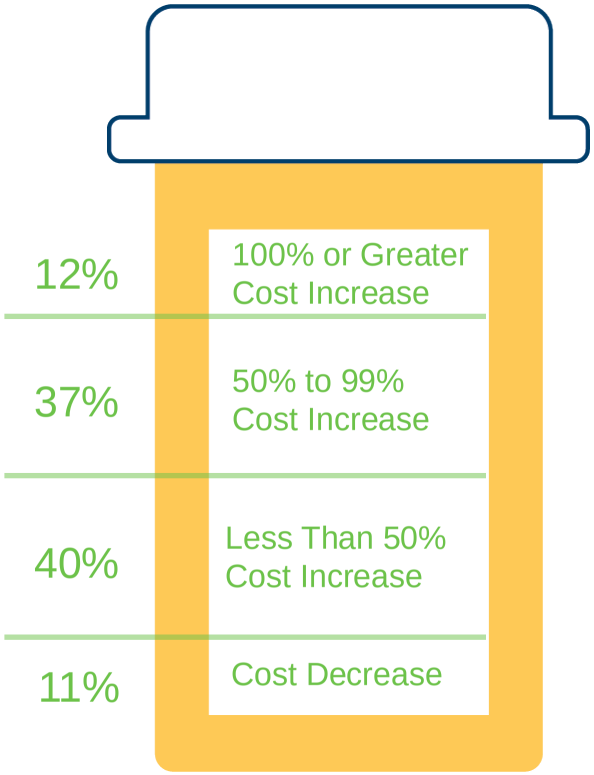
HHS: Part D Brand Drug Benchmark Price Increases Outpaced Inflation, 2011-2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

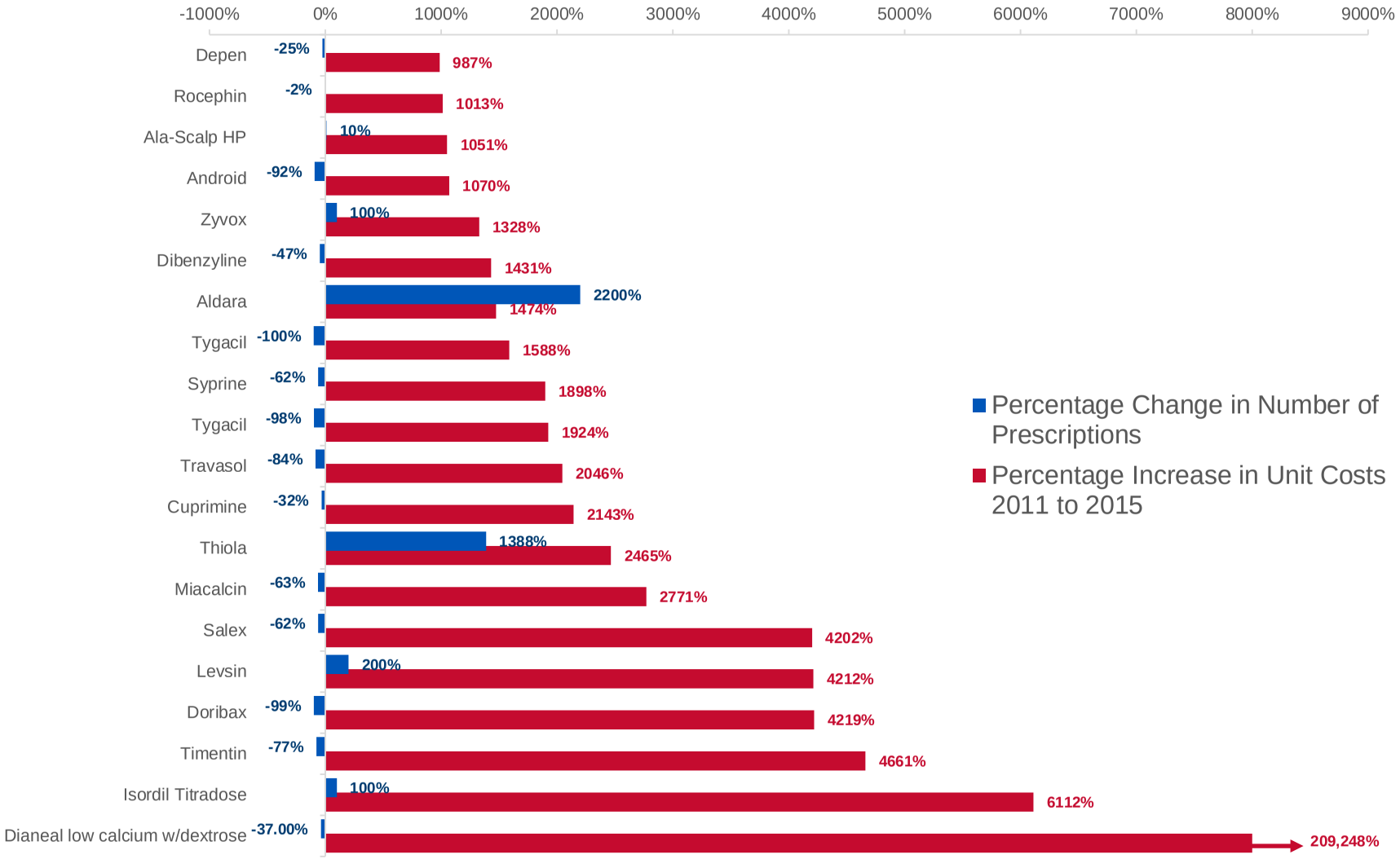
PCMA

HHS: 89% of Part D Drug Unit Costs Increased, 49% by Half or More, 2011-2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015.

Part D Top 20 Brand Drugs, 2011–2015



Source: OIG analysis of Medicare Part D data, 2011 to 2015. Note: Because of different package sizes or formulations, a drug name may appear multiple times.

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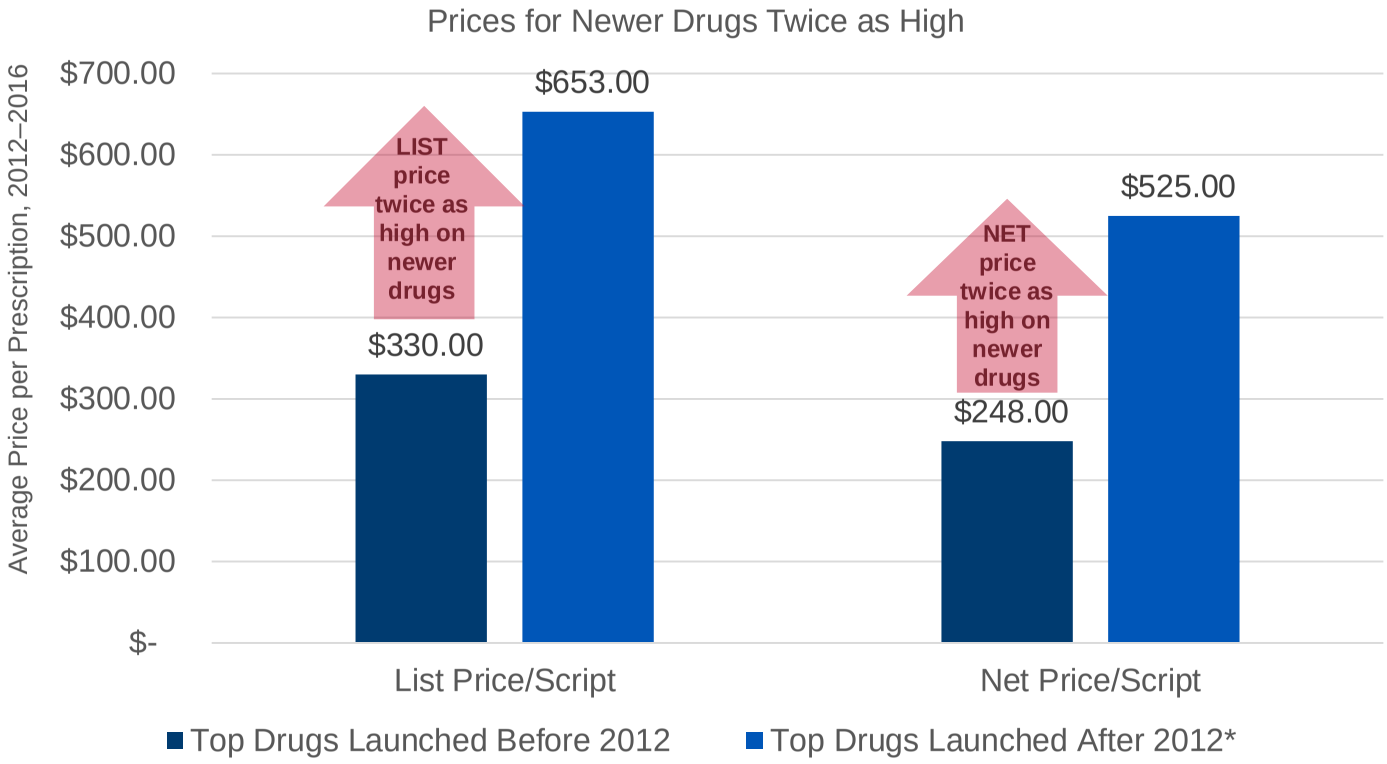
Prices for Top Brand Drugs Have Doubled Since 2012



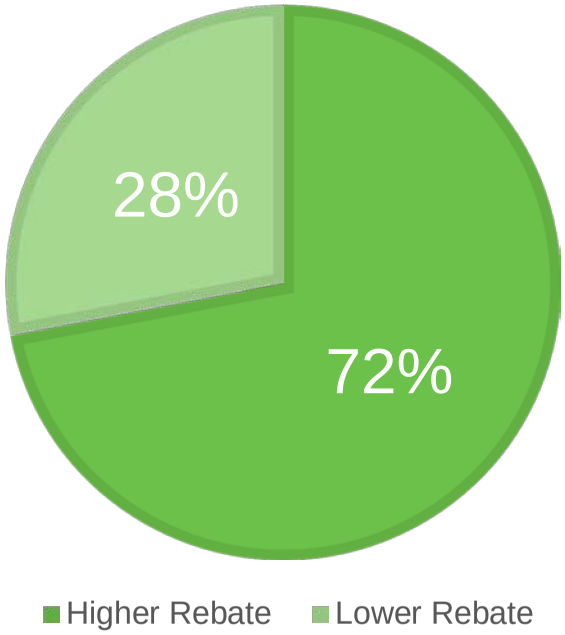
Source: Visante estimates and analysis of SSR Health data, 2017.

Note: Visante analyzed data on the top 200 drugs by 2016 gross sales. Visante examined list prices (WAC) and net prices (net of estimated rebate) during the period 2007-2016, where a category had only one drug, and then a second drug entered the category as a new competitor. Rebates for the new competitor in the category are usually more than the rebates for existing product, but the entry list price for the new competitor is often less than or equal to the existing product.

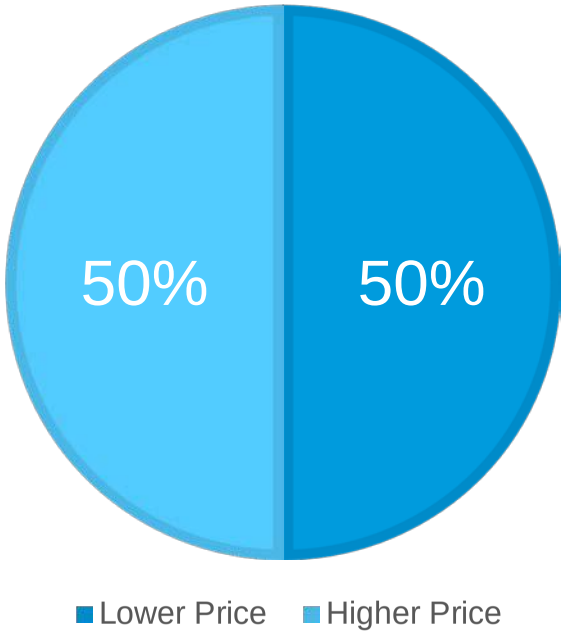
PCMA

Rebates Unrelated to Drug Launch Prices

Rebates for the second drug introduced into a competitive class are higher than the first drug's rebates **72% of the time**…



… but although rebates are often higher, the chance of the second drug having a higher price than the first drug is only **50%**.



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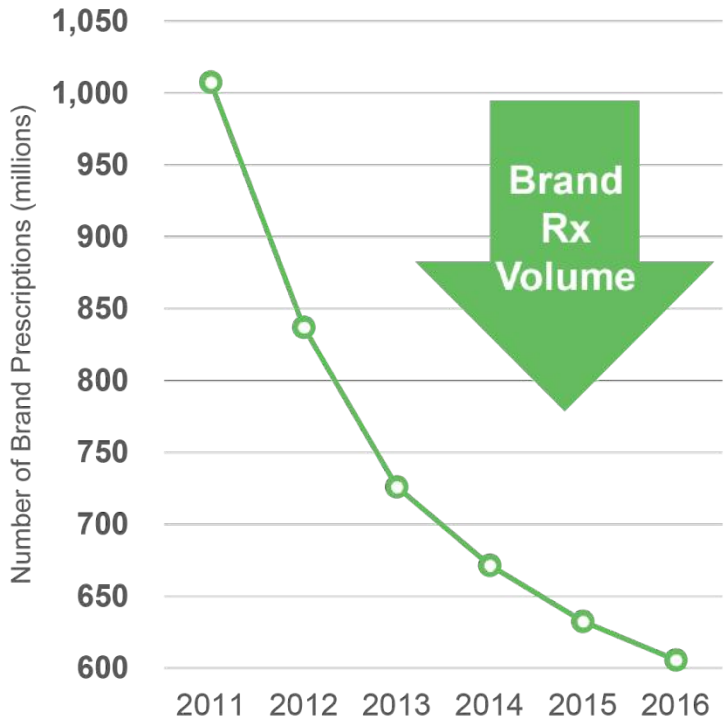
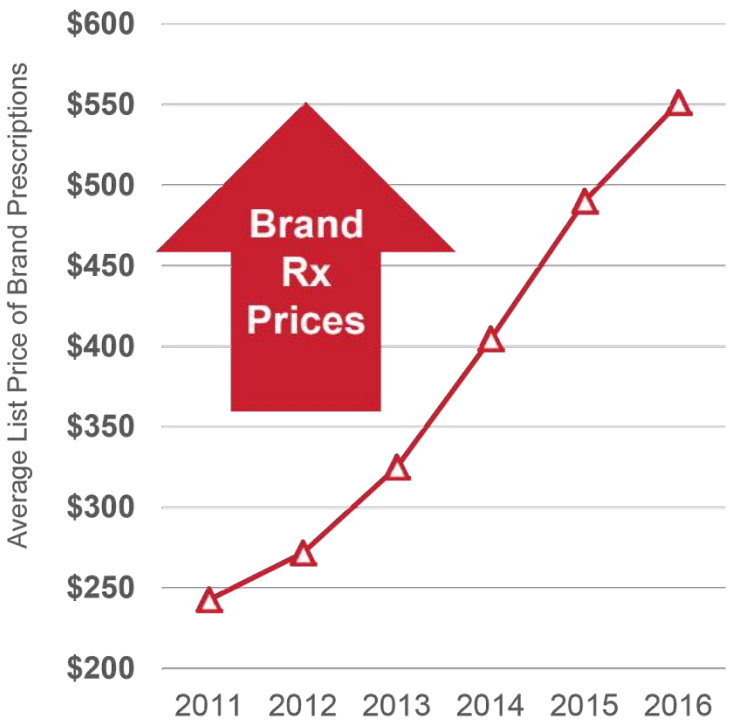
PCMA

Why Are Manufacturers Increasing Prices?

Brand prescription volume has plummeted as generics have replaced brands…



…In the meantime, brand drug prices have skyrocketed to maintain revenues.

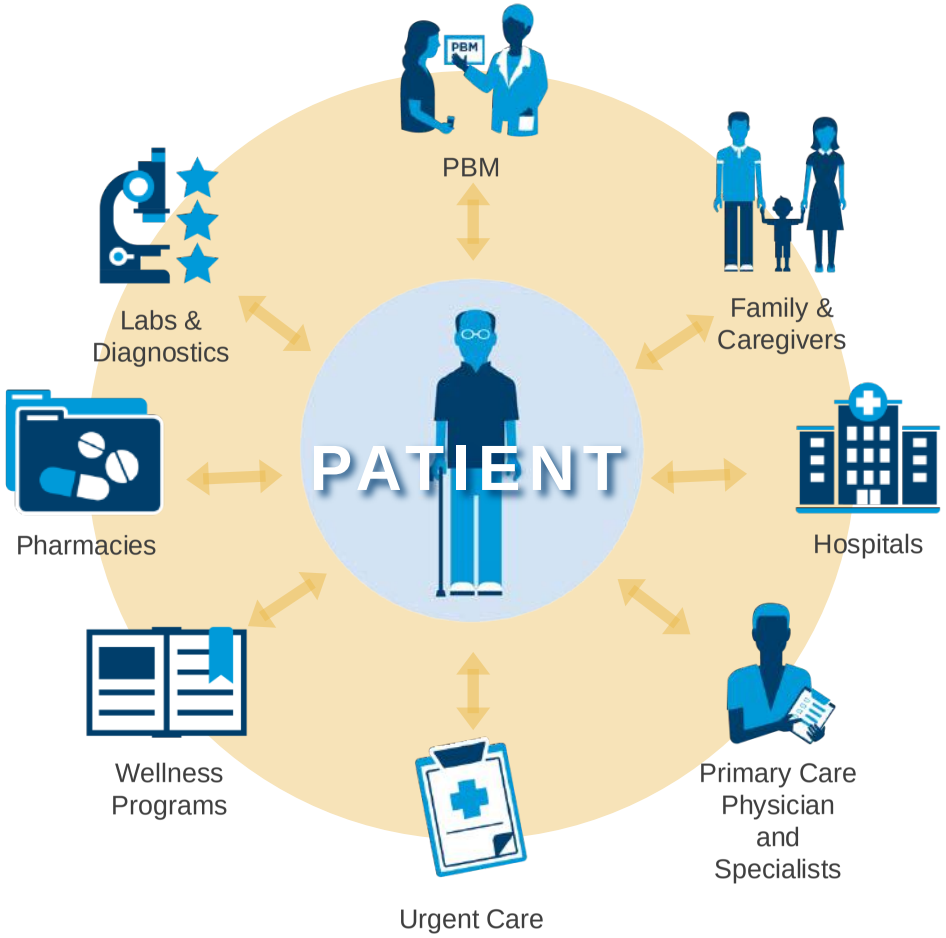


Source: Visante analysis data published by the QuintilesIMS Institute, 2017.

PCMA

PBMs: A Crucial Part of an Integrated Care Management Model

INTEGRATED CARE DELIVERY: Individualized. Proactive. Connected.



Drug Wholesalers Own 3 Largest PSAOs

- Over 80% of independent pharmacies belong to pharmacy services administrative organizations (PSAOs), which provide a range of services, including: negotiating third-party payer contracts, providing access to pooled purchasing power/inventory, and back-office functions.
- PSAOs give independent pharmacies significant bargaining clout in negotiations with payers.

