June 6, 2017

The Honorable Brian Sandoval
Office of the Governor
101 N. Carson Street #1
Carson City, Nevada 89701

Re: Veto Request for SB 539: Prescription Drugs

Dear Governor Sandoval:

On behalf of the Pharmaceutical Care Management Association (PCMA) we must respectfully request your veto on SB 539. 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.

PBMs exist to make drug coverage more affordable for plan sponsors. PBMs achieve this by aggregating the buying clout of millions of enrollees through their payer clients, enabling health care consumers to obtain lower prices for their 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 health policy problem and policy makers have a role in helping change the trajectory of this problem. However, SB 539 is counterproductive because it presents significant legal problems including federal ERISA and Medicare preemption and adopts policy that the Federal Trade Commission has indicated could actually *raise* drug prices. The legislative process for SB 539 provided no legitimate opportunity for discussion or debate about the impact of the bill on Nevada employers, unions, and health care consumers, as the final amended version was publicly available less than 48 hours before the legislature passed it. Finally, the bill fails to address key problems identified in the SB 265 veto message, which dealt with similar issues as SB 539.

SB 539 Is Unconstitutional and Likely to be Struck Down under Federal Law

A number of sections of SB 539 are unlikely to be upheld by the courts as constitutional under federal law. We focus here on two particular provisions that impact PBMs, namely:

- Sec. 4.2, which requires PBMs to submit reports to the State Department of Health and Human Services on total amount of pharmaceutical rebates negotiated and retained, as well as rebates for drugs covered by Medicare and Medicaid. Sec. 4.2 is invalid under both the Employee Retirement Income Security Act of 1974 (ERISA), and under the Medicare Modernization Act (MMA), the 2003 law that established the Medicare Part D prescription drug benefit.

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- Sec. 19, which provides that a PBM has "a fiduciary duty" to its clients, and mandates that the PBM notify the client "in writing of any activity, policy or practice…that presents a conflict of interest that interferes with the ability of the PBM to discharge that fiduciary duty." Sec. 19 is invalid under ERISA as interpreted by a string of federal court decisions.

The Employee Retirement Income Security Act of 1974 (ERISA) is the federal benefits law that applies to all employer-based health plans, whether insured or self-insured. Nevadans who work for private sector employers (whether large or small) are for the most part enrolled in ERISA plans. PBMs administer prescription drug benefits for ERISA plans as well as non-ERISA plans, like governmental plans. PBMs administer those benefits on behalf of their payer clients by, among other things, developing lists of covered prescription drugs, negotiating drug prices with pharmaceutical manufacturers and retail pharmacies, establishing networks of pharmacies to fill prescriptions, and processing drug benefit claims. The majority of health plans retain PBMs (and other entities, such as behavioral health firms) to act as third party administrators (TPAs) to their plans.

Congress in ERISA included a broad preemption clause that provides that federal law alone applies to employer-provided health plans, and that federal law supersedes state laws and regulations that impact such plans, including prescription drug plans. When Congress provides for preemption in a federal statute, based on the Supremacy Clause of the U.S. Constitution, it effectively excludes the states from legislating in that area. ERISA provides a "comprehensive system for the federal regulation of employee benefit plans."[1] 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] Even invocation of the states' traditional power to regulate "public health" will not overcome ERISA's broad preemption, as Congress "contemplated preemption of substantial areas of traditional state power."[3] 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 or imposing a "fiduciary" mandate.

Requiring PBMs to Report Rebate Information is Preempted by ERISA

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 like PBMs. Only the Secretary of Labor has authority to establish additional reporting and disclosure requirements, or require any data or information needed to carry out the purposes of ERISA.

Sec. 4.2 of SB 539 requires PBMs to report pharmaceutical rebate data to the State. Requiring reporting and disclosures to a state official or agency about the economic bases for plan's provision of prescription drug benefits in Nevada intrudes on what the federal courts have called "a matter central to plan administration," and further "interferes with nationally uniform plan

[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).
[3] Id.

administration."[4] 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. Nevada is attempting to do such a thing in SB 539.

