



Federal Update

Kristin Bass

Senior Vice President, Policy and Federal
Affairs

PCMA

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PCMA Priorities: Snapshot

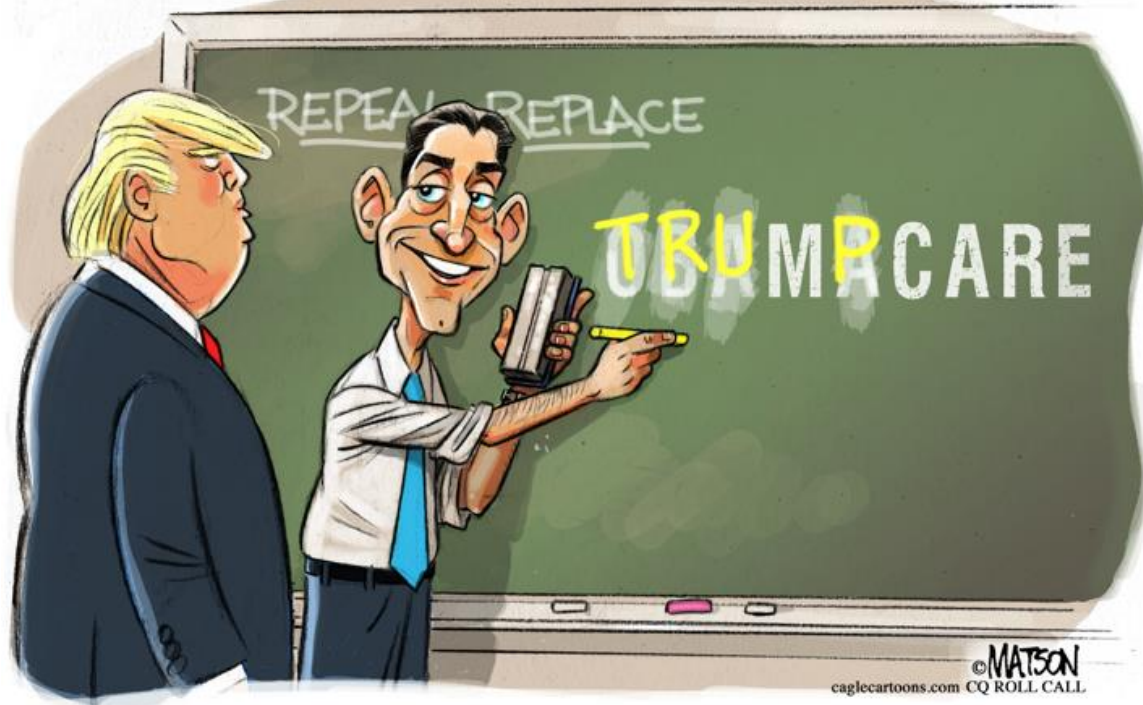
Priorities	2017	
	Regulatory	Congressional
High-Cost Drugs	<ul style="list-style-type: none"> ➤ Medicare POS rebates ➤ Medicare other DIR limitations ➤ Medicare tiering exceptions ➤ Medicare specialty tier limitations ➤ Medicare protected classes ➤ Medicare drugs per class ➤ Medicare application of any willing pharmacy to specialty networks ➤ Medicare Part B coding for biosimilars ➤ ACA market stabilization ➤ ACA formulary requirements ➤ Medicaid drug coverage and expanded use of PBM tools ➤ FDA biosimilar naming ➤ FDA direct to consumer advertising 	<ul style="list-style-type: none"> ➤ POS rebates/DIR legislation ➤ Formulary and rebate transparency ➤ Direct negotiation ➤ MAC pricing transparency ➤ REMS abuses ➤ Pay to delay generics ➤ Third-party cost sharing payment ➤ Insulin costs
Opioids	<ul style="list-style-type: none"> ➤ Lock-in implementation 	<ul style="list-style-type: none"> ➤ Seven-day fill for acute meds ➤ eRx for controlled substances ➤ PDMP interoperability ➤ Opioid abuse deterrence
Other Issues	<ul style="list-style-type: none"> ➤ Section 1557 ➤ Prescriber enrollment ➤ Regulatory relief 	<ul style="list-style-type: none"> ➤ Section 1557 ➤ Manufacturer-payer pre-market data sharing ➤ Off-label Rx promotion to physicians ➤ Medicare Parts A and B data sharing w/ Part D plans ➤ Medicare any willing pharmacy ➤ Medicare clawback ➤ FDA user fee agreements (generic approvals / watch list / exclusivities)

Major Federal Health Care Issues

- Affordable Care Act: Repeal/Replace or Subsidies?
- Drug Costs
- Children's Health Insurance Plan (CHIP) reauthorization
- Block granting or constraining Medicaid
- Possible haircuts to Medicare
- Opioid Abuse

ACA Repeal/Replace/Fund Machinations Go On

- Repeal/replace efforts will continue into 2018
 - Votes on Cassidy-Graham expected again
- Meanwhile, Administration appears intent on undermining however possible
- Note presidential vacillation over efforts to fund subsidies
- Uses significant oxygen, staff and Member time otherwise potentially devoted to drug costs



"WE MADE FOUR MAJOR CHANGES."