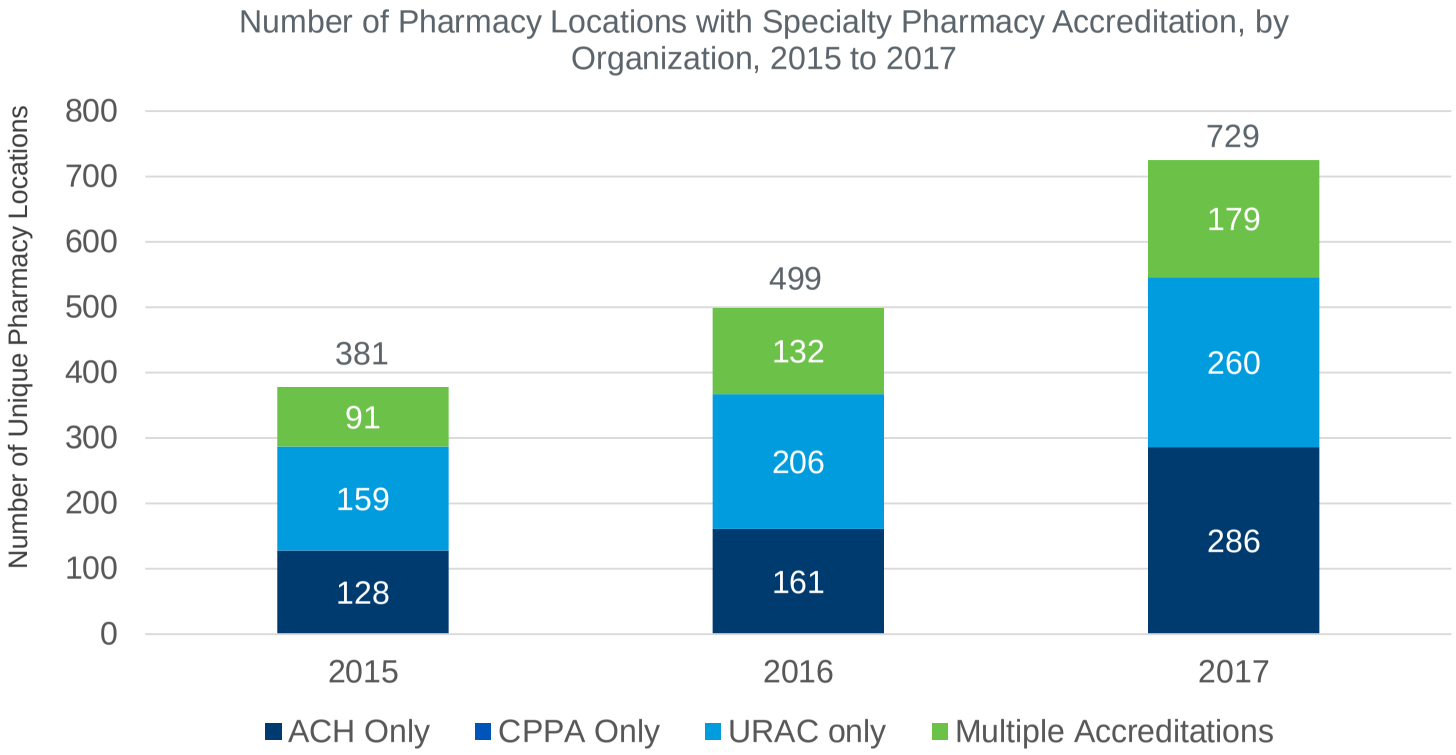
Pharmacy Franchise and Marketing Programs, 2016

PROGRAM	Health Mart	Good Neighbor Pharmacy	Medicine Shoppe/Medicap	CARE Pharmacies	Sav-Mor Drugstores	Benzer Pharmacy
Ownership	McKesson	AmerisourceBergen	Cardinal Health	Independent	Independent	Independent
# of Participating Pharmacies	4,800	2,800	515	82	65	71
2016 Prescription Revenues (billions)	$10.2	$7.3	$1.9	$.07	$.03	$.02

Source: Drug Channels Institute estimates; company reports; *Drug Store News.*

PCMA

Market Trend: Plan Sponsors Requiring Specialty Pharmacy Accreditation



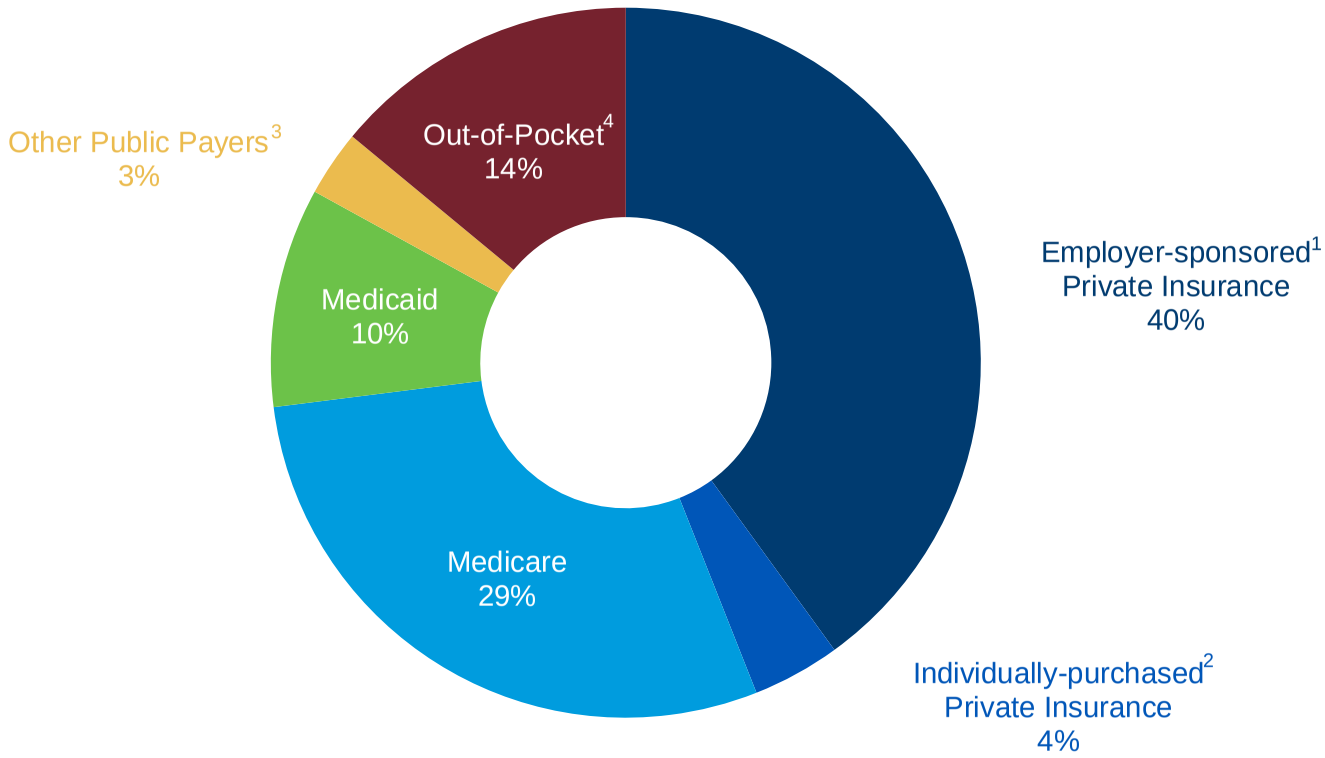
ACHC = Accreditation Commission for Health Care; CPPA = Center for Pharmacy Practice Accreditation; URAC = Utilization Review Accreditation Commission

Source: Drug Channels Institute research. Figures show number of unique accredited locations at the end of the year. For comparability, data for ACHC and CPPA exclude certain accredited pharmacy spoke locations within retail chains. Multiple category includes locations with accreditation from two or three of the accrediting organizations. Figures exclude locations with provisional, conditional, and expected accreditation.

PCMA

Who Pays for Prescription Drugs?

Source of Payment for Outpatient Prescription Drug Expenditures, 2016

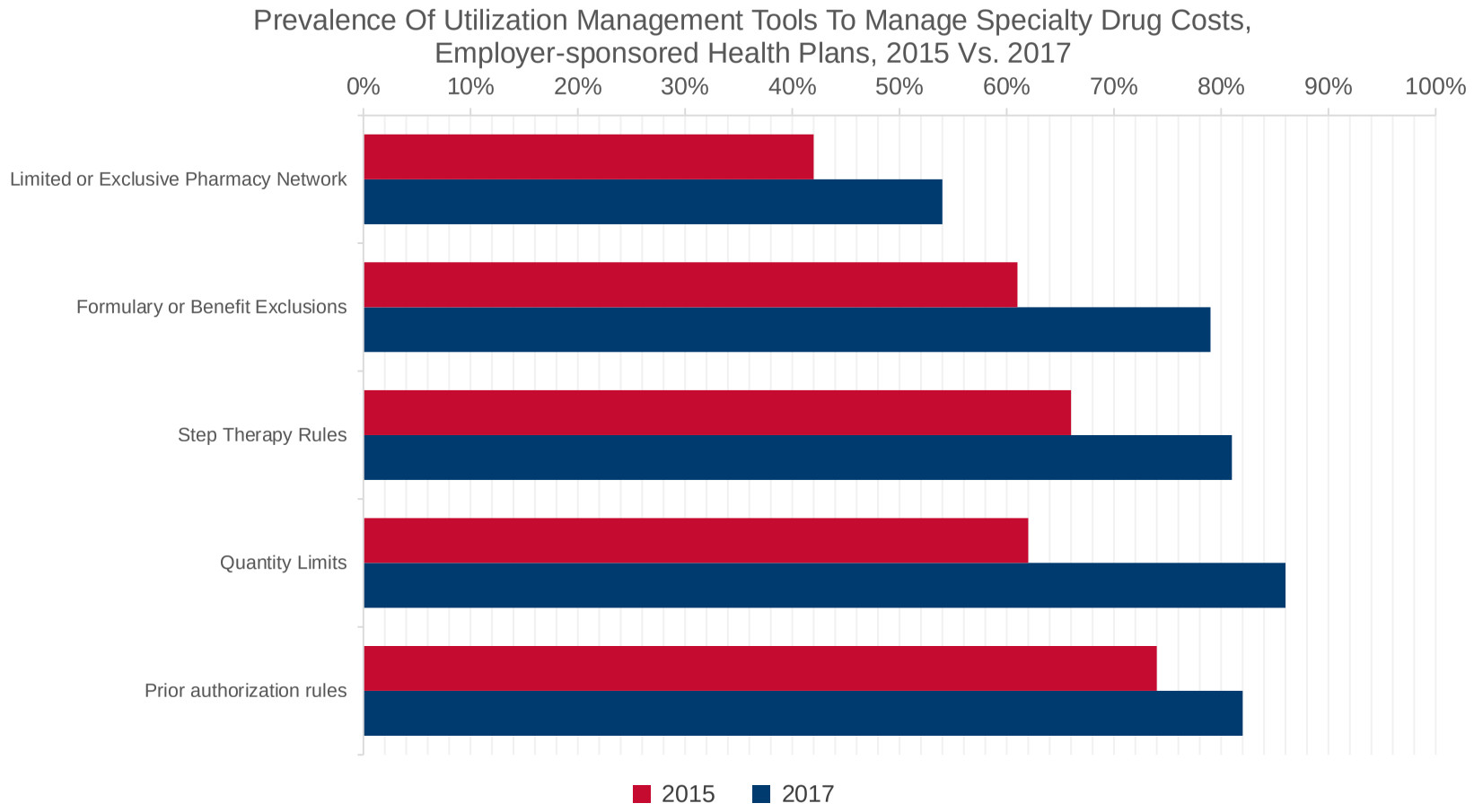


1. Includes workers' compensation and Pembroke Consulting estimates for employer share of private insurance.
2. Includes those with Medicare supplemental coverage and all individually purchased plans, including coverage purchased through the Marketplaces. Figure reflects Drug Channels Institute estimates for prescription drug spending for individually purchased private insurance.
3. Includes Children's Health Insurance Program (Titles XIX and XXI), Department of Defense, Department of Veterans Affairs, Indian Health Service, workers' compensation, general assistance, maternal and child health, and other federal, state, and local programs. Other federal programs include OEO, Federal General and Medical, Federal General and Medical NEC, and High Risk Pools under ASA. Other state and local programs include state and local subsidies and TDI.
4. Consumer out-of-pocket expenditures equal cash-pay prescriptions plus copayments and coinsurance.

Source: Drug Channels Institute analysis of National Health Expenditure Accounts, Office of the Actuary in the Centers for Medicare & Medicaid Services, December 2017. Totals may not sum due to rounding. Data exclude inpatient prescription drug spending within hospitals and nearly all provider-administered outpatient drugs.

PCMA

Payers Increasingly Reliant on PBM Tools



Source: Drug Channels Institute analysis of *Health and Well-Being Touchstone Survey Results*, PwC, various years.

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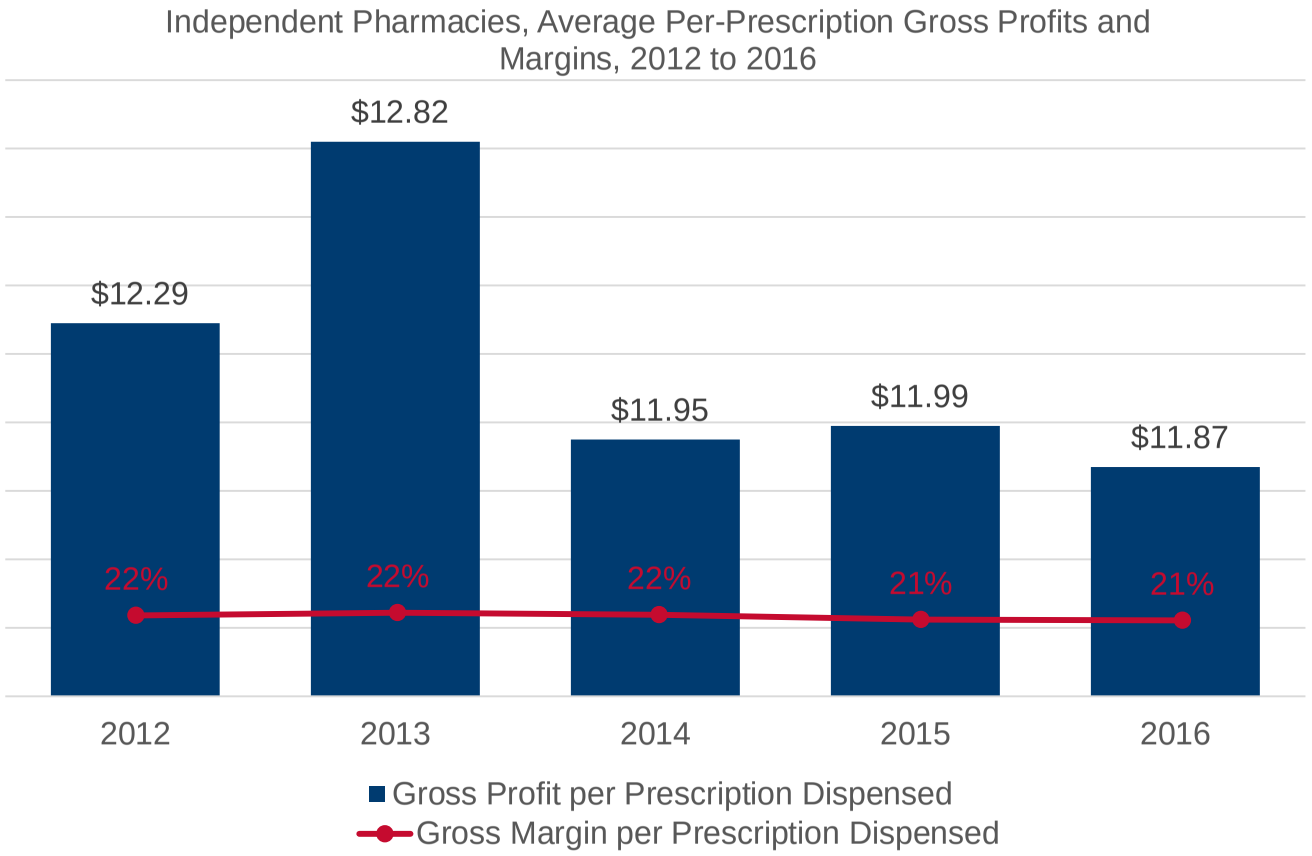
Independent Pharmacies Profitable, Stable



Source: Drug Channels Institute analysis of *NCPA Digest*, various years.

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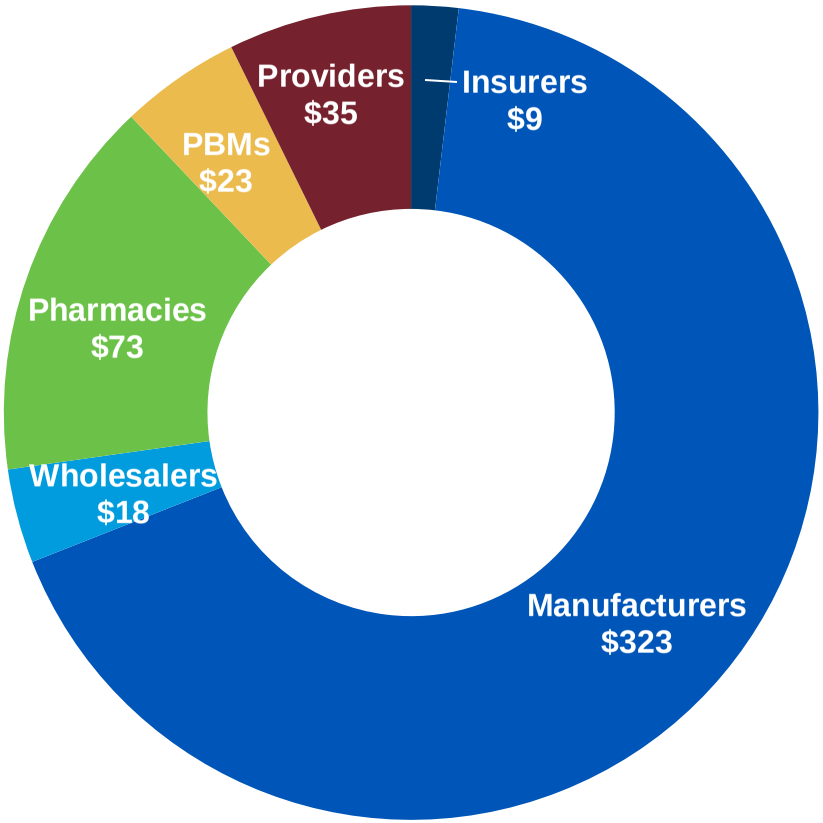
Drug Manufacturers Reap 67% of Rx Dollars

Retained Revenue Across U.S. Pharmaceutical Sector, 2016 ($billions)



Source: Nancy L. Yu, Preston Atteberry, Peter B. Bach. "Spending On Prescription Drugs In The US: Where Does All The Money Go?" *Health Affairs*, July 31, 2018.
Note: Study does not take into account the full amount of manufacturer rebates that PBMs may pass along to clients, which may lower estimated PBM retained revenue.

PCMA

Research and Presentations

Increased Costs Associated With Proposed State Legislation Impacting PBM Tools

Prepared for

February 2018

Table of Contents

I. Executive Summary

Visante was commissioned by the Pharmaceutical Care Management Association (PCMA) to estimate the potential cost impact of four types of state legislation impacting pharmacy benefit management (PBM) tools: PBM disclosure mandates, PBM fiduciary mandates, limits on prior authorization (PA) and step therapy (ST), and any willing specialty pharmacy requirements. As a general rule, such state legislation would affect only plan sponsors for commercial, fully insured plans. These plans provide prescription drug benefits to an estimated 90 million Americans. To make our estimates, we conducted a comprehensive review of the published evidence on how much PBM tools save as they are currently used in the marketplace and created an economic model of the impact of legislative proposals on the use of these tools and the resulting impact on projected drug expenditures for the fully insured commercial market for the next 10 years.

Proposals to restrict the use of PBM tools limit options that plan sponsors can use to manage their drug benefit costs. Some legislation may prohibit the use of a PBM tool entirely, driving savings to zero. Other legislation may negatively affect the full use of PBM tools and compress the range of savings achieved in the marketplace. We modeled how the savings from those tools would be reduced and how projected drug expenditures might increase over the next 10 years as a result.