Though Section 4.2(2) purports to exclude ERISA plans from its scope, this section fails to protect the constitutionality of this section of the bill. Nevada simply cannot impose state requirements by "reference to" ERISA-covered programs when the existence of those plans is "essential to the law's operation."[5] The fact is that the bill singles out ERISA plans for different treatment under Nevada law, and is therefore preempted by ERISA.

Requiring PBMs to Report Medicare Rebate Information is Preempted by Federal Medicare Law

SB 539 also improperly mandates disclosure of rebates for the federal Medicare program. PCMA's members provide pharmacy benefit management services to their customers, which include Medicare Part D plans. However, state law cannot apply here, as federal law—the Medicare Modernization Act—includes a broad preemption provisions prohibiting enactment of state laws with respect to Part D plans.[6] Part D was designed as a comprehensive statutory and regulatory scheme which contains its own detailed provisions regulating PBM disclosures. Nevada simply cannot, either directly or indirectly, attempt to regulate Medicare plans by imposing its own requirements for reporting rebates or other plan data.

SB 539's Fiduciary Mandate is Preempted by ERISA

The imposition of "fiduciary" duties on PBM is improper, since PBMs are not ERISA fiduciaries. PBMs enter into arms' length (and heavily bargained for) contracts with their clients, such as health plans and unions, to administer their prescription drug plans. Those contracts are specifically tailored to meet the needs of clients. PBMs have no "discretionary authority" over plan assets, as defined by the U.S. Department of Labor, which is an essential threshold requirement for fiduciary status under federal law. Nevada cannot step in and create a new definition of "fiduciary." Nor can Nevada impose penalties, as specified in Sec. 8 of the bill, for failing to provide the requisite information, or for any "fiduciary" breach since ERISA contains the exclusive remedies for any breach of fiduciary duties.

Federal courts across the country have struck down such fiduciary mandates as preempted by ERISA.[7] It is worth noting that were SB 539 to be enacted, Nevada would be the sole state in the nation with such a requirement. The District of Columbia attempted to impose fiduciary responsibilities on PBMs, but the law was struck down by the D.C. Circuit in 2010. In 2011, the only remaining fiduciary mandate in the country was repealed in Maine.

From a policy perspective, the imposition of "fiduciary" duties on PBMs in Sec.19 of the bill will do nothing to make diabetes medications less costly in Nevada. In fact, such an inappropriate

[4] Gobeille, 577 US _____ (2016),136 S.Ct at 945.
[5] Gobeille, 577 US _____ (2016),136 S.Ct at 943.
[6] 42 U.S.C. sec. 1395w-26(b)(3); 42 U.S.C. sec. 1395w-112(g).
[7] Pharm. Care Mgt. Ass'n v. District of Columbia, 613 F.3d 179 (D.C. Cir. 2010)

designation is likely to have the opposite effect. First, such a provision would limit the ability of PBMs and their clients like health plans to design and implement cost-savings practices for distributing pharmaceuticals, such as utilizing mail-order pharmacies or establishing preferred pharmacy networks. Moreover, such a provision would also add to administrative costs to design plans that meet the requirements of Nevada law rather than ERISA's vision of a "single uniform national scheme."[8]

SB 539 Likely Violates Other Constitutional Provisions

SB 539 is also vulnerable to challenge under other constitutional provisions, including the Due Process Clause of the Fifth Amendment, the Commerce Clause, and the First Amendment.

For example, under the First Amendment to the Constitution, Sec. 4.9 of the bill could be challenged as requiring speech. It is also unclear what benefit consumers would obtain by having nonprofits post on their websites information including "anything else of value" that was received from a drug maker or a PBM, which could include information on medication adherence or helpful objects such as pill dispensers, or seminars on living more comfortably with diabetes.

