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Memo

Date:	September 13, 2019
To:	Barbara Levy, Vice President and General Counsel, Pharmaceutical Care Management Association April Alexander, Vice President, State Legislative and Regulatory Affairs, Pharmaceutical Care Management Association
From:	Dean Richlin Kristyn Bunce DeFilipp Andrew M. London
Regarding:	New York Senate Bill 6531

The New York State Legislature recently passed Senate Bill 6531 ("S. 6531" or "the Bill"), which amends the Public Health Law and the Insurance Law in relation to Pharmacy Benefit Managers ("PBMs"). The Bill creates new duties and obligations for PBMs in relation to covered individuals, health plans, or providers for whom the PBMs provide services. The Bill also mandates the registration and licensure of PBMs operating in the State of New York.

You have asked us to review whether S. 6531 would be preempted by the express preemption clause of the Employee Retirement Income Security Act of 1974 ("ERISA"). We have also considered whether the Bill would be preempted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") as applied to the Medicare Part D Program. At your request, we have focused our analysis on the Bill's proposed duties and obligations for PBMs toward covered individuals, health plans, and providers and the Bill's disclosure requirements. Based on our review, we conclude that both ERISA and the MMA preempt significant portions of S. 6531. The following memorandum discusses our analysis in further detail. This memorandum is a preliminary review of S. 6531, and it is not intended as an exhaustive description of potential legal defects of the Bill.

Overview of the Act

S. 6531 regulates PBMs and the tools they use to reduce prescription drug prices in several ways. You have asked us to review two key provisions.

Fiduciary Obligations in S. 6531

S. 6531 disrupts the arms-length contractual relationship between PBMs and health plans and providers by requiring PBMs to adopt of a series of fiduciary obligations. The Bill creates the following obligations and duties on behalf of PBMs to both health plans and providers:

- Establishes a duty of care. *See* Proposed Public Health Law Section 280-a(2)(a) (a PBM shall have a "duty and obligation to … the health plan or provider, and shall perform pharmacy benefit management services with care.");

- Establishes a duty of loyalty. *See* Proposed Public Health Law Section 280-a(2)(a) (a PBM "shall perform pharmacy benefit management services… for the best interests of … the health plan or provider.");

- Establishes a duty of disclosure. *See* Proposed Public Health Law Section 280-a(2)(d) (a PBM must disclose to the health plan or provider the terms and conditions of any contract between the PBM and "any party relating to pharmacy benefit services provided to the health plan or provider");

- Establishes the PBM as a trustee for the health plan or provider. *See* Proposed Public Health Law Section 280-a(2)(b) (funds received by the PBM for PBM services "shall be received… in trust for the health plan or provider"); *see also* Proposed Section 280-a(2)(c) (requiring a PBM to pass through any portion of income, payments, and financial benefits to the health care plan or provider).

These duties are consistent with the obligations of a fiduciary to a principal in other areas of New York law. *See e.g.* NY Estate, Powers, and Trust Law §13-A-4.1 (fiduciary duties for trustees managing tangible property and digital assets include the duty of care, duty of loyalty, and duty of confidentiality); NY General Obligations Law §5-1505 (agent acting under a power of attorney has a fiduciary duty to act in the best interest of the principal and to disclose all receipts, disbursements, and transactions entered on the principal's behalf); *Birnbaum v. Birnbaum*, 73 N.Y.2d 461, 466 (1989) (stating that a fiduciary owes a duty of loyalty to serve the interests of those to whom he owes a duty).[1] By replacing what are arms-length transactions with fiduciary obligations, S. 6531 fundamentally changes the nature of the

[1] As discussed further below, we conclude that S. 6531 is preempted by ERISA because it changes the standard of conduct between PBMs and health plans or providers. Whether the standards of conduct imposed by S. 6531 would designate a PBM as a "fiduciary" under New York state law is immaterial to the ERISA analysis. We include this discussion of fiduciary obligations, however, because it is illustrative of how S. 6531 alters that nature of the duties between PBMs, health plans, and providers.

relationship between PBMs, health plans, and providers. *C.f. In-re Mid-Island Hosp., Inc. v. Empire Blue Cross & Blue Shield*, 276 F.3d 123, 130 (2d Cir. 2002) ("[W]hen parties deal at arms-length in a commercial transaction, no relation of confidence or trust sufficient to find the existence of a fiduciary relationship will arise absent extraordinary circumstances.").