Major Findings:

- **PBM Disclosure Mandates:** Proposed disclosure mandates include legislative and regulatory measures that would require PBMs to divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies. According to the Federal Trade Commission (FTC), disclosure mandates could result in tacit collusion and standardization of contract terms. We predict that disclosure mandates **would increase projected drug expenditures by an estimated 4.3% over the next 10 years**.

- **PBM Fiduciary Mandates:** Fiduciary mandates are state proposals to designate PBMs as fiduciaries for their health plan/employer clients. Such mandates would reduce savings from many PBM tools, including PA, ST, and other PBM tools that improve formulary performance and manage drug utilization. Fiduciary mandates would also likely increase PBM costs for liability insurance. We predict that fiduciary mandates **would increase projected drug expenditures by an estimated 5.8% over the next 10 years**.

- **Limitations on Prior Authorization and Step Therapy:** Some states are considering proposals to limit or prohibit the ability of health plans and their PBMs to implement PA and ST protocols. We predict that prohibiting the use of PA and ST **would increase projected drug expenditures by an estimated 4.6% over the next 10 years**.

- **Any Willing Specialty Pharmacy Requirements:** Some states are considering proposals to restrict the ability of health plans and PBMs to selectively contract for the provision of specialty pharmacy services by imposing any willing pharmacy requirements on such contracts. Such proposals would likely reduce specialty pharmacy network discounts and negatively impact the use of PBM tools that improve formulary performance and manage drug utilization. We predict that any willing specialty pharmacy requirements **would increase projected drug expenditures by an estimated 2.9% over the next 10 years**.

In this report, we review the evidence and methods underlying these estimates.

II. Costs Associated With Proposed State Legislation Impacting PBM Tools

A. PBM Disclosure Mandates

Issue: Proposed disclosure mandates include legislative and regulatory measures that would require PBMs to divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies.

Cost Impact of Disclosure Mandates: Mandatory disclosure would reduce savings from manufacturer rebates and pharmacy network discounts. Savings delivered by these PBM tools are significant. Some brand drugs have rebates of more than 50%. Preferred pharmacy networks deliver incremental discounts of up to 8 percentage points greater than traditional retail networks. We predict the following cost impacts:

- Disclosure mandates would likely result in tacit collusion among manufacturers, creating less variability and standardization around the lower end of the current range of rebates in the market. We predict that this compression in rebates would reduce average rebates by about 3% across all brand drugs.
- Disclosure mandates would also negatively impact pharmacy network discounts, with standardization and a compression of the range of network discounts toward the low end of the current marketplace range. Pharmacy network discounts would be compressed for different pharmacy channels and types of networks. Average retail network discounts (baseline discounts) would be cut by a half of a percentage point relative to cash prices charged to uninsured patients, while the incremental discounts over baseline associated with other pharmacy options such as preferred pharmacies, specialty, and mail-service would be cut in half.
- Combined, these negative effects on rebates and network discounts would increase projected drug expenditures by an estimated 4.3% over the next 10 years.
- PBM clients that currently maximize the use of the affected PBM tools would experience a much greater negative impact than others. These clients would see their projected drug expenditures increase by 8.6%, double the market average.

Discussion: Transparency remains a watchword in the healthcare cost debate. State policymakers have considered various proposals to mandate the disclosure of intermediate prices and discounts within the drug supply chain, including the price concessions that PBMs negotiate with drug manufacturers and pharmacies. However, government agencies—including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC)—have cautioned that such proposals can raise costs.

CBO Says Disclosure Mandates Could "Compress" Rebates and Discounts

CBO has noted that disclosure requirements could allow firms to "observe the prices charged by their rivals, which could lead to reduced competition."[1] According to CBO, the "disclosure of rebate data would probably cause the variation in rebates among purchasers to decline," leading to a "compression in rebates."[2] This compression would likely most adversely impact large program sponsors that would otherwise be able to extract the largest discounts.[3] At the inception of the Part D program, CBO estimated that PBM disclosure mandates would have increased costs in that program by $40 billion over 10 years.[4]

[1] "Increasing transparency in the pricing of health care services and pharmaceuticals," Congressional Budget Office, Jun. 5, 2008.
[2] Letter to Rep. Joe Barton and Rep. Jim McCrery, U.S. House of Representatives, Congressional Budget Office, Mar. 12, 2007.
[3] "Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector," The Moran Company, Apr. 2017.
[4] "H.R. 1 Medicare Prescription Drug and Modernization Act of 2003 as passed by the House of Representatives on June 27, 2003 and S. 1 Prescription Drug and Medicare Improvement Act of 2003 as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees," Congressional Budget Office Cost Estimate, Jul. 22, 2003.

FTC Says Disclosure Mandates Could Lead to Tacit Collusion

FTC has warned that "whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely."[5] FTC concluded that PBM disclosure mandates could "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[6]

Compare PBM Negotiations to Sealed-Bid Auctions

In the current marketplace, contract negotiations between PBMs, manufacturers, and pharmacies are like sealed-bid auctions: manufacturers and pharmacies are encouraged to offer aggressive price concessions since they don't know what's being offered by their competitors. Without confidentiality, economists argue, "disclosure of commercially sensitive contract terms will tend to short-circuit this competitive dynamic" because manufacturers and pharmacies would "know that the granting of any concession will likely lead to pressure for its widespread adoption."[7]

Confidential Plan Sponsor RFP Process Drives Competition Among PBMs

Confidentiality of contract terms is also vital to encourage competition among PBMs as they bid to win contracts with their clients (plan sponsors). Most plan sponsors use sophisticated consultants to prepare requests for proposals (RFPs) that specify their needs and requirements in both price and non-price terms, auditing rights, and guarantees. The RFPs are typically sent out to four to 12 PBMs,[8] with each competing PBM blind to how its competitors will respond.

Plan Sponsors Can Negotiate Full Pass-Through of Manufacturer Rebates

Through the RFP process, plan sponsors can negotiate how manufacturer rebates will be handled and what levels of disclosure and reporting they desire from their PBM. Today, about 49% of PBM-client contracts in the commercial sector are negotiated to include full pass-through of manufacturer rebates to the plan sponsor.[9] Other clients elect to have PBMs retain a portion of the rebates to lower administrative fees.

"With no indication that clients of PBMs lack accurate information on the price and quality of the service that they intend to purchase, it is unclear how requiring PBMs to reveal information related to rebates received from pharmaceutical companies would improve market outcomes," according to FTC.[10] More broadly, FTC has concluded that "allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms regulated by government regulation."[11]

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[5] "Improving health care: a dose of competition," U.S. Federal Trade Commission and the U.S. Department of Justice, Jul. 2004.
[6] Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, Jul. 15, 2005; Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, Sept. 3, 2004.
[7] "Declaration of Adam B. Jaffee, Ph.D. in support of plaintiff's motion for preliminary injunction," Pharmaceutical Care Management Association v. G. Steven Rowe, Attorney General of the State of Maine.
[8] Statement of the Federal Trade Commission concerning the proposed acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210, Apr. 2, 2012.
[9] "PBMI research report: 2017 trends in drug benefit design," Pharmacy Benefit Management Institute, 2017.
[10] Letter from FTC to Rep. Patrick T. McHenry, U.S. Congress, Jul. 15, 2005.
[11] Letter from FTC to Assemblywoman Nellie Pou, New Jersey General Assembly, Apr. 17, 2007.

B. PBM Fiduciary Mandates

Issue: Fiduciary mandates for PBMs are state proposals to designate PBMs as fiduciaries for their health plan/employer clients.

Cost Impact of Fiduciary Mandates: Fiduciary mandates would reduce savings from many PBM tools, including PA, ST, and a number of other PBM tools. Fiduciary mandates would also increase PBM costs for liability insurance. More specifically, we predict the following impacts:

- Fiduciary mandates would reduce savings from PA, ST, and a number of other PBM tools that improve formulary performance and manage drug utilization. Savings delivered by these PBM tools are significant. Studies have demonstrated that PA can generate savings of up to 50% on drug expenditures for targeted drugs or drug categories, and ST has demonstrated savings of more than 10% for targeted categories. Optimal formulary management tools have demonstrated savings of up to 20% for targeted categories. Other PBM utilization management (UM) tools have demonstrated a reduction of almost 30% in unsafe opioid use.
- Fiduciary mandates would increase liability risks for PBMs and result in more conservative use of PBM tools, which would compress the range of savings achieved in the market. In other words, the PBM clients that are highly conservative in their use of these tools may see little impact, but the majority of clients that make greater use of PBM tools would see compression and reduction of savings. Average savings (across all drug expenditures) would be reduced by an estimated 1 to 2 percentage points for each affected category of PBM tools: PA (1%), ST (1%), and other PBM tools that work to improve formulary performance (2%) and manage drug utilization (1%).
- Fiduciary mandates would also increase PBM costs for additional liability insurance, which would be passed through to PBM clients and would add another 1% to projected drug expenditures.
- Combined, the negative effects of fiduciary mandates would increase projected drug expenditures by an estimated 5.8% over the next 10 years.
- Some PBM clients that currently maximize the use of the affected PBM tools would experience a much greater negative impact than the marketplace average. These clients that are maximizing their savings would see their drug expenditures increase by double the average or 11.6%.

Discussion: In today's marketplace, PBMs serve in administrative and advisory roles for health plans and employer plan sponsors, performing claims processing and other administrative tasks based on negotiated contracts. Proposed state legislation would override these contracts by designating PBMs as fiduciaries for their clients. A fiduciary mandate imposed upon PBMs would entail having discretionary authority over plan assets or making decisions about the scope and design of the benefits being offered by the plan. Today, those responsibilities lie with health insurance plan sponsors, not PBMs. Imposing fiduciary duties on PBMs would raise drug benefit costs by increasing their legal liability and undermining their ability to effectively implement cost management tools for their clients.

PBMs Are Not Fiduciaries According to DOL and Federal Courts

According to the Department of Labor (DOL), Third Party Administrators (TPAs), such as PBMs "who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan…are not fiduciaries of the plan."[12] Likewise, PBMs have no "discretionary authority" over plan assets as defined by DOL, which is an essential threshold

[12] 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.

requirement for fiduciary status under federal law. Moreover, federal courts have struck down state PBM fiduciary mandates as being preempted by the Employee Retirement Income Security Act (ERISA).[13]

Fiduciary Status Would Create Conflicting Obligations for PBMs

Imposition of a fiduciary mandate would create a conflict between PBMs' contractual obligations to their clients and the fiduciary duty to act "solely in the interest of plan participants." For example, a PBM's contract may call for the use of PBM tools such as PA and ST that are designed to reduce costs for ALL participants, but which may result in higher costs or less access to a given drug for a particular group of participants. In this case, implementing the contract would conflict with a fiduciary duty. Indeed, such conflicting obligations would likely be common, resulting in second-guessing of every element of the contracts PBMs have negotiated with their clients and requiring substantial and burdensome analysis by both parties to determine if a legally prohibited conflict exists.

Legal Liabilities and Costs Would Increase Under Fiduciary Mandates

Fiduciary mandates would subject PBMs to broader legal liabilities than under current law because they would transform an arm's length contractual relationship into one where one party is responsible for assets that belong to another, such as a trustee relationship. This could result in increased risk for litigation between PBMs and their clients. In addition, consumers could argue they have a private right of action to sue PBMs because they are plan participants protected by ERISA. Increased legal risk could result in PBMs needing to purchase additional liability insurance. The added cost of this insurance would then drive prescription drug benefit costs higher for both PBM clients and the individuals enrolled in their plans.

Fiduciary Mandates Would Decrease the Use of PBM Tools

Increased legal liability and conflicting obligations between fiduciary duties and client contracts could result in PBMs adopting defensive business strategies to mitigate the risk of lawsuits. This could lead to PBMs decreasing their use of formulary compliance and drug UM tools such as PA, ST, and quantity limits. This would raise drug benefit costs for both plan sponsors and their enrollees.

Performance-Based Contracting Would Be Undermined by Fiduciary Mandates

DOL has indicated that certain performance fee arrangements may result in fiduciary self-dealing. This could preclude PBM contracts from containing provisions where some of their fees are contingent on performance. Likewise, creating fiduciary responsibilities for PBMs could limit how they structure manufacturer rebate and pharmacy network contract agreements and negatively impact their bargaining leverage. In addition, the increased reporting requirements that would go hand-in-hand with a fiduciary duty would increase the risk of public disclosure of negotiated price concessions, although we have not explicitly factored that into our modeling.

Fiduciary Mandates Would Increase Administrative Costs

State fiduciary mandates would increase costs as PBMs are forced to develop unique administrative processes and revise contracts with other supply chain entities to comply with a state's new requirements, which would be completely different than other states' and at odds with ERISA's goals of a "uniform administrative scheme" for processing claims and distributing benefits.

[13] Pharm. Care Mgt Ass'n v. District of Columbia, 613 F.3d 179 (D.C. Cir. 2010).

C. Limitations on Prior Authorization and Step Therapy

Issue: Some states are considering proposals to limit or prohibit the ability of health plans and their PBMs to implement clinical PA and ST protocols.

Cost Impact of Limitations on PA and ST: Prohibiting the use of PA and ST would eliminate the savings delivered by these PBM tools. Our analysis reveals:

- Studies have demonstrated that PA can generate savings of up to 50% for targeted drugs or drug categories. ST has demonstrated savings of more than 10% in targeted categories.
- PA and ST are widely used by PBM clients to help ensure appropriate and cost-effective use of high-cost and/or high-risk drugs. These tools are becoming increasingly important in managing the rapidly growing use of high-cost specialty pharmaceuticals, so the lost savings associated with restrictions on PA and ST would become greater as specialty drug expenditures grow.
- The loss of savings from PA and ST would increase projected drug expenditures by an estimated 4.6% over the next 10 years.

PBM clients that currently maximize the use of the affected PBM tools would experience a much greater cost impact. These clients would see their drug expenditures increase by double the average increase or 9.2%.

Discussion: Health plans and pharmacy benefit managers utilize independent Pharmacy & Therapeutics Committees, comprised of experts that include physicians, pharmacists, and other medical professionals to develop evidence-based guidelines used in drug management programs—including PA and ST—and to ensure that these management controls do not impair the quality of clinical care.

PA is a requirement that a plan pre-approves a drug before a pharmacy can dispense it to the enrollee as a covered benefit. The major goals of PA are to ensure appropriateness and suitability of the prescribed medication for the specific patient as well as to control costs.

ST requires an enrollee to try a medically appropriate first-line drug, typically a generic alternative to a branded product, when a new therapy is initiated. The prescriber is asked to consider ordering a therapeutic alternative. If that medically appropriate alternative was tried earlier and the patient did not achieve optimal outcome, the brand product is approved and dispensed.

As with other drug benefit management techniques, it is up to each PBM client to decide if and how PA and ST will be applied to its health benefit plan.

PA and ST Used to Help Ensure Prescriptions Are Safe and Appropriate

Many drugs can have harmful side effects or adverse interactions with other medications. Some drugs, such as pain medications or antipsychotics, have a high risk of abuse or overuse so PA is required to help ensure appropriate use. Likewise, specialty medications often have significant side effects and require patient education to be taken effectively, so they also often require PA. Many drugs that commonly appear on PA lists are those that are heavily advertised directly to consumers or have off-label uses not approved by the Food and Drug Administration (FDA).

ST ensures that prescribers consider the medically appropriate available therapeutic alternatives before settling on a course of therapy for a specific patient, which can improve quality of care when that patient is on multiple medications. PA is often used to encourage or require physicians to use ST where they try an appropriate but less expensive medication first before moving the patient to a more expensive option.

FTC Finds Plans Use PA and ST to Lower Costs

According to FTC, "large PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance."[14] FTC also found that "prior authorization often involves a clinical justification for the use of drugs that are prone to misuse or are especially costly."[15] Any limits or prohibitions on PA and ST could thus raise costs.

NASEM Suggests Formulary Controls Keep Premiums Low

According to the National Academy of Sciences, Engineering, and Medicine (NASEM), "Formularies are used to steer patients and prescribing clinicians toward generic substitutes, biosimilars, drugs with similar therapeutic efficacy for the same disease, or other therapeutic options."[16] Without formulary controls, "insurance premiums would rise," notes NASEM.[17] PA and ST are among the most effective formulary controls, thus any state legislation to limit or prohibit their use would likely raise premiums.

NASEM Recommends More, Not Less, Formulary Flexibility

"Some other countries operate formulary systems that provide much greater ability to restrict or exclude drugs from coverage than is the case in the United States," according to NASEM.[18] One of NASEM's recent consensus recommendations to make medicines more affordable was to "Expand flexibility in formulary design to allow the selective exclusion of drugs, such as when less costly drugs provide similar clinical benefit."[19] Since PA and ST are less aggressive formulary controls than outright formulary exclusions, it is reasonable to extrapolate that state proposals limiting or prohibiting their use would be an approach at odds with NASEM's recommendation.

Every Plan Has an Appeals Process

As noted by NASEM, "Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a physician provides information about side effects the patient has experienced from a lower-tiered drug or offers another medical reason for switching."[20] In the case of an appeal, health insurers and PBMs work with the patient and the physician to provide access to non-formulary drugs where medically necessary and/or likely to achieve the best outcome. This process safeguards against the use of PA and ST being too restrictive.

[14] "Pharmacy benefit managers: ownership of mail-order pharmacies," FTC, Aug. 2005.
[15] Ibid.
[16] "Making medicines affordable: a national imperative," NASEM, Nov. 2017.
[17] Ibid.
[18] Ibid.
[19] Ibid.
[20] Ibid.

D. Any Willing Specialty Pharmacy Requirements

Issue: Some states are considering proposals to restrict the ability of health plans and PBMs to selectively contract for the provision of specialty pharmacy services, by imposing any willing pharmacy (AWP) requirements on such contracts.

Cost Impact of Any Willing Specialty Pharmacy Requirements: Any willing specialty pharmacy requirements would reduce savings on specialty drugs achieved through the use of tools such as PA, ST, and other PBM tools that improve formulary performance and manage drug utilization. Our analysis reveals:

- Specialty pharmacy network discounts typically deliver incremental discounts of up to 2 percentage points more than traditional retail networks. In addition, specialty formulary management has demonstrated savings of 20% in a drug category, while drug UM has demonstrated savings of 5% to 10% in targeted categories.
- Any willing specialty pharmacy legislation would effectively eliminate specialty pharmacy network discounts, which are typically 1–2 percentage points greater than baseline retail network discounts.
- Average savings associated with other PBM tools would be compressed and reduced because the effectiveness of the tools is often dependent upon specialized, advanced services delivered by specialty pharmacies in close coordination between the PBM and the specialty pharmacy. Most pharmacies are not prepared to deliver such sophisticated and coordinated services, so the optimal savings would not be as feasible under an AWP scenario. Average savings across all drug expenditures would be reduced by an estimated 1–2 percentage points for each affected category of PBM tools: PA (1%), ST (1%), and other PBM tools that work to improve formulary performance (2%) and manage drug utilization (1%).
- This legislation would affect specialty drug expenditures, which are the fastest growing component of prescription drug expenditures and projected to comprise approximately 50% of total drug expenditures over the next 10 years.
- The overall impact of an any willing specialty pharmacy requirement would be to increase projected drug expenditures (combined specialty and non-specialty) by an estimated 2.9% over the next 10 years.
- PBM clients that currently maximize the use of the affected PBM tools would experience an even greater cost impact and see their projected drug expenditures increase by 5.8%.

Discussion: Over the next 10 years, specialty drugs—high cost, often injectable or infusible medications—will likely account for just 1% of prescriptions but roughly 50% of projected drug expenditures.[21] Today, entities known as specialty pharmacies fulfill the complex product handling, clinical support, patient education, and UM requirements associated with specialty drugs. Health plans and PBMs typically contract to include only selected specialty pharmacies in their pharmacy networks to ensure high-quality services for consumers, avoid waste, and ensure appropriate use of high-cost specialty medications. Thus, an AWP requirement could be particularly harmful when applied to specialty pharmacies, resulting in additional costs beyond the already anti-competitive impact associated with AWP requirements more generally.