There also could be a challenge under the Commerce Clause, as the bill fails to take account of the national nature of the prescription drug industry, involving numerous entities from manufacturers to wholesalers to PBMs to retailers to health plans. The burdens the bill would impose on commerce, including reporting requirements as well as revealing in the public domain proprietary information, are clearly excessive in relation to the local benefits that might be achieved by the bill's rather narrow definition of "transparency." Rebates apply to brand name drugs only, and it is hard to comprehend how aggregate figures on rebates obtained by PBMs (the vast majority of which are passed back to health plans under the terms of contracts) help those consumers become more efficient purchasers.

As for Due Process violations, the bill recognizes that its terms are radical: it calls for PBMs and others to supply information deemed confidential and even trade secrets to the State. Sec. 9 accomplishes that goal by circular reasoning: redefining what constitutes a "trade secret" so that such proprietary information and trade secrets are no longer protectable, thus improperly overturning decades of settled law and setting the bill (should it become law) up for an inevitable court challenge.

SB 539's Terms May Damage PBMs' Ability to Negotiate Lower Cost Diabetes Drugs

SB 539 calls for revealing drug rebates negotiated between PBMs and manufacturers, in the mistaken belief that this so-called transparency would lower costs. In fact, the opposite is true. If rebates were made public, the companies giving the biggest rebates would likely stop giving them and costs would rise. Drug price negotiations operate like sealed-bid auctions where bidders offer the lowest price they can in hopes of winning business. Public purchasers are well acquainted with the sealed-bid purchasing process; most states require sealed bids for contracts over a certain amount. Discounts are predicated on confidentiality of terms.

[8] Gobeille, 577 US ____ (2016), 136 S.Ct. at 947

The exclusion of the rebate data from the statutory definition of “trade secrets” creates a significant risk of public disclosure, and because the rebate reports are on individual drugs, it will be exceedingly simple to “back into” average rebate amounts for particular drugs. Public exposure of rebates paves the way for tacit collusion among drug manufacturers and eliminates the incentive for manufacturers to offer deep discounts on their products. Once the manufacturers know what their competitors are offering in rebates, there is an incentive only to offer their drug slightly below the highest-cost competitor.

The Federal Trade Commission has warned against public disclosure of rebates because the potentially damaging effects on prices for consumers. Specifically, it 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."[9] 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.”[10]

Another bill, SB 265, dealing with drug price transparency issues and vetoed on June 2, is worth noting in this discussion. There were several reasons that SB 265 was vetoed, according to the veto message. They included:

- It was a “selective and narrow approach” to the problem;
- There were “constitutional and other legal concerns” with the bill; and,
- There was “insufficient evidence that [the bill] will in fact lead to lower drug costs.”

SB 539 fails for the same reasons. SB 539 does not address others in the pharmacy supply and benefits coverage chain, including wholesalers, pharmacies, pharmacy services administrative organizations (PSAOs), and health care payers. And as indicated above, there are several legal issues presented, the most glaring being legislating in an area preempted by federal ERISA and Medicare law.

Finally, given the fact that SB 539 was amended on Sunday, June 4, less than 48 hours before its passage on Monday June 5, there was no time for true discussion, debate, or analysis of the impact on Nevada consumers, employers, labor unions, and the state employees’ health plan. Not only is there insufficient evidence to show that SB 539 would lead to lower drug costs, there was insufficient time in this process to examine any evidence on *either* side. As indicated above, the Federal Trade Commission has warned that disclosure of rebate amounts could raise prices rather than lower them. This legislation is costly, likely unconstitutional, and counterproductive to the State’s policy goals.

[9] U.S. Federal Trade Commission and the U.S. Department of Justice, Improving Health Care: A Dose of Competition (July 2004).
[10] 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).

It is for these reasons that PCMA must respectfully request your veto of SB 539. Please contact me at 202-756-5715 if you would like to discuss our request further. Thank you.

Sincerely,

Barbara A. Levy
General Counsel

cc: The Honorable Adam Paul Laxalt, Attorney General
The Honorable Barbara Richardson, Commissioner of Insurance
The Honorable Richard Whitley, Director, Department of Health and Human Services

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