Preliminarily, we observe that the creation of a duty of loyalty from PBMs to both health plans and providers creates conflicting obligations for PBMs and undercuts the current system that creates downward pressure on drug prices. Health plans hire PBMs to obtain lower drug prices for plan beneficiaries. Maximum allowable cost pricing is one way many PBMs incentivize pharmacies to obtain multi-source generics from lower price wholesalers, resulting in lower prices for health plans and covered individuals. A PBM cannot simultaneously act in the best interest of health plans (who demand lower prices) and providers (who seek higher reimbursements). By requiring a PBM to perform pharmacy benefits services in the best interest of providers, S. 6531 prevents PBMs from seeking the savings health plans hire PBMs to obtain.

We further note that S. 6531 would mark a significant departure from prevailing principles of New York insurance law. Generally, under New York law, the provision of insurance benefits does not create a fiduciary relationship with the insured. *See e.g. Schandler v. N.Y. Life Ins. Co.*, 09-Civ-10463, 2011 U.S. Dist. LEXIS 46322 at *46 (S.D.N.Y. Apr. 26, 2011) ("[U]nder New York law the relationship between an insurance company and a policyholder is a contractual relationship, not a fiduciary one.") *quoting Freeman v. MBL Life Assur Corp.*, 60 F. Supp. 2d 259, 266 (S.D.N.Y. 1999). In contrast, S. 6531 creates a duty of loyalty and duty of care from the PBM to covered individuals. *See* Proposed Section 280-a(2)(a) (a PBM "shall perform pharmacy benefit management services with care… for the best interests of the covered individual"). Accordingly, S. 6531 creates new standards of conduct between a benefits manager and the insured that exceed those that typically exist between an insurance provider and the insured.

Lastly, S. 6531 appears to create a private right of action for providers and covered individual to collect damages or seek injunctive relief to enforce the duties and obligations under the Bill. *See* Public Health Law Proposed Section 280-a(2)(h) ("a health care provider and a covered individual… shall be entitled to legal or equitable relief for any injury or loss to the health care provider or the covered individual caused by any violations of [the] duties, obligations, or requirements [under this section].").

<u>Disclosure Requirements in S. 6531</u>

S. 6531 requires a PBM to make a number of disclosures to State officials, health plans, and providers regarding its contractual arrangements for the provision of pharmacy benefits management services. Many of these disclosures, in particular those to health care providers, will compromise a PBMs ability to negotiate lower drug prices for plans and covered individuals.

The Bill requires PBMs disclose the following information to health plans and providers:

- "[A]ny pricing discounts, rebates of any kind, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements, or other benefits received by the pharmacy benefits manager..." Proposed Public Health Law Section 280-a(2)(c);

- "[A]ll financial utilization information of the pharmacy benefit manager in relation to pharmacy benefit management services provided to the health plan or provider." Proposed Public Health Law Section 280-a(2)(c);

- "[T]he terms and conditions of any contract or arrangement between the pharmacy benefit manager and any party relating to pharmacy benefit management services provided to the health plan or provider including but not limited to, dispensing fees paid to the pharmacies." Proposed Public Health Law Section 280-a(2)(d);

- "[A]ny activity, policy, practice, contract or arrangement of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the pharmacy benefit manager's relationship with or obligation to the health plan or provider." Proposed Public Health Law Section 280-a(2)(e);

A PBM must also submit annual reports to the Superintendent of Financial Services including much of the same information. Proposed Insurance Law Section 2904.

Overview: Federal Preemption of State Laws

States are prohibited from interfering with federal law, including provisions of the United States Constitution and federal statutes. A state law that interferes with federal law is preempted. Two federal statutes – the MMA and ERISA – are particularly relevant to state regulation of PBMs and pharmacy benefit plans. The MMA applies to the Medicare Prescription Drug Benefit, also known as Medicare Part D. ERISA regulates pharmacy benefits provided through an employee benefit plan. Both the MMA and ERISA include express preemption provisions prohibiting state laws related to plans covered respectively by each statute.[2] Below, we review the basic frameworks for analyzing whether a state law is preempted by the MMA and ERISA.

Medicare Part D Preemption

The MMA establishes a broad rule of preemption. It preempts a state law when (1) Congress or the Centers for Medicare and Medicaid Services ("CMS") has established "standards" in the area regulated by the state law; and (2) the state law acts "with respect to those standards." 42 U.S.C. §1395w-26(b)(3). A standard within the meaning of the preemption provision is either a statutory provision or a duly promulgated and published regulation. *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010). "Conflict between the state law and the federal standard is unnecessary." *Pharm. Care Mgmnt. Ass'n v.*

[2]A large portion of pharmacy benefit plans are covered by Medicare Part D or ERISA. The remainder include commercial and government employee benefit plans not covered by ERISA.

Rutledge, 891 F. 3d 1109, 1113 (8th Cir. 2018). If the state law in question merely acts with respect to the standard, it is preempted.