FTC Says Any Willing Pharmacy Provisions Would Reduce Discounts

AWP requirements significantly reduce providers' incentive to engage in price competition, according to FTC. If pharmacies know they will automatically be included in a network, they have a reduced incentive to offer plans and PBMs their most competitive terms. FTC has noted that "requiring prescription drug plans to contract with any willing pharmacy would reduce the ability of plans to obtain price discounts based on the prospect of increased patient volume and thus impair the ability of prescription drug plans to negotiate the best prices with

[21] Visante estimates.

pharmacies."[22]

Academic Analysis Finds Any Willing Pharmacy Laws Associated With Higher Costs

An academic analysis of AWP laws concluded that such legislation leads to less competition and higher prices for consumers while providing no compensating benefits with "cost increases of at least 3%."[23] Likewise, another academic analysis specific to state AWP laws found that such legislation "is associated with increased pharmaceutical expenditures."[24]

Low Volume of Specialty Prescriptions Amplifies Impact of Any Willing Pharmacy Legislation

When applied to specialty pharmacies, the consequences of AWP legislation would likely be greater than when simply applied to brick-and-mortar pharmacies. Because specialty drugs are dispensed in such low volumes and target rare conditions, it is infeasible for most retail drugstores to stock these medications and provide the specialized services patients require. Specialty pharmacies can serve an entire region or country using sophisticated information technology and logistics to dispense medications directly to the patient's home or physician's office. This approach allows specialty pharmacies to achieve economies of scale and offer deeper discounts due to a predictable volume of prescriptions flowing through the pharmacy. These economies of scale would not be possible if AWP legislation were to result in drugstores across the country dispensing these medications.

Only Select Pharmacies Typically Meet Specialty Pharmacy Network Requirements

States do not legally differentiate specialty pharmacies from traditional pharmacies, so essentially any licensed pharmacy can market itself as a specialty pharmacy. Some pharmacies that market themselves as specialty pharmacies are actually affiliated with drug manufacturers, which has led to the use of questionable practices to circumvent the benefit design choices of plan sponsors in some cases.[25] PBMs actively work with payers to identify specialty pharmacies that can best serve patient and healthcare provider needs. These payer-aligned specialty pharmacies must meet payers' terms and conditions to be included in preferred pharmacy networks. Terms and conditions focus on quality clinical care, performance, and cost-saving criteria. Qualified specialty pharmacies must also meet payer reimbursement rates to be included in networks.

Payer-Aligned Specialty Pharmacies Provide Unique Clinical and Operational Services

Unlike traditional brick-and-mortar drugstores, payer-aligned specialty pharmacies included in plan networks employ highly trained teams of pharmacists, nurses, and clinicians to work with doctors and patients to ensure that complex specialty medications are administered on time, conveniently, safely, and effectively. The unique clinical services that specialty pharmacies provide include:

- Providing around-the-clock access to specially trained clinicians who offer patients guidance and insight on disease states, as well as the use of specialty drugs;
- Consulting directly with physicians to address patient side effects, adverse drug reactions, non-adherence, and other patient concerns;
- Performing disease- and drug-specific patient care management services;

[22] "Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs," FTC letter to CMS, Mar. 7, 2014.
[23] Klick, J., and Wright, J., "The effect of any willing provider and freedom of choice laws on prescription drug expenditures," *American Law and Economics Review*, Dec. 2012.
[24] Durrance, C., "The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures," *Atlantic Economic Journal*, 2009.
[25] Chen, C., and Elgin, B., "Philidor said to modify prescriptions to boost Valeant sales," Bloomberg Business, Oct. 29, 2015.

- Collecting data and tracking outcomes for specific patients;
- Managing patient adherence and persistency of drug regimens; and
- Managing care for manufacturer Risk Evaluation and Mitigation Strategies, including reporting, Phase IV trials, the dispensing of FDA trial drugs under strict protocols, and related clinical and cognitive counseling.

Unique operational services provided by payer-aligned specialty pharmacies in plan networks include:

- *Supply chain management:* Adheres to rigorous storage, shipping, and handling standards to meet product label shipping requirements, such as temperature control and the timely delivery of products in optimal conditions.
- *Care coordination:* Offers coordinating services with other healthcare providers, including those providing skilled nursing services, custodial care, infusion administration, and direct-to-physician distribution.
- *Insurance navigation:* Expedites access to therapy by working directly with insurers and navigating their benefits, UM, and PA processes.
- *Patient assistance:* Facilitates eligible patients' enrollment in patient assistance programs and access to charitable resources.
- *Plan optimization:* Aligns economic incentives across medical and pharmacy benefits while helping patients navigate the complexity of these benefit structures.

Physicians Say Not All Pharmacies Capable of Dispensing Specialty Drugs

A 2015 survey of 400 physicians in the cardiology, neurology, gastroenterology, endocrinology, rheumatology, nephrology, infectious disease, oncology, pulmonology, and hematology specialties who prescribe specialty medications showed that two-thirds of those who work with specialty pharmacies think that only some or none of traditional drugstores have the expertise to provide the range of specialty medications to patients.[26]

Accreditation and Credentialing a Key Aspect of Network Requirements

Specialty pharmacy accreditation and credentialing are among the baseline requirements a pharmacy must meet for inclusion in a plan's network. Of the roughly 64,000 pharmacies in the U.S., only about 400—less than 1%—are accredited as specialty pharmacies by the Utilization Review Accreditation Commission. In addition, PBMs utilize credentialing to evaluate a pharmacy's ability to implement plan design, encourage formulary compliance, and meet other contractual obligations.

Impact of Any Willing Pharmacy Legislation on Savings From Specialty Benefit Management

Legislation that prevents PBMs from creating limited networks of specialty pharmacies would likely significantly impact the performance of formulary management, UM, and care management programs for patients using specialty medications. The effective use of these tools has a significant impact on costs. For example, the Pennsylvania Medicaid program's use of specialty pharmacies helped save 21% on overall health expenditures for beneficiaries using specialty drugs, including 12% on specialty drug costs and 56% on inpatient hospital costs.[27] Numerous other studies have demonstrated that specialty pharmacies save 10% to 50% on drug costs and non-drug medical costs.[28,29,30,31,32,33,34,35,36,37,38,39,40,41]

[26] "Key findings from the survey of New York physicians regarding specialty medications," North Star Opinion Research, Apr. 2015.
[27] "Managing Medicaid pharmacy benefits: current issues and options," Kaiser Commission on Medicaid and the Uninsured, Sept. 2011.
[28] Baldini, C., and Culley, E. "Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program," *J Managed Care Pharm*. 2011;17(1):51-59.

III. Supporting Evidence and Methods

A. Methodology: Impact of Restricting PBM Tools

To assess the cost impact of legislation restricting the use of PBM tools, Visante conducted a comprehensive review of the published evidence on how much PBM tools save as they are currently used in the marketplace. Our evidence comes from a wide range of sources that often use different benchmarks against which to measure savings. While we report on each of these sources using their original benchmarks, it was necessary to then translate and restate this evidence in terms of a common benchmark that we refer to as "projected drug expenditures." These projections are discussed in more detail in Section B below, but it is important to note that our "projected drug expenditures" for the next 10 years are based on the Centers for Medicare & Medicaid Services (CMS) projected national health expenditures and are assumed to reflect the average use of PBM tools.

We use our model to produce estimates that reasonably isolate the impact of individual PBM tools and predict realistic costs and savings under different legislative scenarios that would restrict the use of specific tools. We do this by comparing the savings achieved by the following plans:

1. Plans that use PBM tools to a limited extent or "limited use of PBM tools."
2. Plans that use PBM tools to an average extent or "average use of PBM tools."
3. Plans that optimize the use of PBM tools to their full extent or "full use of PBM tools."

In the PBM marketplace, plan sponsors determine the extent to which they use PBM tools based on their resources and objectives. Decisions made by plan sponsors not only guide how actively benefits are managed, but also determine formulary coverage, copayment tiers, UM, and pharmacy channel options. In making choices about the drug benefits being offered to their enrollees, plans' sponsors weigh many factors, including clinical quality, cost, and member satisfaction. The need to control costs is typically weighed against minimizing change for their enrollees, all while ensuring access to needed care.

Government mandates to restrict the use of PBM tools limit the options that plans' sponsors can use to manage their drug benefit costs. Some legislation may prohibit the use of a PBM tool entirely, driving savings to zero. Other legislation may negatively affect the "full use" of PBM tools, thereby compressing the range of savings in the marketplace toward the low end. In these cases, we model how the savings from those tools would be reduced and how projected drug expenditures would change over the next 10 years as a result. We have examined savings associated with PBM tools falling into the following categories:

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[29] "Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.
[30] "Specialty pharmacy: rare disease management," Russek, S., and Szymanski, J., Medco, presented at the PCMA Specialty Pharmacy Symposium, Jun. 2005.
[31] Barlow, J. et al., "Impact of specialty pharmacy on treatment costs for rheumatoid arthritis," *Am J Pharm Benefits*. 2012;4(Special Issue):SP49-SP56.
[32] Dorholt, M., "Advancing drug trend managementt in the medical benefit," *Managed Care*, Jun. 2014.
[33] "Personalizing the specialty business," Miller, S., presentation at the PCMA Specialty Pharmacy Business Forum, Apr. 4, 2012.
[34] Visaria, J., and Frazee, S., "Role of pharmacy channel in adherence to hepatitis C regimens," *Am J Pharm Benefits*. 2013;5(1):17-24.
[35] "Exploring the impact of dispensing channel on medication adherence among multiple sclerosis patients," Tang, J., and Faris, R., presented at the 14th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), May 2009.
[36] Mitra, et al., "Treatment patterns and adherence among patients with chronic hepatitis C virus in a US managed care population," *Value Health*. 2010;Jun-Jul;13(4):479-486.
[37] Tan, et al., "Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis," *Adv Ther*. 2011;28(1):51-61.
[38] *Specialty Pharmacy News*, Jun. 2013;10(6).
[39] Tschida, et al., "Outcomes of a specialty pharmacy program for oral oncology medications," *Am J Pharm Benefits*. 2012;4(4):165-174.
[40] Tschida, et al., "Managing specialty medication services through a specialty pharmacy program: the case of oral renal transplant immunosuppressant medications," *J Managed Care Pharm*. 2013;19(1):26-41.
[41] Visaria, et al., "Specialty pharmacy improves adherence to imatinib," *Am J Pharm Benefits*. 2013;5(Special Issue):SP33-SP39.

- Manufacturer rebates
- Pharmacy network contract discounts (e.g., retail, preferred, mail-order, specialty)
- PA and ST
- Other PBM tools that improve formulary performance
- Other PBM tools that manage drug utilization

Manufacturer Rebates

Based on Visante estimates and analysis of data from SSR Health and other sources, manufacturer rebates negotiated by PBMs across all branded drugs in the commercial sector average 27% of Wholesale Acquisition Cost (WAC).[42] This is a sales-weighted average across brand drugs. Some brands may have rebates of 50% or more, while other brand drugs may have no rebates at all. Visante's estimates, which exclude Medicaid rebates, are roughly consistent with other published estimates.[43,44,45,46]

Average rebates for commercial sector payers depend on how fully plan sponsors elect to have their drug benefit managed. It is reasonable to assume that plan sponsors that opt to use the full range of PBM formulary management tools may achieve average brand rebates of up to 5 percentage points greater than the average for the marketplace as a whole, while plans that make limited use of formulary management may achieve rebates averaging 5 percentage points below the marketplace average. Under these assumptions, the average rebate across all brand-name drugs ranges from a high of 32% of WAC to a low of 22% of WAC.

We note that many high-cost specialty medications often have less competition and lower (or no) rebates compared with non-specialty medications. However, manufacturer competition is also becoming more important in the specialty area. For example, in late 2014, AbbVie obtained FDA approval to compete against Gilead's market-leading drugs for hepatitis C. PBMs immediately took advantage of the opportunity to obtain discounts of approximately 46%,[47] creating savings estimated at $4 billion in the U.S. for 2015.[48] However, the weighted average rebate for the 47 top specialty drug products in 2016 was less than 20% of WAC, and more than half of these specialty products had rebates of less than 10% of WAC, based on our estimates and analysis of data from SSR Health.[49]

Potential Impact of State Legislation on Rebates: As discussed earlier in this report, FTC and CBO each have concluded that government policies resulting in the disclosure of rebates could lead to tacit collusion among manufacturers and result in higher costs as rebate contracts standardize toward terms more favorable to the drugmakers. We believe that such policies could cause average rebates to cluster toward the lower bound of the current marketplace range of 22% to 32% of WAC. To model this effect, we have assumed that the current 22% to 32% range of average rebates compresses to a new range bounded by the current low of 22% and a new upper bound equal to the current marketplace average of 27%. Assuming a normal distribution, this would result in a new marketplace average rebate of approximately 24% of WAC, a compression of about 3 percentage points from the current marketplace average. This estimated impact is reasonably consistent with a 2017 analysis of

[42] Visante estimates and analysis of non-Medicaid markets based on 2016 data from SSR Health. Further discussion of Visante's methodology for estimating average rebates is available in our June 2017 analysis for PCMA, "Increasing prices set by drugmakers not correlated with rebates."
[43] "Medicines use and spending in the U.S. a review of 2016 and outlook to 2021," IQVIA Institute (formerly Quintiles IMS), May 2017.
[44] "The pharmaceutical supply chain: gross drug expenditures realized by stakeholders," Berkeley Research Group, Jan. 2017.
[45] "How do PBM's make money?" Barclay's Equity Research, Mar. 2017.
[46] "Exploring future US pricing pressure," Credit Suisse Equity Research, Apr. 2017.
[47] "What Gilead's big hepatitis C discounts mean for biosimilar pricing," Drug Channels, Feb. 5, 2015.
[48] "Express Scripts' Miller says hepatitis C price war to save billions," Reuters, Jan. 22, 2015.
[49] Visante estimates and analysis of non-Medicaid markets based on 2016 data from SSR Health. Further discussion of Visante's methodology for estimating average rebates is available in our June 2017 analysis for PCMA, "Increasing prices set by drugmakers not correlated with rebates."

disclosure mandates by budget analysts, which suggests that "CBO could reasonably conclude that the effect on branded drug pricing could be greater than 2% over time."[50]

We understand that there are a variety of PBM business models and pricing schemes in the marketplace today, some of which factor "rebate retention" into the overall administrative fee structure for the PBM client. We see this as independent from our analysis. In other words, we are examining the potential impact on the manufacturer rebate contracts themselves. Whether some clients choose to use a portion of their rebate dollars to help reduce their administrative fees is independent from our analysis.

To assess the impact on overall drug expenditures by a reduction in average rebates on brand drug expenditures, we estimate that brand drugs will account for 82% of total drug expenditures over the next 10 years, based on current marketplace dynamics. Therefore, rebates of 22% to 32% of WAC for brand-only drugs would be equivalent to 18% to 26% of total drug expenditures (i.e., brands and generics). Mandatory disclosure would compress the range to the lower end, resulting in a new range of 18% to 22%. The market average would be reduced from 22% to 20%. With this decrease in average rebates due to mandatory disclosure requirements, projected drug expenditures would increase an estimated 2.6%.[51] This estimated impact does not include the impact such mandates would have on pharmacy network discounts, as discussed below.

Pharmacy Network Contract Discounts (Retail, Specialty, Mail)

Retail Pharmacy Network Discounts: Plan-sponsor survey data indicate that pharmacy network discounts amount to 18% of the average wholesale price for brands and 64% of the average wholesale price for generics.[52] These reported pharmacy network discounts have increased somewhat as a percent of average wholesale price in recent years. However, the historically large gap between cash prices and pharmacy network prices has actually narrowed for generic drugs due to the widespread adoption of generic drug discount programs (such as $4 prescription programs) now offered by a range of major retailers.

Visante analysis of CMS data on prices paid to pharmacies for prescriptions filled by individuals with commercial third-party insurance versus cash-paying customers indicates average savings for third-party insurers of 9% to 10% on brands and 20% to 25% on generics.[53] Assuming that brand drugs will be 82% and generics will 18% of projected drug expenditures over the next 10 years, we estimate retail network discounts of 13% relative to full retail prices charged by pharmacies to cash-paying consumers. To be conservative, we assume 13% is upper bound of an 11% to 13% marketplace range. We consider this range as a baseline network discount achieved through all PBM-managed pharmacy channels, with additional discounts then available from preferred pharmacies, mail-service, and specialty pharmacies, as outlined below.

Preferred and Limited Retail Pharmacy Networks: In the commercial market, half of employer-sponsored plans now offer a preferred network, and about 20% of employer-sponsored plans offer a limited network.[54] Because data on preferred pharmacy network savings are more readily available for Part D plans, we are using

[50] "Assessing the budgetary implications of increasing transparency of prices in the pharmaceutical sector," The Moran Company, Apr. 2017.
[51] For example, if projected drug expenditures equal $78 and reflect average rebate savings of 22%, then drug expenditures in the absence of rebates would be $100. If mandatory disclosure restricts the size of negotiated rebates, and reduces average savings from 22% to 20%, such legislation would cause projected drug expenditures to increase from $78 to $80 or increase by 2.6%.
[52] Pharmacy Benefit Management Institute, op. cit.
[53] Visante analysis of CMS National Average Retail Price (NARP) survey data from 2Q2013. NARP data provided average prescription revenues for more than 4,000 of the most commonly dispensed brand and generic outpatient drugs. The NARP data included: (1) the amounts paid for drug ingredient costs, (2) customer copayments or coinsurance, and (3) dispensing fees. These monthly data were based on 50 million nationwide retail pharmacy claims gathered from independent data suppliers. NARP data reflected prices paid for drugs to retail community pharmacies for individuals with (1) commercial third-party insurance (including Medicaid managed care and Medicare Part D) and with (2) Medicaid fee-for-service, and (3) cash-paying customers. The NARP survey was suspended by CMS in July 2013.
[54] Pharmacy Benefit Management Institute, op. cit.

Part D data as a proxy for savings in the commercial sector. According to CMS, preferred pharmacies had average weighted unit costs that were about 6% less expensive than other network pharmacies. CMS also reports that the four largest plans, accounting for 93% of claims, had average unit cost savings of 8% at preferred pharmacies.[55,56] Therefore, we estimate savings for prescriptions filled through preferred/limited network pharmacies can be up to 8% relative to baseline retail pharmacy network discounts.

CMS analysis also indicates that preferred retail pharmacies dispense up to 63% of retail, non-specialty prescriptions in plans that are using preferred networks in Part D.[57] But since preferred retail networks mainly fill non-specialty prescriptions, their impact is limited to the approximately 50% of overall drug expenditures that we estimate will be on non-specialty drugs over the 2019 to 2028 period.[58] Therefore, preferred or limited retail networks may deliver up to 2.5% in additional savings (e.g., 8% × 63% × 50% = 2.5%), in addition to baseline retail pharmacy network discounts. But since a portion of plans doesn't use preferred/limited retail networks, the savings impact on a plan-by-plan basis ranges from 0% to 2.5% relative to expenditures without preferred pharmacies. Assuming a normal distribution, we estimate an average savings of 1.25% across all plans.

Mail-Service Pharmacy Discounts: Based on a national survey of employer plan sponsors, the median mail-service pharmacy discount on brand drugs is 23% of the average wholesale price, which is 7 percentage points better than the discount achieved by retail drugstores.[59] For generics, the mail-service discount is 64%, which is 1–3 percentage points better than drugstores.[60] In addition, the survey found that 55% of plan sponsors pay no dispensing fees to mail-service pharmacies,[61] which we estimate adds close to 1 additional percentage point of savings for brands and 4% of savings for generics.