High-Cost Drug Debate

- Back-burnered during ACA repeal machinations
- New high-priced approvals keep spotlight on issue
- White House -- Executive Order, bipart commission?
- FDA Commissioner playing lead role
- Dem voters flag Rx costs as highest health issue
- Probably more hearings, little action
- PhRMA: need point-of-sale rebates to shield consumers from cost
- PhRMA: it's the PBMs' fault
- PhRMA: it's the hospitals' fault

High-Cost Drug Debate

PhRMA Campaign: Axios

A MESSAGE FROM PHRMA

Why should patients pay more than their insurer?



Unlike care received at an in-network hospital or physician's office, patients with high deductibles or coinsurance pay cost sharing based on the list price of a medicine, even if their insurer may receive a steep discount. Providing access to discounted prices at the point-of-sale could dramatically lower patients' out-of-pocket costs.

Get the facts and find out where the discounts are going at PhRMA.org/Discounts

PCMA Campaign: Axios

A MESSAGE FROM DRUG BENEFIT SOLUTIONS

How do prescription drug rebates reduce costs?

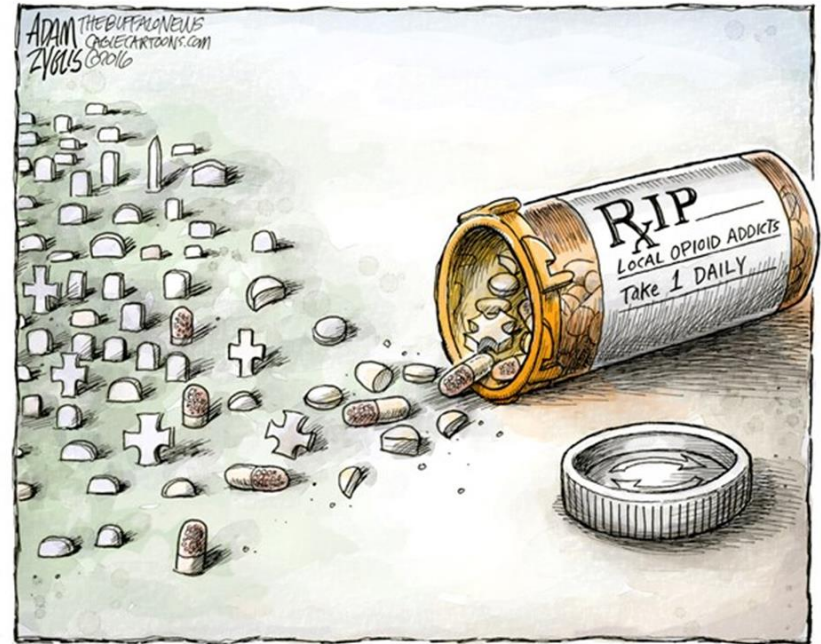


Drug manufacturers choose to negotiate discounts on drug prices with pharmacy benefit managers (PBMs) using rebates. These rebates are used by payers to reduce premiums and out-of-pocket costs for patients.



Opioid Abuse

- “CARA” bill last year included lock-in for Medicare
 - States already using for Medicaid
- PCMA has suite of additional proposals
 - 7-day fill for acute pain, eRx for controlled substances, interoperable PDMPs, prescriber checks of PDMPs
- Congress may find additional \$\$ to address opioid abuse
- 60 Minutes piece – Congress looking into law clarifying DEA standard for stopping wholesale shipments



Other Core PBM Issues in Congress

Threats for PBMs: Bills in Congress

- **Transparency**
 - Wyden bill (C-THRU Act, S. 637, 4 cosponsors)
- **Any willing pharmacy/Network limitations**
 - (S. 1044/H.R. 1939, 6 Senate/22 House cosponsors)
- **POS Rebates and DIR**
 - (S. 413/H.R. 1038, 14 Senate/54 House cosponsors)
 - Rep. Carter/PhRMA letter to HHS Sec. urging POS rebates in Part D via regulation
- **Medicare A, B data sharing w/ Part D plans**
 - (H.R. 3447, 4 cosponsors)
 - PCMA & members working to improve language to avoid unintended consequences and allow input into formularies/coverage

Opportunities for PBMs: Bills in Congress

- **FDA fast-track approval** (Win: enacted as part of FDA user fee bill)
 - Expedited generic approval and increased FDA accountability
- **Pay for delay prohibitions**
 - Eliminate manufacturer payments to generics to keep competition from the market (S. 124, 2 cosponsors; S. 771/H.R. 1776, 16 Senate/18 House cosponsors)
- **Limiting REMS abuse**
 - Could be offset for CHIP (Creates Act - S. 974/H.R. 2212, 12 Senate/2 House cosponsors; or FAST Act - H.R. 2051, 2 cosponsors)
- **ePrior Auth** (bill still in draft)
- **eRx of controlled substances** (H.R. 3528, 3 cosponsors)
- **7-day fill for acute pain opioids** (S. 892, 2 cosponsors)

Independent Pharmacy-Inspired Legislative Challenges to PBM Tools

- PCMA strategy: Position PBMs as pro-competitive and pro-beneficiary/taxpayer/employer in holding down costs
 - Cite performance- and value-based pharmacy contracting
- Medicare Part D pharmacy DIR prohibition (H.R.1038/S.413 – 53 House/13 Senate cosponsors)
- MAC Transparency Act (H.R. 1316 – 36 cosponsors)
- Part D Any Willing Pharmacy (H.R.1939/S.1044 – 21 House /5 Senate cosponsors)
- Specialty tiering prohibition (H.R. 2999)

JOHN COLE
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