ERISA Preemption

Congress enacted ERISA to provide a "uniform regulatory regime over employee benefit plans." 29 U.S.C. §1001, et. seq.; *Aetna Health Inc. v. Davila,* 542 U.S. 200, 248 (2004). Congress included an express preemption clause in ERISA, which preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plans." 29 U.S.C. §1144(a). A state law "relates to" an employee benefit plan, and is therefore preempted, "if it has a connection with or reference to such a plan." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 90 (1983).

A law has an impermissible "connection with" ERISA plans if (1) the state law governs a central matter of plan management, or (2) interferes with national uniformity of benefits, or (3) causes an indirect, but acute, economic impact that forces an ERISA plan to adopt a certain scheme of substantive coverage. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016). A law is preempted due to its "reference to" ERISA plans if it imposes a requirement on a regulated party by reference to ERISA-covered programs. *District of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 130-31 (1992). [3]

Legal Analysis

Duties and Obligations of PBMs

i. Establishment of a Fiduciary Standard of Conduct

By requiring PBMs to act in the best interests of providers, S. 6531 impedes the market-based negotiations between a PBM and a pharmacy. Specifically, S. 6531 replaces an arms-length transaction with a fiduciary standard of conduct.

In establishing the Medicare Part D program, Congress intentionally sought to create a market-based system to keep prices down and increase access to drugs for Medicare beneficiaries. *See* 70 Fed. Reg. 4194, 4244 (Jan. 28, 2005). To further this goal, Congress included both the express preemption provision to prohibit state interference in this market-based system, and prohibited the federal government from interfering between Part D sponsors and pharmacies. 42 U.S.C. §42 U.S.C. §1395w-111(i)(1)(the "Non-Interference Clause"). Proposed Section 280-a(2) of the Public Health Law interferes with this market-based negotiations by replacing the arms-length contractual agreements (and the negotiated prices that result from those agreements) with an obligation by the PBM to act in the best interests of providers. *See Pharm. Care Mgmt. Ass'n v. Rutledge*,891 F. 3d 1109, 1113 (8th Cir. 2018) (holding Medicare Part D preempts a state law interfering with the price

[3] This memorandum reviews whether the fiduciary obligations in Proposed Section 280-a(2) have an impermissible "connection with" ERISA plans. While we believe S. 6531 may also have an impermissible reference to ERISA plans, a full review of this issue is outside the scope of this memorandum. We can provide further analysis on this issue upon request.

negotiated between a pharmacy and PBM). For this reason, S. 6531 acts with respect to CMS standards and is likely preempted.

The fiduciary obligations in S. 6531 are also preempted by ERISA because they govern a central matter of plan administration. Specifically, S. 6531 sets a standard of conduct for PBMs with covered individuals, health plans, and providers. "One of the principal goals of ERISA is to enable employers to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits." *Egelhoff v. Egelhoff*, 532 U.S. 141, 147 (2000). S. 6531 attempts to prescribe the ways an ERISA plan provides pharmacy benefits by imposing duties of care to restrain the ways a PBM makes disbursements of those benefits.

In *Pharm. Care Mgmt. Ass'n v. District of Columbia* ("*District of Columbia"*), the D.C. Circuit held a similar statute to be preempted by ERISA. *See generally*, 613 F.3d 179, 185 (D.C. Cir. 2010). The District of Columbia had passed a law imposing on PBMs a fiduciary duty to the health plan and requiring a PBM to act "in accordance with the standards of conduct applicable to a fiduciary." *Id.* at 183. The D.C. Circuit noted that by "specifying the standard of conduct to which a PBM must adhere," the D.C. statute sought to "prescribe the way PBMs decide which pharmaceuticals to provide to plan beneficiaries and to prevent PBMs from inflating the price the plan pays for those pharmaceuticals." *Id.* at 185. The D.C. Circuit concluded that pharmacy benefit management services were central to plan management and core areas of ERISA concern protected from state law by the express preemption provision.[4] S. 6531 is no different; it replaces the contractually agreed-to standard of conduct between the ERISA plan and its PBM with a state imposed standard.