Visante estimates that 10% to 15% of 30-day equivalent prescriptions are currently filled via mail ("30-day equivalent prescriptions" were adjusted so that one 90-day prescription is normalized to three 30-day prescriptions).[62] Reports on drug trends published by PBMs indicate that plan sponsors can achieve mail-service penetration of 30% or more.[63,64] Approximately 28% of employers report that they require the use of mail-service pharmacies for prescriptions needed on an ongoing basis.[65] Based on this evidence, we estimate savings from mail-service pharmacies range from zero savings for plans with no mail-service pharmacies to up to 1.2% of total expenditures for plans with full use of mail-service. The upper bound 1.2% estimate is based on a discount of 8 percentage points relative to retail, 30% mail-service penetration for non-specialty prescriptions, and 50% of total prescription expenditures being non-specialty.[66] Assuming a savings range with a normal distribution of 0% to 1.2%, we estimate average mail-service savings of 0.6% on overall drug costs relative to expenditures without mail-service pharmacies. These savings are in addition to "baseline" retail network discounts.

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[55] "CMS Part D claims analysis: negotiated pricing between preferred and non-preferred pharmacy networks," CMS, Apr. 30, 2013.
[56] "New CMS study: preferred pharmacy networks are cheaper," Drug Channels, Jul. 11, 2013.
[57] "CMS Part D claims analysis," op. cit.
[58] During the next 10 years, Visante assumes that 50% of drug spending is "traditional drugs" and 50% of drug spending is "specialty drugs." This is based on Visante estimates of historical and projected trends in the growth of specialty expenditures.
[59] Pharmacy Benefit Management Institute, op. cit.
[60] Pharmacy Benefit Management Institute, op. cit.
[61] Pharmacy Benefit Management Institute, op. cit.
[62] According to Quintiles IMS Institute ("Medicines use and spending in the U.S. a review of 2016 and outlook to 2021"), prescription counts are adjusted for length of prescriptions and re-aggregated, with prescriptions for an 84-day supply or more factored by three and those under 84 days unchanged.
[63] "Changing rules, changing roles," CVS Caremark Insights, 2011.
[64] "Driving mail service usage reduces pharmacy costs," OptumRx, 2013.
[65] Pharmacy Benefit Management Institute, op. cit.
[66] During the next 10 years (2018-2027), Visante assumes that 50% of drug spending is "traditional drugs" and 50% of drug spending is "specialty drugs." This is based on Visante estimates of historical and projected trends in the growth of specialty expenditures.

Specialty Pharmacy Discounts: Plan-sponsor survey data indicate that discounts off average wholesale price for specialty pharmacy networks are approximately 2 points better than average network discounts through retail drugstores.[67] To estimate the marketplace impact of specialty pharmacy network discounts, we apply this 2-point discount to expenditures on specialty pharmaceuticals (50% of total drug expenditures), which results in specialty pharmacy network discounts generating savings of approximately 1% relative to drug expenditures without specialty network discounts. Because a portion of the market does not take advantage of specialty pharmacy network discounts, the savings range is estimated to be a normal distribution of 0% to 1%, with an average of 0.5%. These savings are in addition to "baseline" retail network discounts.

Potential Impact of State Legislation on Network Discounts

Impact of Disclosure Mandates: Anti-competitive government policies, such as disclosure mandates, would restrict the ability to negotiate pharmacy network discounts, eliminate the largest network discounts, compress the range of discounts toward the low end of the range, and (assuming a normal distribution) thereby reduce the market average discounts to the midpoint of the new range. We predict that retail network discounts would be reduced from a range of 11% to 13% to a new range of 11% to 12%, so the average would decrease from 12% to 11.5%. Preferred pharmacy savings would be cut from 0% to 2.5% to a new range of 0% to 1.25%, with the average savings dropping from 1.25% to 0.63%. Mail-service savings would change from 0% to 1.2% down to 0% to 0.6%, with the average cut from 0.6% to 0.3%. Savings from specialty network discounts would change from 0% to 1% down to 0% to 0.5%, and average savings would drop from 0.5% to 0.25%. Again, these savings are all relative to expenditures in the absence of these negotiated discounts. Based on these reductions in average network discounts, projected drug expenditures would increase 1.7%. This estimated impact is only for lost savings related to pharmacy network discounts and does not include other cost impacts on savings from manufacturer rebates discussed above.

We understand that there are a variety of PBM business models and pricing schemes in the marketplace today, some of which factor pharmacy network discounts and direct and indirect remuneration fees into the overall administrative fee structure for the PBM client. We see this as independent from our analysis. In other words, we are examining the potential impact on the pharmacy contracts themselves. Whether some clients choose to use a portion of their pharmacy savings to help reduce their administrative fees is independent from our analysis.

Impact of Any Willing Specialty Pharmacy Legislation: "Any willing specialty pharmacy" legislation would effectively eliminate specialty pharmacy network discounts. Because specialty drugs account for just 1% of prescription volume, we believe that an any willing pharmacy requirement would spread this small volume across too many pharmacies and effectively eliminate the ability of any one pharmacy to achieve the economies of scale necessary to offer the level of discounting currently offered by in-network specialty pharmacies. Under this scenario, specialty pharmacy contract discounts would revert to the lower baseline discounts associated with standard retail pharmacies. We estimate this would increase projected drug expenditures (including specialty and non-specialty) by 0.5%. This estimated impact is only for lost network discounts and does not include the additional cost impact that any willing pharmacy legislation would have on savings derived from other PBM tools, which we have modeled separately.

Prior Authorization and Step Therapy

PA: Today, PA is used by 92% of employer plan sponsors to improve clinical safety and decrease inappropriate utilization and waste.[68] A range of studies demonstrate that PA substantially reduces expenditures in targeted

[67] Baldini, C., and Culley, E., "Estimated cost savings associated with the transfer of office-administered specialty pharmaceuticals to a specialty pharmacy provider in a medical injectable drug program," *J Manag Care Pharm.* 2011;17(1):51-59.
[68] Pharmacy Benefit Management Institute, op. cit.

drug categories. For example, one study found that PA for a high-cost antibiotic resulted in 37% lower pharmacy costs and 38% lower total cost of care for patients prescribed the antibiotic.[69] One specialty pharmacy program that used PA to identify inappropriate utilization across six drug categories based on nationally recognized clinical guidelines achieved a 24% cost reduction in targeted categories.[70] A study of 22 state Medicaid programs found that PA lowered total drug expenditures by 0.6% based on its use in just one drug category alone.[71] Other studies have demonstrated that PA for specialty drugs can generate savings of up to 50% for targeted drugs or categories.[72,73] While most plan sponsors use PA, the number of drugs to which it is applied varies widely across plans. We also believe the use of PA is increasing in tandem with the growth of specialty pharmaceuticals. Based on these sources and assumptions, we estimate PA savings to range from 1% to 5%. Assuming a normal distribution, we estimate a market average of 3%, relative to drug expenditures without PA.

ST: About 82% of employer plan sponsors used ST to some degree in 2017.[74] A number of studies have found that ST generates savings. For example, one study examined ST applied to three drug classes and found it generated savings of approximately 2.3% relative to *total* drug expenditures without ST (i.e., total expenditures for the plan, not limited to only the three targeted drug classes).[75] Another study evaluated ST for antihypertensive drugs and found that antihypertensive drug costs were 13% lower for the patients in the ST intervention group.[76] Another study examined ST for antidepressants and reported average antidepressant drug cost per day decreased by 9% for patients following the protocol.[77] Taken together, the evidence suggests savings from ST of up to 2% to 3% relative to drug expenditures in the absence of ST. Trends indicate that ST is being used by an increasing number of plan sponsors and being applied to an increasing number of therapeutic categories. Thus, we assume the higher savings of up to 3% relative to expenditures without ST. Since nearly 20% of employer plan sponsors are not yet using ST, we assume a range of ST savings in the market of 0% to 3%. Assuming a normal distribution, we estimate a market average savings of 1.5% relative to drug expenditures without ST.

Potential Impact of State Legislation on Prior Authorization and Step Therapy

Impact of Limits on Use of PA and ST: Various limitations on PA and ST have been proposed in different states, including prohibiting the use of these important PBM tools. Such a prohibition would eliminate the savings generated from these tools altogether, eliminating the average PA savings of 3% and ST savings of 1.5% relative to expenditures without these tools, respectively. With the loss of these savings, projected drug expenditures would increase 4.6%.

Impact of Fiduciary Mandate on PA and ST: Government policies, such as fiduciary mandates, would increase liability risks for PBMs and result in more conservative use of PBM tools, including limited use of PA and ST. With scaled back PA and ST, the range of savings would be compressed toward the low end of the range and, assuming a normal distribution, reduce the market average savings to the midpoint of the new range. Thus, savings from PA would be reduced from a range of 1% to 5% to a range of 1% to 3%, and the market average would decrease from 3% to 2%. ST savings would be cut from 0% to 3% to 0% to 1.5%, with average savings dropping from 1.5% to 0.75%. Again, these savings ranges are all stated relative to drug expenditures in

[69] Starner, et al., "A linezolid prior authorization program: clinical and economic outcomes," *Am J Pharm Benefits*. 2014;6(2):81-88.
[70] "Specialty pharmacy: historical evolution and current market needs," op. cit.
[71] Fischer, et al., "Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors," *N Engl J Med.* 2004;351:2187-2194.
[72] "Specialty utilization management proves effective: ampyra prior authorization improves safety and saves money," Prime Therapeutics, 2011.
[73] "Specialty prior authorizations reduce costs and enhance medication safety," Walgreens Specialty Pharmacy, 2009.
[74] Pharmacy Benefit Management Institute, op. cit.
[75] Motheral, et al., "Plan-sponsor savings and member experience with point-of-service prescription step therapy," *Am J Manag Care*. 2004;10:457-464.
[76] Yokoyama, et al., "Effects of a step therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy," *J Manag Care Pharm.* 2007;13(3):235-244.
[77] Dunn, J., et al., "Utilization and drug costs outcomes of a step-therapy edit for generic antidepressant in an HMO in an integrated health system," *J Manag Care Pharm.* 2006;12(4):294-302.

the absence of PA and ST. Based on these reductions in savings, projected drug expenditures would increase 1.8% as a result of fiduciary mandates limiting the application of PA and ST. Fiduciary mandates would also have other impact savings from formulary and UM programs, which we have modeled separately.

Other PBM Tools That Improve Formulary Performance

In addition to PA and ST, PBMs use a variety of other tools to improve formulary management and promote the use of more cost-effective formulary drugs. These additional tools all work together to improve formulary performance and deliver drug cost savings:

- Formularies and therapeutic substitution
- Copay tiers
- Consumer education

Formularies and Therapeutic Substitution: Based on the decisions of plan sponsors, PBMs implement a variety of tools to improve formulary management/compliance and reduce costs. For example, 73% of plan sponsors opt to have PBMs implement formulary exclusions and 58% opt for mandatory generic programs among many other tools and techniques used alone or in combination.[78] CBO examined potential substitution for seven therapeutic classes and concluded that if generics were used in lieu of single-source brand-name prescriptions, prescription drug costs would have fallen by 7%.[79] Several other studies have demonstrated significant cost savings associated with more aggressive approaches to formulary management.[80,81,82,83,84,85,86,87] Research on PBM therapeutic substitution suggests savings of 1% to 5% relative to drug expenditures without such substitutions.[88] One PBM reported commercial clients that adopted a more highly managed formulary approach saved 8 percentage points more than clients that did not use this approach.[89]

Formulary management savings are available for both traditional and specialty drugs. Specialty drug categories with formulary-preferred brands have most often included growth hormone, multiple sclerosis, rheumatoid arthritis, blood modifiers, and hepatitis C. One plan increased the market share of the formulary-preferred human growth hormone from 27% to 82% within 12 months, generating savings of 20% in this expensive category.[90] As more biosimilars are approved during the next several years—with discounts of up to 50% relative to their brand competitors—these savings will extend to more specialty categories and become

[78] Pharmacy Benefit Management Institute, op. cit.
[79] "Effects of using generic drugs on Medicare's prescription drug spending," Congressional Budget Office, Sept. 2010.
[80] Shirneshan, et al., "Impact of a transition to more restrictive drug formulary on therapy discontinuation and medication adherence," *J Clin Pharm Ther*. 2016;41(1):64-69.
[81] Parra, et al., "Retrospective evaluation of the conversion of amlodipine to alternative calcium channel blockers," *Pharmacotherapy*. 2000;20(9):1072-1078.
[82] Usher-Smith, et al., "Evaluation of the cost savings and clinical outcomes of switching patients from atorvastatin to simvastatin and losartan to candesartan in a primary care setting," *Int J Clin Pract*. 2007;61(1):15-23.
[83] Good, et al., "Therapeutic substitution of cimetidine for nizatidine was not associated with an increase in healthcare utilization," *Am J Manag Care*. 2000;6(10):1141-1146.
[84] Benedetto, et al., "Impact of interventions designed to increase market share and prescribing of fexofenadine at HMOs," *Am J Health Syst Pharm*. 2000;57(19):1778-1785.
[85] Meissner, et al., "Drug and medical cost effects of a drug formulary change with therapeutic interchange for statin drugs in a multistate managed Medicaid organization," *J Manag Care Pharm*. 2006;12(4):331-340.
[86] McKinley, et al., "Intraocular pressure control among patients transitioned from latanoprost to travoprost at a Veterans Affairs Medical Center Eye Clinic," *J Ocul Pharmacol Ther*. 2009;25(2):153-157.
[87] Schneeweiss, et al., "A therapeutic substitution policy for proton pump inhibitors: clinical and economic consequences," *Clin Pharmacol Ther*. 2006;79(4):379-388.
[88] Kaiser Family Foundation, op. cit.
[89] "Mid-year drug trend: prime held spending increases to 0.8% for commercial clients, generated negative trend for government program clients," Prime Therapeutics, Oct. 2017.
[90] "Specialty pharmacy: historical evolution and current market needs," presented at PCMA Specialty Pharmacy Symposium, May 5, 2008.

increasingly significant for specialty drug expenditures. A recent Rand study predicted that biosimilars will lead to a $54 billion reduction in direct spending on biologic drugs from 2018 to 2027, or about 3% of total biologic spending over the same period.[91]

We estimate that formulary management and therapeutic substitution programs save 1% to 5% on drug expenditures across all therapeutic categories. However, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depend on them being implemented together in an integrated fashion. Therefore, to be conservative and avoid double-counting of savings, we adjust these estimated savings down to a range of 0.5% to 2.5%, relative to expenditures without the use of these PBM tools.

Copay Tiers: During the past 20 years, plan sponsors have dramatically increased the use of tiered copay structures to encourage greater use of generics and preferred brands. Benefit designs with three or more tiers have replaced two-tier benefit designs; the difference between the copay tiers has increased from about $10 up to approximately $30.[92] The implementation of tiered copays has created stronger aligned incentives for consumers and helped create more effective formulary management. One study examined the addition of a three-tier copay, with relatively modest copays of $8/$15/$25. Payer costs dropped 17%, with 10% attributed to the absolute increase in copayments and 7% to the utilization of lower-cost drugs.[93] Another study found that changing from a single-tier or two-tier formulary to a three-tier formulary was associated with a decrease in total drug spending of 5% to 15%, depending on the copay structures.[94] Other studies demonstrated that the introduction of a third tier for non-preferred brands induced a shift to lower-tiered drugs and strengthened plans' ability to negotiate price discounts.[95,96] Another study examined the effect of the size of the copay differential and found that each $5 increase in copayment was associated with decreased rates of switching to a relatively more expensive drug and an increased rate of switching to drugs of equal or lesser cost.[97]

Our savings model examines combined drug expenditures for both payers and consumers, so reallocating costs from payers to consumers is not counted as savings. That said, there is uncertainty about what the "optimal amount of consumer cost sharing" should be. According to one literature review, 85% of studies that examined changes in patient cost sharing revealed that increasing cost sharing had a negative effect on adherence.[98] Cost-related non-adherence has prompted some employers to reevaluate their cost-sharing policies. Some plan sponsors have reduced or eliminated copayments for selected medications in accordance with value-based insurance designs and demonstrated improvements in adherence as a result.[99,100]

Based on the published evidence, we estimate a range of savings of 2% to 10% associated with more advanced approaches to copay tiers. Again, we count only savings associated with the use of lower-cost drugs. Any shift in the distribution of costs from plan sponsors to consumers is not counted as savings. However, as stated above, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depends on these tools being used in an integrated fashion. Therefore, in order to be conservative and avoid double-counting of savings, we adjust these estimated savings down to 1% to 5%. In other words, moving from a one- or two-tiered copay to more advanced copay tiers may promote use

[91] Mulcahy, et al., "Biosimilar cost savings in the United States," The Rand Corporation, Oct. 2017.
[92] "2017 Employer Health Benefits Survey," Kaiser HRET, Sept. 2017.
[93] Motheral, et al., "Effect of three-tier prescription copay on pharmaceutical and other medical utilization," *Med Care*. Dec. 2001;39(12):1293-1304.
[94] Landon, et al., "Incentive formularies and changes in prescription drug spending," *Am J Manag Care*. Jun. 2007;13(part 2):360-369.
[95] Joyce, et al, op. cit.
[96] Huskamp, et al., "The impact of a three-tier formulary on demand response for prescription drugs," *J Econ Manag Strategy*. Jul. 2005;14(3):729-753.
[97] Saito, et al., "Copayment level and drug switching: findings for type 2 diabetes," *Am J Pharm Benefits*. 2010;2(6):412-420.
[98] Eaddy, et al., "How patient cost-sharing trends affect adherence and outcomes—a literature review," *Pharm Ther*. Jan. 2012;37(1):45-55.
[99] Chernew, et al., "Impact of decreasing copayments on medication adherence within a disease management environment," *Health Aff (Millwood)*. 2008;27(1):103-112.
[100] Maciejewski, et al., "Copayment reductions generate greater medication adherence in targeted patients. *Health Aff (Millwood)*. 2010;29(11):2002-2008.

of lower-cost drugs, creating savings of 1% to 5%. Assuming a normal distribution, we estimate average savings of 3%, relative to expenditures with rudimentary copay structures.

Consumer Education: PBMs use a variety of educational programs to increase consumer understanding of their pharmacy benefit. For example, a recent survey revealed that 71% of employer clients provide online tools and mobile apps, 57% provide clinical support and counseling, and 42% provide personalized health information.[101] In addition to stand-alone consumer education programs, PBMs may include incentives in their pharmacy network contracts to achieve improved formulary compliance and use of generic alternatives. For example, one PBM study estimated that consumer education can save up to 4% by combining generic incentives with consumer education.[102]

While some plans and PBMs may save up to 4%, other plans invest little time or money in consumer education.

Therefore, we estimate a range of savings of approximately 0% to 4% associated with consumer education. However, as stated above, Visante assumes the effectiveness of these three categories of PBM tools (e.g., formularies and therapeutic substitution, copays, consumer education) depend on working together in an integrated fashion. To be conservative and avoid double-counting of savings, we adjust these estimated savings down to a savings range of 0% to 2%. Assuming a normal distribution, we estimate average savings of 1%, achieved relative to drug expenditures by plans with no consumer education programs.

Other PBM Tools That Manage Drug Utilization

Prior authorization is often used as a UM tool, but PBMs offer their clients other UM tools as well, including drug utilization review (DUR), refill-too-soon checks, and quantity limits.

DUR: DUR programs improve quality and safety by preventing drug duplication, drug interactions, and polypharmacy. Such programs also reduce dangerous over-utilization of prescription drugs. Some DUR programs occur while the prescription is being filled in the pharmacy and the prescription claim is processing through the PBM. These checks include drug-drug interactions, drug duplications, and potential overuse. In addition to these concurrent checks during the claims processing, many employers also use retrospective DUR programs that occur after the prescription has been filled. Approximately 50% of employer plan sponsors now use retrospective DUR services, and 30% use prescriber profiling. More than 75% of employers use DUR programs focused on opioids and other controlled substances, while more than 80% of employers use specialty care management programs that include DUR activities.[103] Numerous studies have documented drug cost savings associated with DUR programs. One study examined DUR programs and found average savings of 6.9% relative to total drug expenditures without DUR programs (i.e., total expenditures under the plan, not limited to only drug categories targeted by the DUR programs).[104] An opioid DUR program demonstrated a 28% reduction in potentially unsafe opioid use.[105] DUR savings apply to both traditional (i.e., non-specialty) and specialty drug expenditures. Specialty pharmacies also use DUR to reduce product waste. One specialty pharmacy demonstrated that hemophilia assay management and waste reduction using DUR reduced targeted expenditures by 7.7%, that dose optimization using DUR saved 6.6% on a targeted medication, and that a waste reduction program using DUR reduced drug expenditures on targeted therapy by 1%.[106] Based on this evidence,

[101] Pharmacy Benefit Management Institute, op. cit.
[102] Visante analysis of PBM Drug Trend Reports.
[103] Pharmacy Benefit Management Institute, op. cit.
[104] Moore, et al., "Systemwide effects of Medicaid retrospective drug utilization review programs," *J Health Polit Policy Law.* Aug. 2000;25(4):653-688.
[105] Qureshi, et al., "Effectiveness of a retrospective drug utilization review on potentially unsafe opioid and central nervous system combination therapy," *J Manag Care Spec Pharm.* Oct. 2015;21(10):938-944.
[106] "Specialty Pharmacy: Historical Evolution and Current Market Needs," op. cit.

we estimate a range of DUR savings in the marketplace of 3% to 7%. Assuming a normal distribution, we estimate a market average savings of 5% relative to drug expenditures without DUR.

Refill-Too-Soon Checks: About 92% of employer health plan sponsors use refill-too-soon checks in the claims processing system.[107] A refill-too-soon alert is sent to the pharmacy if, say, a pharmacy dispenses a 30-day supply of medication and the patient tries to refill it 10 days later. We estimate that virtually all plan sponsors obtain savings of 1% based on refill-too-soon checks (savings relative to expenditures without refill-too-soon checks).

Quantity Limits: More than 90% of employers report using quantity limits for top drug categories.[108] Research suggests that specific drug limits and general limitations can save up to 1% of drug expenditures.[109] PBMs publish their standard lists of drugs and quantity limits, which are all very similar.[110] We estimate that virtually all plan sponsors obtain savings of 1% (savings relative to drug expenditures without the use of quantity limits).

Potential Impact of State Legislation on Other Formulary and Utilization Management Programs

Impact of Fiduciary Mandate: Government policies such as fiduciary mandates would increase liability risks for PBMs and result in more limited use of formulary and UM programs. As these programs are scaled back, the range of savings would be compressed toward the low end of the current marketplace range, and thereby reduce the average. We predict that the range of formulary management savings would compress from 1.5% to 9.5% to 1.5% to 5.5%, with market average savings dropping from 5.5% to 3.5%. Savings from DUR programs would decrease from 3% to 7% to 3% to 5%, with the average savings cut from 5% to 4%. Again, these savings are all relative to drug expenditures in the absence of these PBM tools. Based on these reductions in average savings, projected drug expenditures would increase 3%. This estimated impact is only for lost savings related to formulary and UM, and does not include other cost impacts on savings from PA and ST discussed above.

Impact of Any Willing Specialty Pharmacy Legislation: The effectiveness of PA, ST, formulary management, and UM programs in managing specialty drug expenditures often hinges on active participation by specialty pharmacies. Specialty pharmacies have highly trained teams of pharmacists, nurses, and other experts to deliver advanced patient care services, customized for individual patients and individual drug therapies. Specialty pharmacy operations may be coordinated with a PBM's PA, ST, formulary, and UM programs, including special training, staff, and information systems. Any willing specialty pharmacy legislation would bring in specialty pharmacies that do not have specialized resources and expertise and are not coordinated with PBM programs. Therefore, the effectiveness of these PBM programs would be hampered. Without active participation by specialty pharmacies, the range of savings would be compressed toward the low end of the range and, assuming a normal distribution, thereby reduce the market average savings. The range of formulary management savings would decrease from 1.5% to 9.5% to 1.5% to 5.5%, with the market average savings dropping from 5.5% to 3.5%. Savings from DUR programs would decrease from a range of 3% to 7% to a range of 3% to 5%, with the average savings dropping from 5% to 4%. Again, these savings are all relative to drug expenditures in the absence of these PBM tools. This negative impact on PBM savings would be limited to specialty drug expenditures, which are expected to represent approximately 50% of projected drug expenditures during the next 10 years. Based on these reductions in average savings on specialty drug costs, overall projected drug expenditures (i.e., specialty and non-specialty) would increase 2.4%. This estimated impact is only for lost savings related to formulary and UM and does not include other negative impacts on savings from other PBM tools discussed above (e.g., specialty pharmacy, network discounts, PA, and ST).

[107] Pharmacy Benefit Management Institute, op. cit.
[108] Pharmacy Benefit Management Institute, op. cit.
[109] Visante analysis of PBM Drug Trend Reports.
[110] Visante analysis of PBM published quantity limits.

Potential Impact of Fiduciary Mandates: Additional Costs of Liability Insurance

Requiring PBMs to owe a fiduciary duty to covered entities would expose PBMs to increased legal risk that may result in the need to adopt defensive business and operating strategies to avoid the threat of litigation. The added cost of increased insurance exposure could drive pharmaceutical costs higher. Operationally, we believe that an important impact of the legislation is to expose PBMs to legal liability for the drug benefits that they manage. PBMs would have to boost their liability insurance and might limit the use of utilization techniques to avoid potential lawsuits.

The most reliable data on medical liability insurance costs were published in 2010.[111] These data suggested that total liability insurance costs for doctors and hospitals were approximately 1% of total U.S. expenditures for doctors and hospitals. We estimate that PBMs would be forced to purchase liability insurance that might be priced in a similar manner. Therefore, we apply the same ratio to PBMs and drug expenditures (i.e., additional PBM liability insurance costs will be approximately 1% of covered drug expenditures). In other words, projected drug expenditures would increase 1%. This estimated impact is only for the additional cost of liability insurance and does not include other cost impacts on savings from other PBM tools discussed above.

We interviewed a number of legal experts who believe that this methodology is reasonable. However, given the limited information available, it probably understates the potential cost of additional insurance, particularly since this would be a new type of insurance coverage and thus carry additional risk and additional price premiums from liability insurers.

In addition, fiduciary mandates would result in additional costs from administering benefits under a patchwork of varying legal requirements across states. Additional costs and risks could result from private actions for damages by a client or a consumer, as a result of a "fiduciary" label. All those costs would be passed back inevitably to the plan sponsors, but we are unable to specifically estimate these potential costs. Therefore, we believe our estimates for both insurance and other costs associated with fiduciary requirements are conservative and understated.

[111] Mello, et al., "National costs of the medical liability system," *Health Aff (Millwood).* 2010;29(9):1569-1577.

Summary: Potential Impact of State Legislation on PBM Tools and Savings

The table below summarizes which PBM tools would be negatively affected by four types of state legislation.

PBM Tools/Impact	Disclosure Mandate	Fiduciary Mandate	Prohibit PA and ST	Any Willing Specialty Pharmacy
Manufacturer rebates	✓			
Pharmacy network contract discounts	✓			✓
PA and ST		✓	✓	✓
Other PBM tools that improve formulary performance		✓		✓
Other PBM tools that manage utilization		✓		✓
Additional liability insurance		✓		
Increase in projected drug expenditures	**4.3%**	**5.8%**	**4.6%**	**2.9%**

B. Projected Drug Expenditures (2019 to 2028) and State-by-State Breakdowns

To derive baseline drug expenditures managed using PBM tools, Visante began with CMS National Health Expenditure (NHE) projections for outpatient prescription drug expenditures from 2017 to 2026. These expenditures do not include drugs administered in hospitals or physician offices. Visante extrapolated these projections to 2027 and 2028. By these estimates, spending on outpatient prescription drugs will grow from $381 billion in 2019 to $679 billion in 2028, for a total of $5.2 trillion over the 10-year period.[112]

The projections reflect CMS assumptions concerning the impact of health reform, manufacturer price inflation, patent expirations, new drug introductions, follow-on biologics, and other factors. Our model incorporates these assumptions to the extent that they are incorporated into the NHE projections.

CMS outpatient drug expenditure projections reflect net costs to payers, including plan sponsors and consumers. Manufacturer and pharmacy discounts are reflected in CMS figures. CMS segments outpatient prescription drug expenditures by payer, including private insurance, Medicare, Medicaid, and other government programs. Visante assumes that nearly all commercial/private insurer expenditures are associated with the use of PBM tools. Visante also estimated the share of consumer out-of-pocket expenditures arising from copayments/cost sharing for prescriptions associated with PBMs and PBM tools, based on survey data for commercial plan sponsors.[113,114]

After these calculations, we estimate that outpatient prescription drug expenditures for the commercial market (associated with average use of PBM tools, including plan sponsor and consumer payments) will be approximately $191 billion in 2019 and $2.5 trillion over the 10-year period 2019 to 2028. Drug expenditures for the fully insured portion of the commercial market will be $94 billion in 2019 and $1.2 trillion over the 10-year period from 2019 to 2028.

As discussed, CMS's 10-year projections reflect many assumptions regarding marketplace trends. We believe that CMS estimates reasonably capture these trends and reflect the current savings that PBMs achieve in the marketplace. For example, CMS estimates that drug manufacturer rebates to pharmacy benefit managers have increased sharply in the past few years and are expected to have dampened prescription drug spending growth in 2017.[115] However, CMS does not publish the detailed factors underlying its model, so we estimated the factor inputs necessary to model PBM savings and then applied them to baseline expenditures derived from CMS data.

We assume that over the 10-year projection period:

- Expenditures for traditional prescription drugs will show low growth or no growth during the next 10 years, while specialty drug spending will continue to grow rapidly.[116] The generic dispensing rate was 84.6% in 2016[117] and will grow slowly.[118] We assume that these trends are captured in the CMS projections.
- Specialty medications will be the dominant force driving growth in prescription drug expenditures over the next 10 years. One report estimates total specialty drug spending under pharmacy benefits doubling

[112] National Health Expenditure Data (2016 to 2025 data extrapolated to 2028), CMS.
[113] "2017 employer health benefits survey," Kaiser HRET, Sept. 2017.
[114] Pharmacy Benefit Management Institute, op. cit.
[115] Cuckler, et al., "National health expenditure projections, 2017–26: despite uncertainty, fundamentals primarily drive spending growth," *Health Aff (Millwood).* 2018;37(3).
[116] Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.
[117] IQVIA Institute (formerly Quintiles IMS), op. cit.
[118] IQVIA and PBM Drug Trend Reports.

from $120 billion in 2016 to $240 billion in 2021.[119] Most observers project that the specialty pharmacy market will grow much more rapidly than will the market for traditional prescription drugs, at a projected compound annual growth rate greater than 10%.[120] We estimate the total specialty market under the pharmacy benefit growing from $130 billion in 2019 to $400 billion in 2028. A roughly equal amount of specialty drug expenditures covered under the medical benefit and administered in hospitals, clinics, and physician offices is not included in CMS projected outpatient drug expenditures and not included in our analysis.

- While more PBMs are playing a management role in physician-administered specialty injectable drugs covered by medical benefits, our projected drug expenditures and PBM savings estimates do not reflect such activity.

We created a state-by-state breakdown for the national projected drug expenditures for the fully insured commercial population (which includes fully insured employer-sponsored plans and individually purchased insurance both within and outside health exchanges). Projected national outpatient drug expenditures were then calculated for each state based on Visante's state-by-state enrollment estimates, including state-by-state enrollment estimates for commercial fully insured, commercial self-insured, Medicare, and Medicaid based on a number of published references.[121,122,123,124,125]

Our methodology results in state-by-state estimates that capture many—but not all—of the factors that may characterize the prescription drug market in individual states. Any unusual circumstances that would not be captured by enrollment patterns would not be reflected in our estimates. Finally, some states may have already enacted laws related to the legislative areas included in our economic model. To the extent that such laws have already raised costs, those costs would be included in the estimates presented in the report.

[119] "2017 economic report on pharmacies and pharmacy benefit managers," Pembroke Consulting, Feb. 2017.
[120] Drug Trend Reports from CVS Health, Express Scripts, and Prime Therapeutics.
[121] U.S. Census, 2016.
[122] "Health insurance coverage of the total population (2016)," Kaiser Family Foundation, accessed Feb. 2017.
[123] "Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and state: United States," AHRQ Medical Expenditure Panel Survey, 2016.
[124] More than 99% of covered workers in employer-sponsored plans have a prescription drug benefit. "2017 employer health benefits survey," Kaiser HRET, Sept. 2017.
[125] "Health exchange enrollment, total effectuated enrollment and financial assistance by state," CMS, Mar. 15, 2017.

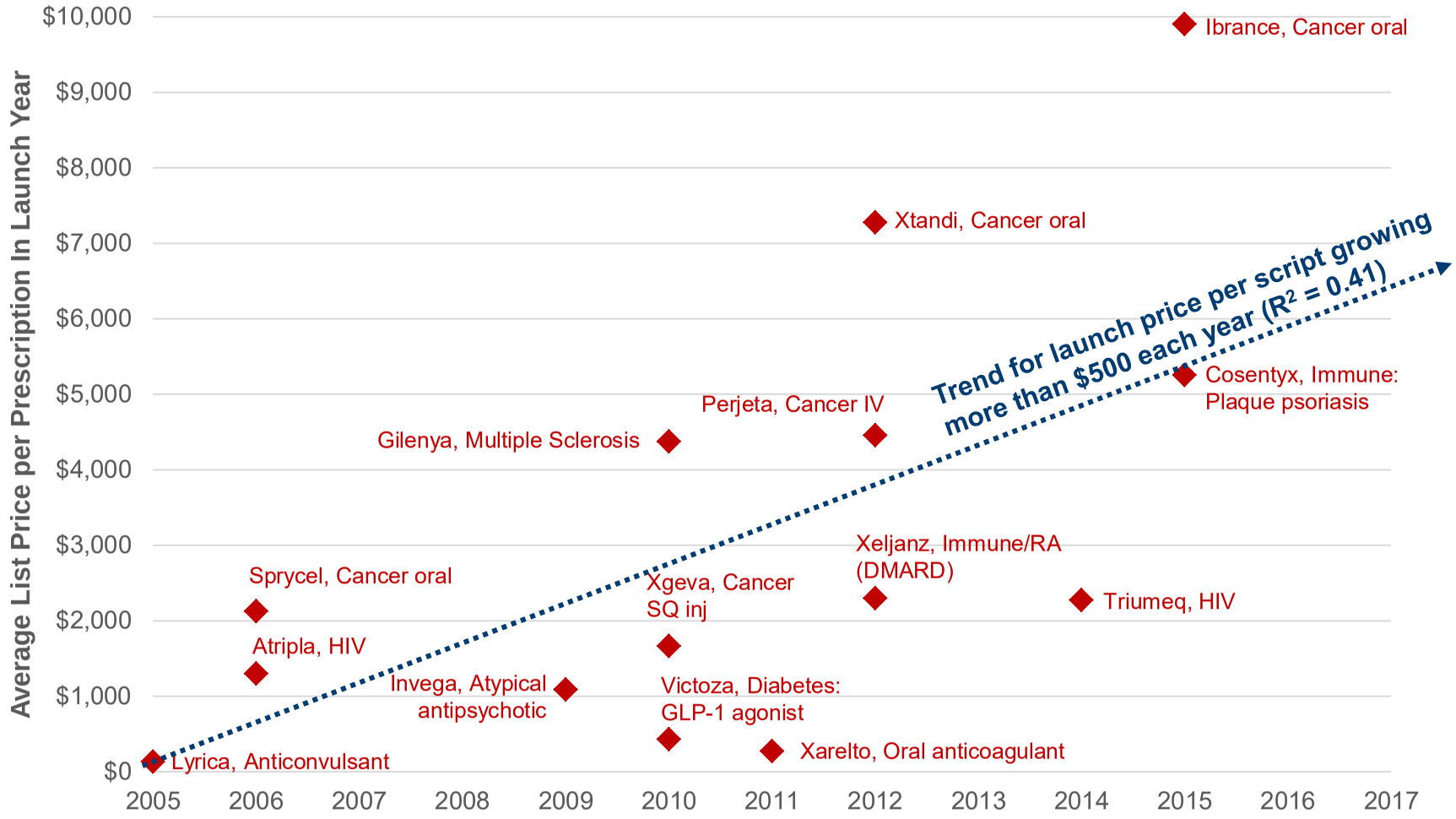
PCMA

Reconsidering Drug Prices, Rebates, and PBMs

An analysis prepared by Visante®

August 2018

Higher Introductory Prices for New Drugs Launched with No PBM Rebates



Source: Visante analysis of data from CMS and SSR Health, 2018. Analysis included drugs with more than $1 billion in sales in 2017, and no estimated rebates in initial launch year. Average list prices based on WAC/unit, multiplied by # of units per Rx based on 2016 Part D data from CMS.

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No PBM Rebates in Part B, Yet Extraordinary Price Increases

Part B Drugs with Extraordinary Price Increases

Brand Name	2012 Price per Part B prescription	2017 Price per Part B prescription*	% Price Increase 2012–17
Miacalcin	$461	$16,375	3,449%
BICNU	$391	$8,530	2,084%
Krystexxa	$2,717	$19,163	605%
Rimso-50	$85	$540	535%
Teflaro	$110	$399	263%
Bicillin	$41	$106	159%
Vibativ	$446	$1,102	147%
Oncaspar	$7,513	$16,717	122%
Levulan	$178	$385	117%
DDAVP	$120	$211	76%

* Estimated inflation adjusted price = 2012 price * weighted average manufacturer increase in list price per unit. Not affected by changes in numbers of units per claim, or mix of doses/dosage forms. Analysis included drugs with Part B spending data for full period 2012-16. PBMs are currently not involved in Medicare Part B program, so no PBM rebates are involved.

Source: Visante analysis of data from CMS and SSR Health, 2018.

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No PBM Rebates in Part B, Yet Prices Increasing for Top Drugs

Commonly Used Part B Drugs with Price Increases

Brand Name	2012 Price per Part B Prescription	2017 Price per Part B Prescription*	% Price Increase 2012–17
Rituxan	$5,125	$6,890	34%
Neulasta	$2,904	$4,436	53%
Remicade	$2,937	$4,561	55%
Avastin	$1,301	$1,618	24%
Prolia	$1,864	$2,640	33%
Herceptin	$2,720	$3,452	27%
Orencia	$1,636	$2,849	74%
Alimta	$5,197	$6,044	16%
Sandostatin LAR	$3,580	$5,042	41%
Xolair	$1,547	$2,294	48%

* Estimated inflation adjusted price = 2012 price * weighted average manufacturer increase in list price per unit. Not affected by changes in numbers of units per claim, or mix of doses/dosage forms. Analysis included drugs with SSR Health data and Part B spending data for full period 2012-16. PBMs are currently not involved in Medicare Part B program, so no PBM rebates are involved. Drugs are listed in decreasing order of Part B spending.

Source: Visante analysis of data from CMS and SSR Health, 2018.

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Unrebated Drugs in Part D Still Increasing Their Prices

Ten Drugs >$50m in Part D Annual Spend, With Largest Price Inflation 2012–2017

Brand Name	2012 Price per Part D Prescription	2017 Price per Part D prescription*	% Price Increase 2012–17
Xeljanz	$2,367	$4,128	74%
Aubagio	$3,978	$6,840	72%
Ampyra	$1,544	$2,619	70%
Risperdal Consta	$715	$1,105	55%
Sprycel	$7,350	$11,178	52%
Noxafil	$3,543	$5,082	43%
Actemra	$1,490	$2,110	42%
Nuedexta	$491	$684	39%
Xgeva	$1,766	$2,267	28%
Acthar	$37,130	$47,540	28%

* Estimated inflation adjusted price = 2012 price * weighted average manufacturer increase in list price per unit. Not affected by changes in numbers of units per claim, or mix of doses/dosage forms.