S. 6531 also undermines the national uniformity of plan administration. *See Gobeille*, 136 S.Ct. at 945 (finding Vermont data reporting law preempted because it "interferes with national uniformity of plan administration"). S. 6531 forces health plans to contract with a PBM to manage pharmaceutical benefits based on the terms and standards of conduct in the legislation. *See District of Columbia*, 613 F.3d at 188 ("[b]y imposing requirements upon-third party providers that administer pharmaceutical benefits for an [employee benefit plan], [the D.C. statute designating PBMs as fiduciaries] functions as a regulation of an ERISA plan itself.") (internal quotation omitted). Thus, while New York may require a PBM to take on fiduciary obligations or hold payments in trust, the 49 other states could pass provisions requiring PBMs and health plans to maintain arms-length negotiations. A single employee benefit plan would have to administer its pharmacy benefits differently for an employee based in New York than an employee based in New Jersey, Connecticut, or any other jurisdiction. "Differing, or even parallel, regulations from multiple jurisdictions could create wasteful administrative costs and threaten to subject plans to wide-ranging liability."

[4] The D.C. Circuit acknowledged that this holding differed from the holding of the First Circuit reviewing a nearly identical Maine statute. *District of Columbia*, 613 F.3d at 190 *citing Pharm. Care Mgmt. Ass'n v. Rowe*, 420 F.3d 294, 303 (1st Cir. 2005). In *Rowe*, the First Circuit held that the statute was not preempted because it imposed duties on the PBMs, not the plans themselves. *Rowe*, 420 F.3d at 303. This holding, however, is inconsistent with the Supreme Court's decision in *Gobeille,* which post-dates *Rowe. See Gobeille*, 136 S. Ct. 936 (finding Vermont statute that imposed duties on third-party administrators preempted by ERISA).

Gobeille, 136 S.Ct. at 945. This is exactly what the ERISA preemption provision was intended to prevent.

ii. Creation of a Private Right of Action

S. 6531 also appears to create a private right of action for health care providers and covered individuals for any damages relating to violations of the Bill's substantive provisions. *See* Public Health Law Proposed Section 280-a(2)(h) ("a health care provider and a covered individual… shall be entitled to legal or equitable relief for any injury or loss to the health care provider or the covered individual caused by any violations of [the] duties, obligations, or requirements [under this section]."). The ability of health care providers and covered individuals to bring claims for violations of this section will be significantly curtailed because, as discussed above, the duties and obligations under Proposed Section 280-a are independently preempted by ERISA and Medicare Part D. To the extent, however, the substantive provisions are not preempted, ERISA would preempt a significant number of potential state law claims arising under S. 6531's private right of action.

ERISA provides for the wholesale displacement of certain state-law claims. *Montefiore Med. Ctr. v. Teamsters Local 272*, 642 F.3d 321, 327 (2nd Cir. 2011). Pursuant to ERISA §502(a)(1)(B), a participant or beneficiary may bring an action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." 29 U.S.C. §1132(a)(1)(B). This civil enforcement scheme "completely preempts any state-law cause of action that duplicates supplements, or supplants an ERISA remedy." *Montefiore Med. Ctr.*, 642 F.3d at 327.

The Supreme Court has established a two-pronged test to determine whether a state-law claim is completely preempted by ERISA. *See generally, Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004). State law claims are completely preempted by ERISA if they are brought (i) by an individual who, at some point in time, could have brought his or her claim under ERISA and (ii) no other independent legal duty is implicated by a defendant's actions. 542 U.S. 200, 209 (2004). The Second Circuit has established a two part test to determine whether an individual could have brought his or her claim under ERISA: (i) whether the plaintiff is the type of party that can bring a claims pursuant to ERISA §502(a)(1)(B), and (ii) whether the actual claim that the plaintiff asserts can be construed as a colorable claim for benefits pursuant to §502(a)(1)(B). *Montefiore Med. Ctr.*, 642 F.3d at 328.

In practice, almost any conceivable claim that a covered individual would bring for injuries under the duties and obligations in S. 6531 would be preempted. First, these claims are the types of claims that can be brought under ERISA. ERISA provides that participants and beneficiaries may bring actions under ERISA, *see* 29 U.S.C. §1132(a)(1)(B), and the most likely instance in which a covered individual would bring a claim under S. 6531 is in the event a PBM denies a claim for benefits. *See Montefiore Med. Ctr.*, 642 F.3d at 330 (claims involving the right to payment are colorable claims for benefits under ERISA).

Second, most claims by covered individuals under S. 6531 would not implicate an independent legal duty. While S. 6531 establishes new state law fiduciary duties for PBMs, these fiduciary duties in S. 6531 will not typically be independent of claims that could be

brought under ERISA. In *Davila*, the Supreme Court held that a duty of care for health maintenance organizations under a Texas statute did not constitute a legal duty independent of the ERISA plan. 542 U.S. at 212. The Court concluded that the interpretation of the terms of the benefit plans formed an essential part of the state law claim and state law liability only existed because of Aetna's administration of ERISA-regulated benefit plans. *Id.* at 213. Similarly, here, the very nature of the duties created by S. 6531 are inextricably tied to plan benefits. In order to demonstrate a violation of S. 6531, a covered individual will typically need to show that they were denied benefits due to them under the plan. Absent a denial of benefits, it is unlikely a separate violation of the duties owed to a covered individual under S. 6531 would exist.