Source: Visante analysis of data from CMS and SSR Health, 2018. Analysis included drugs with Part D spending data for full period 2012-16, and drugs with no estimated non-Medicaid rebates based on data from SSR Health, 2018. Drugs listed in order of decreasing price increases.

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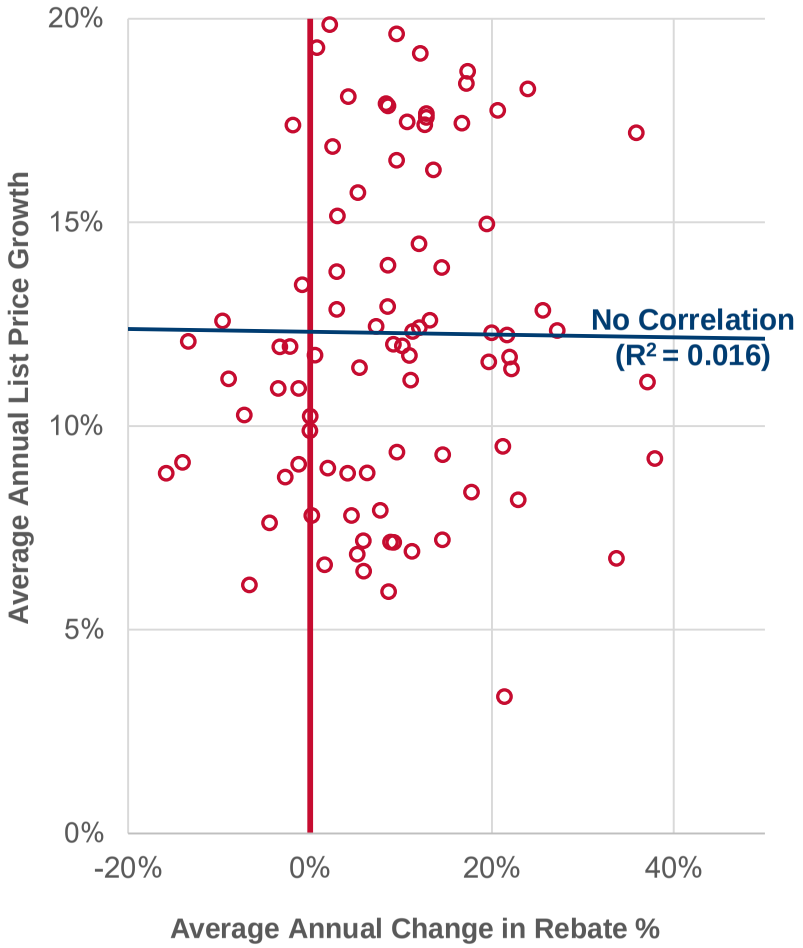
Top Part D Brand Drugs: Growing Drug Prices Show No Correlation With Change in Rebate Levels Over the 2012–2017 Period

Statistical Analysis Shows No Correlation Between Price Growth and Rebate Growth

- Among the top brand drugs in Medicare Part D, there is no correlation between growing prices set by drugmakers and the CHANGE in rebate levels that they negotiate with PBMs.
- Rebates may go up or down, but manufacturer prices only go up.
- Drugs with decreasing rebates still increased their prices during the 2012–2017 period.
- For each of the top Part D brand drugs, the figure at right plots the compound annual growth rate (CAGR) in its list price against the change in average percent rebate (CAGR) over the 2012–2017 period.
- The flat trend line suggests that drug prices are increasing regardless of rebate levels across all top brand drugs.
- Statistical analysis shows the trend line's R2 value equals 0.016 on a zero to one scale, where zero equals no correlation and one equals perfect correlation.



Source: Visante analysis of data from CMS and SSR Health, 2018. Examined the top 250 brand drugs by 2016 spend in Part D, 144 had valid rebate estimates from SSR Health, 109 were on the market the full time period 2012–17.

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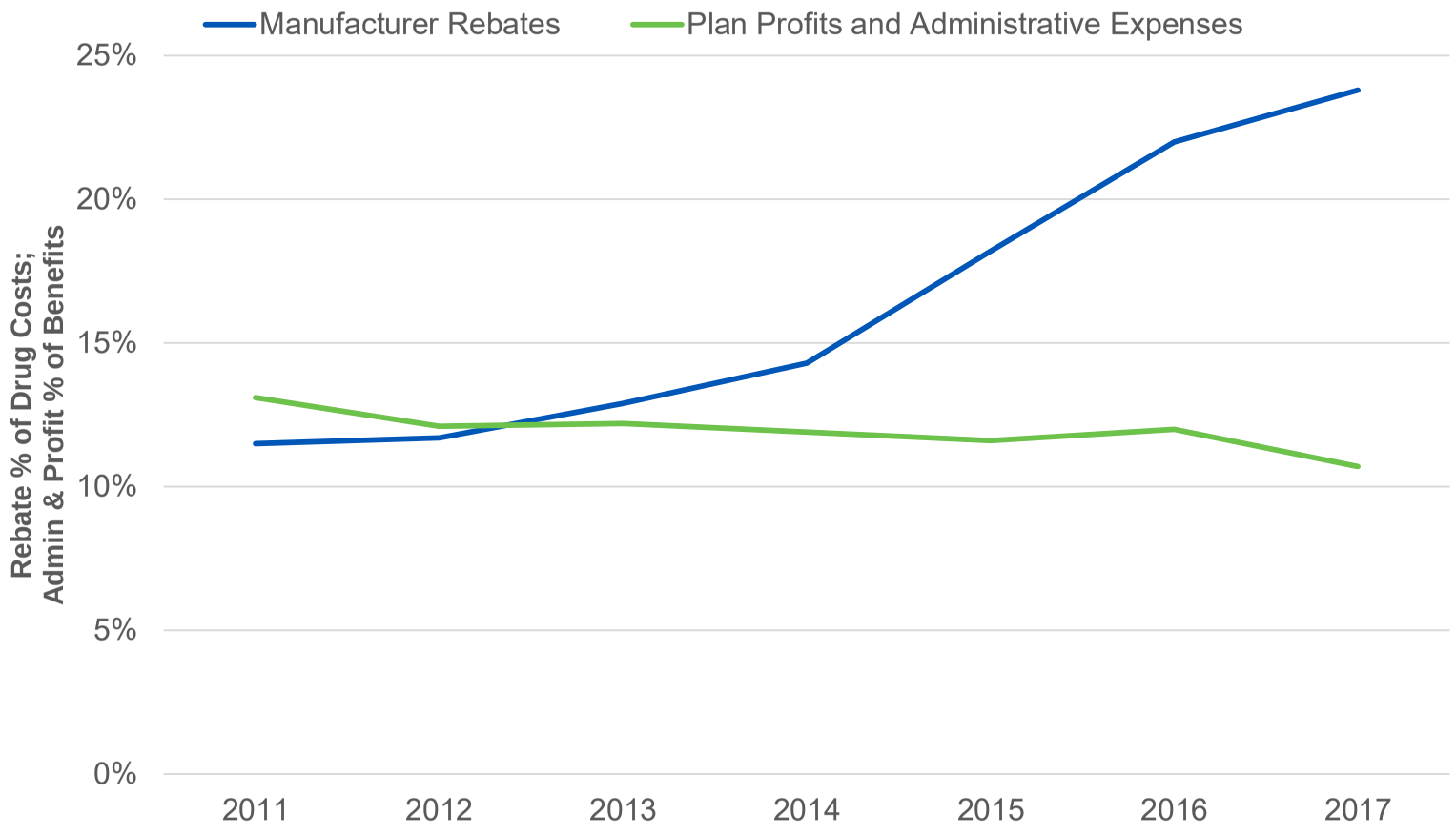
Trend in Part D Manufacturer Rebate Levels NOT Associated With Trend in Part D Profits and Administrative Expenses



Source: Medicare Trustees Report to Congress, March 2018.

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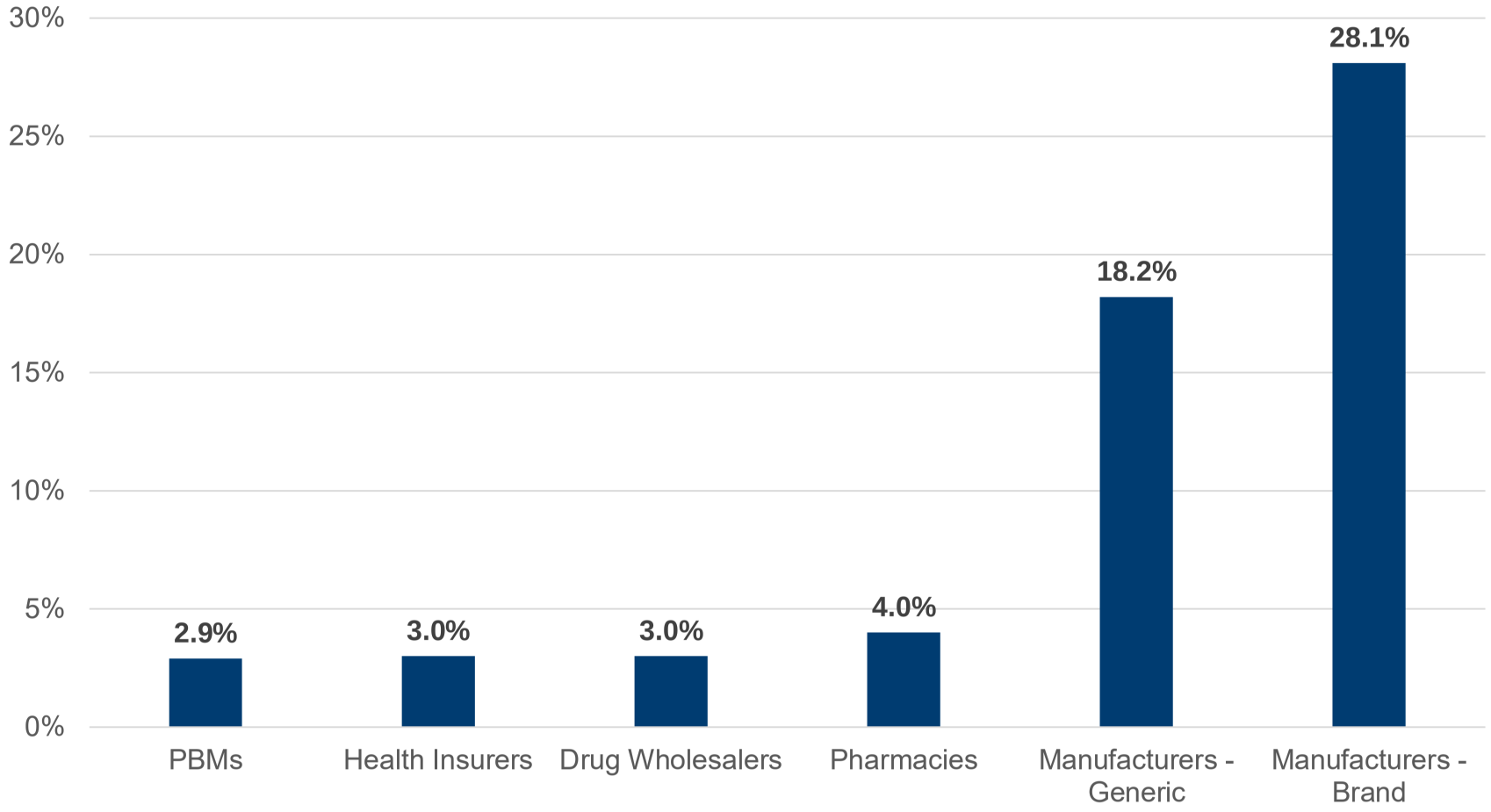
PBM Profit Margins Are the Smallest in Pharmaceutical Supply Chain



Source: *The Flow of Money Through the Pharmaceutical Distribution System.* Schaeffer Center for Health Policy & Economics, University of Southern California. June 2017

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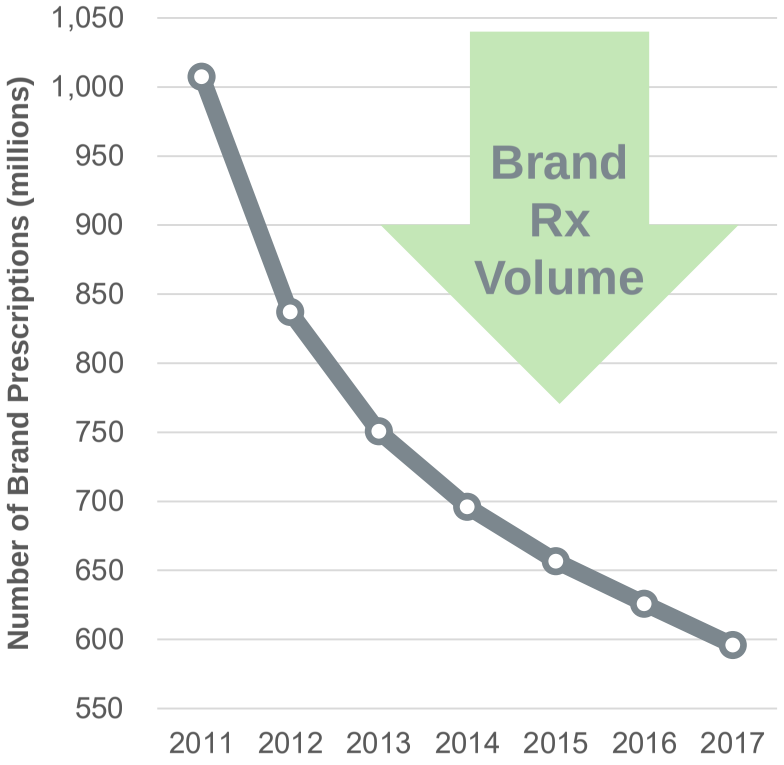
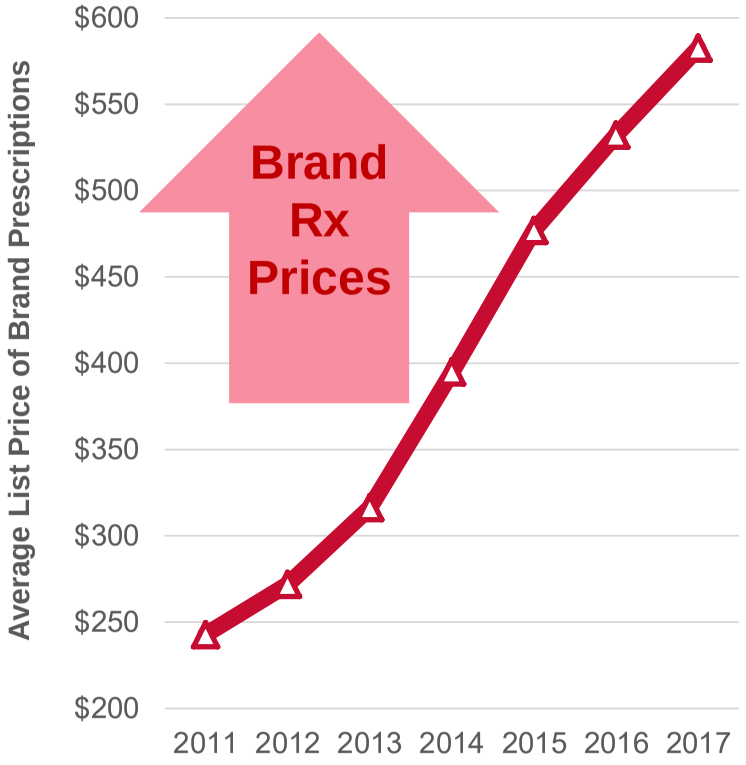
Why Are Manufacturers Increasing Prices? To Counter Shrinking Prescription Volume for Brand Drugs

Brand Prescription Volume Has Plummeted as Generics Have Replaced Brands



Meantime, Brand Drug Prices Have Skyrocketed to Maintain Revenues



Source: Visante analysis data published by the IQVIA Institute, 2018.

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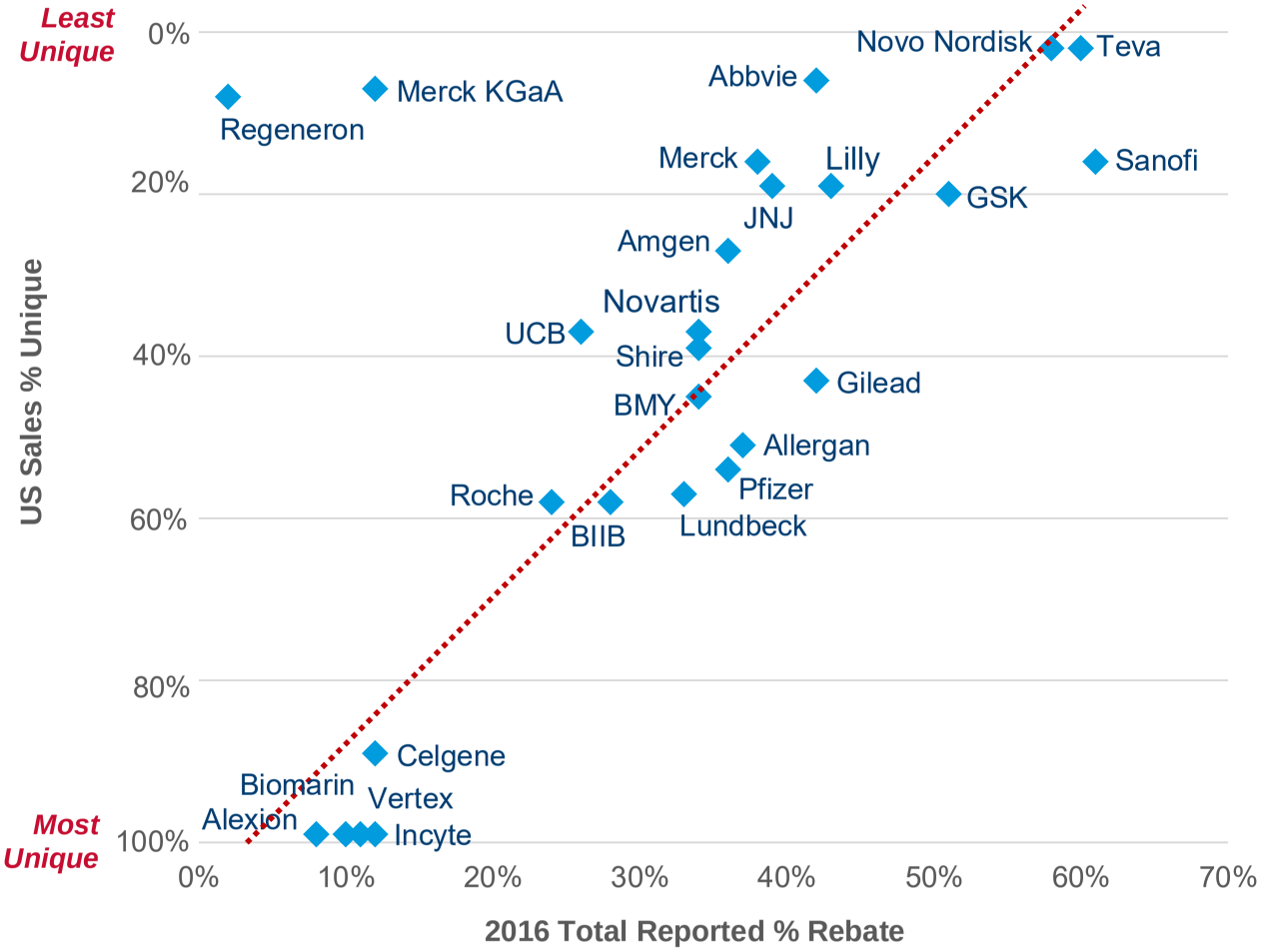
Drug Rebates Vary Based on Each Product's Uniqueness

Credit Suisse on the Relationship Between Product Uniqueness and Rebates



"We find a strong correlation between the level of rebates reported and the uniqueness of a company's portfolio."