Many of the claims that a provider could potentially bring under this section would also be preempted. In-network health care providers to whom a beneficiary has assigned his or her benefits may enforce their rights in an action under ERISA. *Montefiore Med. Ctr.*, 642 F.3d at 329. For the same reasons discussed above, many of the potential claims based on assigned benefits brought by a provider under S. 6531, specifically those challenging the right to payment, would also be colorable claims for benefits and would not implicate an independent legal duty.

For these reasons, we conclude that even in the unlikely event that the substantive duties and obligations under S. 6531 are upheld, many of the claims brought under the private right of action will be preempted.

Disclosure Requirements

CMS has established extensive reporting requirements for PBMs and Part D sponsors related to benefits provided through the Part D program. Among other information, a PBM is required to report: 1) the aggregate amount of rebates, discounts, or price concessions that the PBM negotiates attributable to patients under the plan, 2) the aggregate amount of rebates, discounts, or price concessions passed through to the plan sponsor, and 3) the aggregate difference between the amount a Part D sponsor pays the PBM and the amount the PBM pays the pharmacy. 42 C.F.R. §423.514(d). The PBM must provide this information to the Part D sponsor, who is required, in turn, to report the same information to CMS. *Id.* As discussed above, a state law is preempted by the Medicare Part D program if the state law acts with respect to a Part D standard. 42 U.S.C. §1395w-26(b)(3). "Conflict between the state law and the federal standard is unnecessary." *Rutledge*, 891 F.3d at 1113 (8th Cir. 2018). The disclosure and reporting requirements in S. 6531 overlap those requirements already established by CMS. For this reason, S. 6531's disclosure and reporting requirements act with respect to a Part D standard and are likely preempted.

Reporting and disclosure obligations are also among the core ERISA functions protected from state regulation by ERISA's express preemption provision. *Gobeille*, 136 S. Ct. at 945 ("reporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA."). ERISA's reporting and disclosure requirements are extensive, and state laws requiring third-party plan managers to disclose information related to the cost and payment of claims have an impermissible

"connection with" ERISA plans. *Id.* at 944-45 (holding that ERISA preempted Vermont state law requiring third-party plan managers to disclose costs, prices, quality, utilization, or resources required for health care services). "Pre-emption is necessary to prevent the States from imposing novel, inconsistent, and burdensome reporting requirements on plans." *Id.*

In *Pharm. Care Mgmt. Ass'n v. Gerhart,* the Eighth Circuit held that ERISA preempted an Iowa law that created reporting obligation for PBMs similar to those in S. 6531. *See generally*, 852 F.3d 722 (8th Cir. 2016). The Iowa statute required PBMs to submit information to pharmacies and the Iowa Insurance Commissioner related to the PBMs pricing methodology. *Id.* at 727. Citing the Supreme Court's decision in *Gobeille*, the Eighth Circuit stated that "requiring reports and disclosures to a State official and to private enterprise about the economic bases for a plan's provision of prescription drug benefits in that state intrudes upon a matter central to plan administration and interferes with national uniform plan administration." *Id.* citing *Gobeille*, 136 S. Ct. 945. The court concluded that regulation of this fundamental aspect of ERISA "necessitates preemption." *Id.*

S. 6531 is no different. If passed, S. 6531 would obligate a PBM to report information related to its costs, prices, and contractual arrangements to provide prescription drugs for ERISA plan beneficiaries. The prospect of dueling reporting requirements in each of the 50 states undermines the national uniformity of plan administration and create an unnecessary burden on plans that ERISA preemption is intended to prevent. For these reasons, we conclude that the reporting requirements in S. 6531 are likely preempted by ERISA.

Conclusion

We conclude that S. 6531 is preempted under the MMA and ERISA. Specifically, S. 6531 interferes with a central matter of plan administration and Medicare Part D standards on negotiated prices by replacing the arms-length transactions between PBMs, plans, and providers with a fiduciary standard of conduct. To the extent S. 6531's standards of conduct are not preempted, many of the individual claims brought under S. 6531's private right of action would be independently preempted by ERISA. Further, ERISA and the MMA both include reporting and disclosure obligations that preempt those in S. 6531. We are available to discuss any of these issues with you in further detail. In addition, because this memorandum is only a preliminary analysis and does not address all aspects of the Bill, we are available to supplement our analysis with a review of any additional provisions that we did not feature in this memorandum.