"Companies with more unique products typically report lower levels of rebates."

Source: Credit Suisse, "Global Pharma and Biotech Sector Review: Exploring Future U.S. Pricing Pressure, April 2017.

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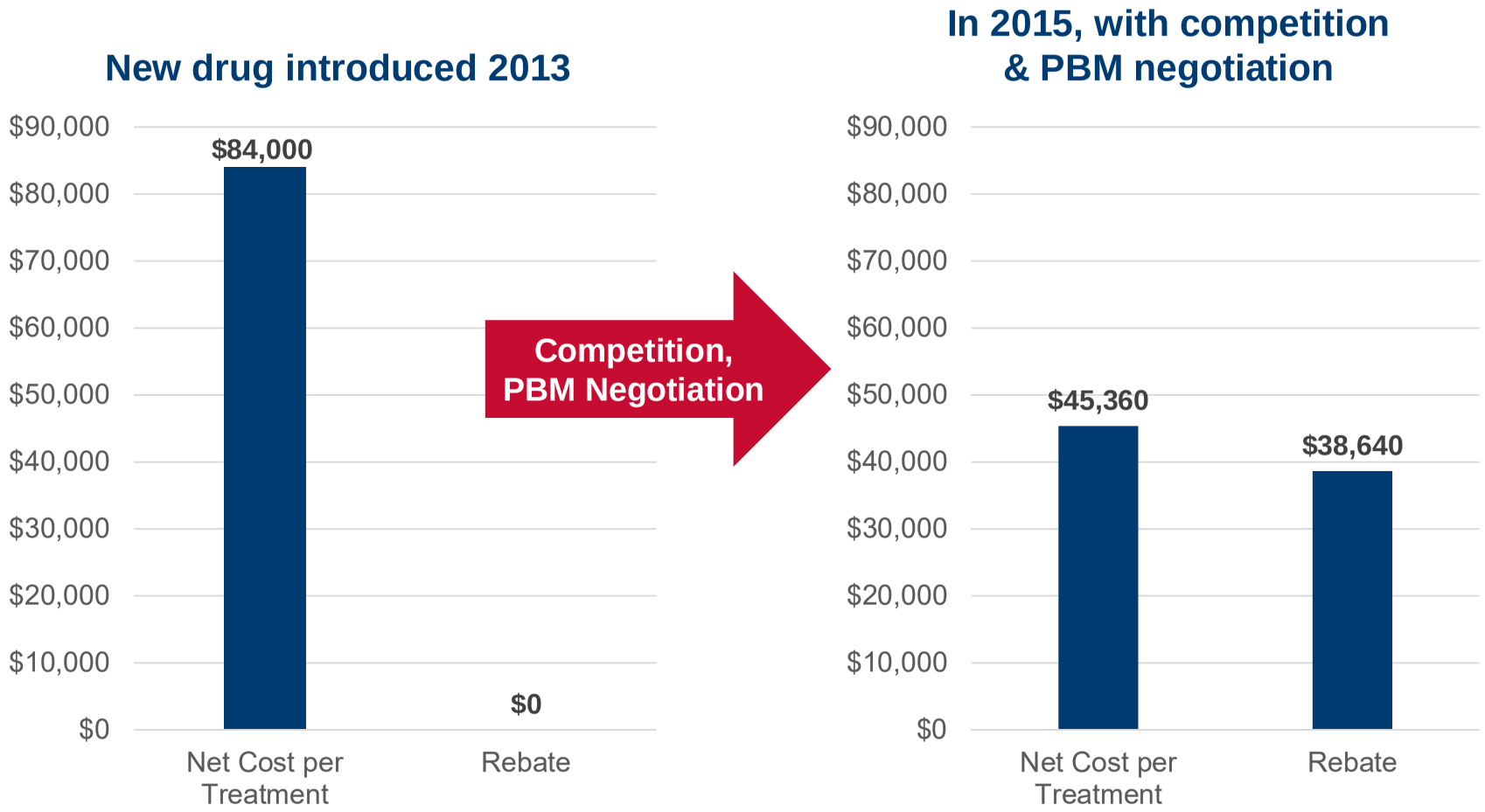
Hepatitis C Experience Shows How PBMs Harness Competition to Lower Costs



Sources: "Express Scripts' Miller Says Hepatitis C Price War to Save Billions," Reuters, Jan. 22, 2015.
"What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing," Drug Channels, Feb. 5, 2015.

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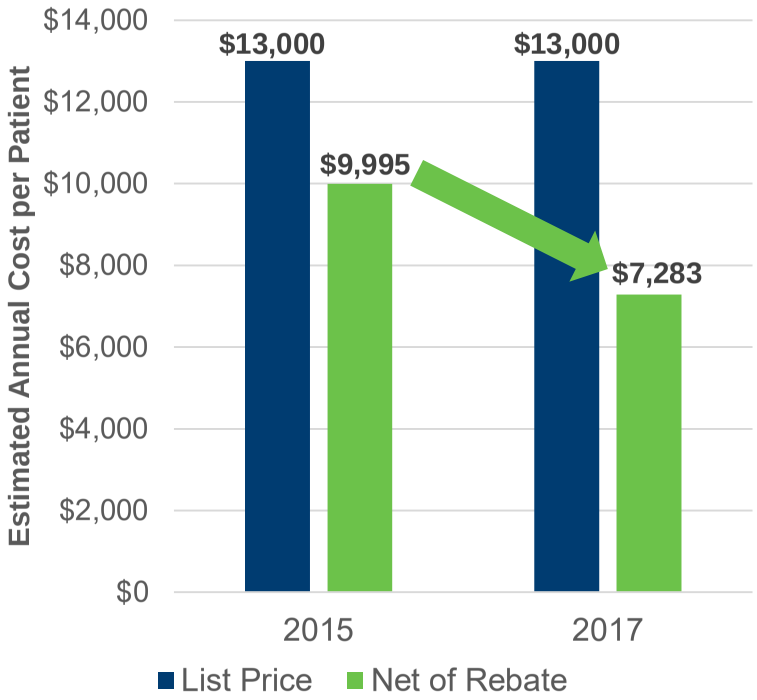
PCSK-9 Experience Demonstrates How PBMs Hold Down Costs for High Cost Drugs

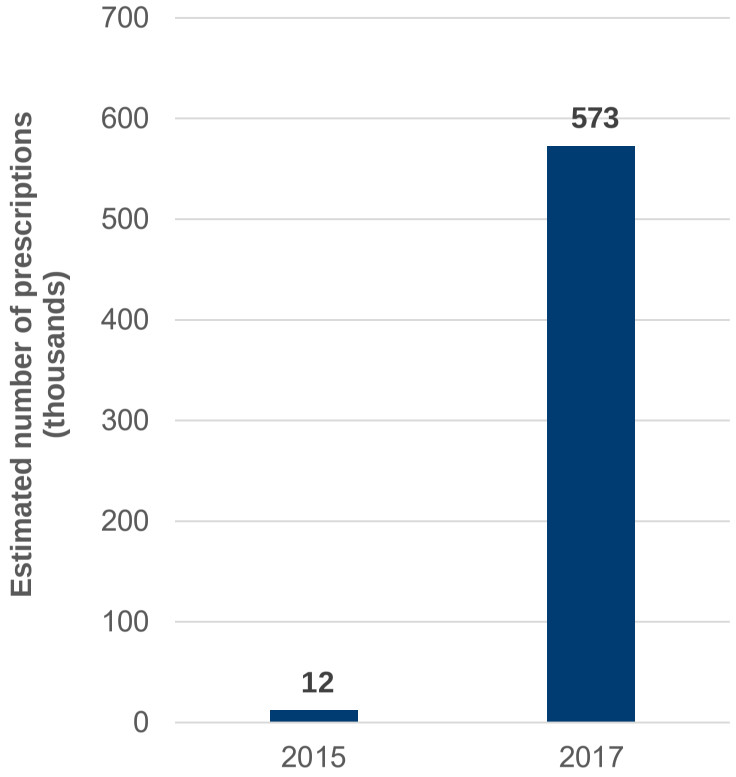
PBMs negotiated better rebates that lowered net cost

Average Net Cost per Prescription



With lower net costs, PBMs increased access

Utilization (Number of prescriptions annually)



Source: Visante analysis of data from SSR Health for Praluent and Repatha. Estimated costs and utilization are for non-Medicaid market.

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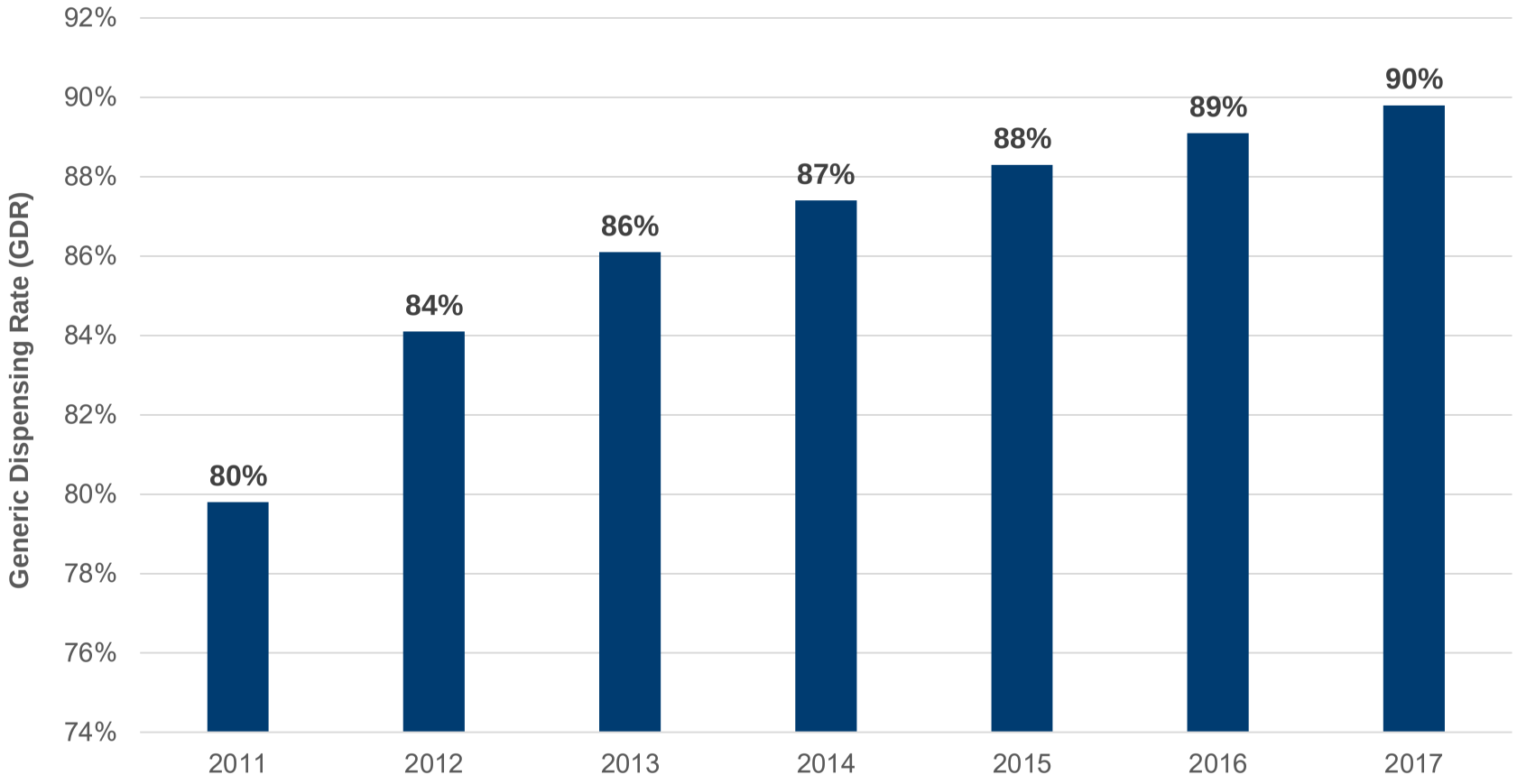
PBMs Aggressively Encourage Generic Drug Use; Generic Dispensing Increasing as a Result



Source: IQVIA

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FOLEY HOAG LLP

Safe Harbor Protection Changes:

Legal, Legislative, and Regulatory Considerations

Thomas R. Barker, Partner, Co-Chair, Health Care Practice

FOLEY HOAG 75 SINCE 1943

Overview

- History of the current rebate system: how did we get here?
- What is the “Anti-Kickback Statute”; What is a “Safe Harbor”; and who is the HHS Inspector General?
- What might be in the proposed rule?

Current Rebate System

- Manufacturers and payers have been entering into agreements to discount drug prices in exchange for formulary placement, volume commitments, and administrative services for decades.

- In the mid-1990s, pharmacies sued manufacturers and health plans, arguing that the rebate system then in place violated the Robinson-Patman Act.
  - The Act is an oft-criticized Depression-era antitrust law that prohibits anticompetitive practices by producers, specifically price discrimination.
  - In particular, under the Robinson-Patman Act, it is a violation for a seller to offer a product for sale on different pricing terms to equally-situated distributors, if the effect of the different pricing terms is to reduce competition.
  - Pharmacies argued that up-front discounts (the rebating model then in effect) available to payers, but not to pharmacies, violated the Act.

Current Rebate System (cont.)

- The case (*In Re: Brand Name Prescription Drug Litigation*) was settled in 1996. Under the settlement agreement, manufacturers agreed to offer the same discounts to pharmacies and to payers, but only if the entity receiving the discount could demonstrate an ability to move market share.
  - But ascertaining movement of market share can only happen after the fact – up front discounts could no longer be used.
  - Thus, the current, retrospective rebate system took effect, under which purchasers receive rebates based on their proven ability to move market share.

- Now, in 2018, federal policy makers have suggested that this post-settlement rebate structure encourages manufacturers, plans and PBMs to raise drug prices.

The AKS and Related Safe Harbors

- The federal Anti-Kickback Statute (AKS) makes it a crime to pay or receive anything of value as an incentive or an inducement to use a health care service that is reimbursable by a federal health care program.
  - The AKS was enacted and signed into law by President Reagan in 1987.

- As such, a rebate paid to encourage a Medicare Advantage plan, a Part D plan or a Medicaid managed care plan to favor a particular drug would be, on its face, a violation of the AKS.

- However, the AKS contains a "statutory exceptions" which protect some arrangements from prosecution, including "a discount or other reduction in price obtained by a provider of services or other entity under [a federal health care program] if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity."

Discount Safe Harbor

- So let's break this down:
  - Let's say there are two equally effective products on the market treating a particular medical condition, and each product meets the definition of a covered Part D drug.
  - Manufacturer A provides a rebate to Part D plans that exceeds the rebate paid by Manufacturer B, so most Part D plans favor Manufacturer A's product in formulary design.
  - The AKS is implicated because Manufacturer A is paying something of value (the rebate) as an inducement to use its product, which is reimbursable by a federal health care program (Medicare Part D).
  - But the discount safe harbor protects Manufacturer A and the Part D plan from accusations of a violation because:
    - The rebate is a "reduction in price";
    - It is obtained by an "other entity" (i.e., the Part D plan); and
    - The rebate will be disclosed to CMS (probably via DIR)

The AKS and Safe Harbors (cont.)

- In addition to the statutory exception for discounts, Congress authorized HHS to create regulatory "safe harbors" from the AKS.
  - There are over 28 safe harbors which "protect" certain arrangements
  - At least four arguably protect the current rebate system:
    - Discount safe harbor (building off the statute)
    - Price reductions to eligible managed care organizations
    - GPO safe harbors
    - Shared risk safe harbor

- It is hard to see how HHS can achieve its policy goal of eliminating rebates under the current AKS safe harbor regime. The government cannot penalize conduct that is expressly permitted by statute and regulations.

The Role of the HHS OIG

- The HHS Inspector General's office is an operating division within the Department of Health and Human Services.
  - Each federal government agency has an IG pursuant to the Inspector General Act of 1978, a post-Watergate reform signed into law by President Carter.
- Although the HHS IG reports to the Secretary of HHS, he has a high degree of independence:
  - The IG "shall not report to, or be subject to supervision by, any other officer" of the Department.
  - The Secretary of HHS shall not "prevent or prohibit the Inspector General from initiating, carrying out, or completing any audit or investigation, or from issuing any subpoena during the course of any audit or investigation."
- The Secretary of HHS delegated enforcement of the AKS to the HHS IG in 1988. Thus, although the views of the current Secretary of HHS on the rebate structure are well known, the HHS IG must make an independent determination that any changes to the AKS safe harbors are warranted.

The (impending) proposed rule

- In mid-July, it was announced that OMB was reviewing a proposed rule submitted by the HHS OIG entitled "removal of safe harbor protection for rebates to plans or PBMs involving prescription pharmaceuticals and creation of new safe harbor protection."
  - The rule is listed as "economically significant"
  - As of today, the proposed rule has not yet been released.

- Another proposal – this time a Request for Information – has been released seeking comment and input on how existing regulations may act as barriers to coordinated or value based care. This was released on August 27th and the HHS Office of Inspector General is still soliciting comments (comment period closes at the end of October).

- Finally, CMS has sent to OMB a proposed rule making policy and technical changes to the MA/Part D programs for Plan Year 2020.

The proposed rule (cont.)

- Until the proposed rule is published, we cannot know what the Inspector General is proposing. However, it is likely that one of four options may be under consideration:
  1. Complete elimination of some or all of the safe harbors that protect the current retrospective rebate system that ties rebates to list price.
  2. Modifications to the existing safe harbors – for example, protection only for rebate arrangements where 100% (or a high percentage) of rebates are passed through at point of sale.
  3. Safe harbor protection only for rebates on high-cost drugs – i.e., drugs above a certain cost threshold.
  4. Safe harbor protection – perhaps in the form of a new safe harbor – that protects value-based payment arrangements meeting certain parameters: for example, rebates permitted only in the case of the attainment of specified clinical parameters (although this could likely in a later rule following the current RFI review)

Key Questions

- How could OIG completely eliminate the discount safe harbor, since that safe harbor is statutory?
- How broadly will the proposed policy apply? Just to Medicare Part D? Or will it also include Medicaid managed care and Part B drugs? Will there be a spill-over effect into the commercial market?
- To the extent that the policy applies to rebates in the Medicare Part D program, how would the policy interact with Part D's non-interference clause?
- What will be the impact on Part D premiums? It is commonly understood – including in the recently-released Medicare Trustee's report – that rebates contribute to lower Part D premiums.
- Will the proposal cause a shift to up-front discounts? If so, how will that affect the prescription drug marketplace and the existing PBM industry? Will the injection of greater price transparency in the system ultimately lead to higher drug costs?
- How could an up-front, fixed price discount system work in the context of antitrust laws, in light of the 1996 settlement?
- What could be the intended and unintended impact on the structure of Part D (e.g., plan finder, preferred networks, prompt payment)?

Conclusion

- Significant proposed changes likely to existing rebate system, but still unclear whether these changes will ever take effect.
- Whatever is finalized is likely to lead to legislative and legal challenges.
- Nothing will take effect without a robust public comment process.
- Legal challenge could be filed shortly after rule is finalized.
- No changes to existing rebate system likely until the 2020 plan year.
  - Although safe harbor changes, when finalized, could immediately impact legal risk of rebating arrangements.