April 2, 2017

Governor Doug Burgum
Office of the Governor, State of North Dakota
600 East Boulevard Avenue
Bismarck, ND 58505

Re: Veto Request for ND SB 2258 Relating to Pharmacy Claim Fees and SB 2301 Relating To Specialty Pharmacy Services;

Dear Governor Burgum:

The Pharmaceutical Care Management Association ("PCMA") is submitting the following comments urging you to veto SB 2258, Relating to Pharmacy Claim Fees and Pharmacy Rights; and SB 2301, Relating To Specialty Pharmacy Services. 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.

SB 2258 and SB 2301 will harm patients and raise drug prices in North Dakota by limiting PBM contracts with pharmacies that would allow underqualified pharmacies to dispense specialty drugs that generally are prescribed for a small segment of the population, require special care and handling, and are extremely expensive. These bills prohibit a PBM from requiring additional accreditation or recertification standards in addition to the state requirements for licensure in North Dakota. **This prohibition is unprecedented nationally, jeopardizes patient safety, and interferes with private contracting, and is contrary to the Employee Retirement Income Security Act of 1974 ("ERISA"). The legislation also violates the Constitution of North Dakota.**

<u>SB 2258 and SB 2301 Would be Harmful to Patient Safety</u>

SB 2258 and SB 2301 allow any pharmacy to serve as a specialty pharmacy in PBM networks without further accreditation. By not allowing PBMs to require any additional accreditation standards above state requirements for licensure, it is falsely being assumed that all pharmacies are capable of providing the same level of highly specialized care to consumers in North Dakota and can dispense clinically complex specialty drugs. This is not true. Not all pharmacies are qualified to offer the same services to

consumers. **New research shows that only two percent of doctors (specialists) who work with specialty pharmacies believe that all drug stores "have the expertise and capability to provide the different types of specialty medications to patients."**[1]

Specialty pharmacies play an important role in a patient's clinical care as they go far above simply dispensing medications. Specialty pharmacies perform a wide range of activities to deliver the complex, innovative and high-priced specialty drugs that are entering the United States health care market at a rapid rate. For example, they provide around-the-clock access to specially trained pharmacists, nurses, and clinicians who offer patients guidance and insight on disease states, as well as the use and management of specialty drugs, collecting data and tracking outcomes for specific patients, and managing patient adherence and persistency of drug regimens. In many cases, these **specialty drugs offer the most effective- and in some cases, the only – treatment for illnesses and conditions** that historically had few treatment options. **They are not stocked at a majority of retail pharmacies in the US because of their cost and unique handling requirements.**

Health plans and PBMs typically contract with selected specialty pharmacies in their pharmacy networks to assure high-quality services for consumers, avoid waste, and ensure appropriate use of specialty medications. Specialty pharmacy accreditation is a baselines requirement for inclusion in PBM preferred specialty pharmacy networks.[2] PBMs sometimes have additional quality requirements to ensure even higher levels of clinical and logistical support for patients.

The Willis Towers Watson 2016 Employer Best Practices in Healthcare study reported that 87 percent of employer respondents indicated **"Cost pressures – notably specialty drugs – continue to drive employers to change their benefit programs."** Here in North Dakota the **average cost of a specialty drug claim paid by Blue Cross Blue Shield of North Dakota (BCBSND) exceeds $5,000. In 2016 less than one percent of BCBSND members were on a specialty medication**, **but the specialty costs accounted for 44 percent of all pharmacy spending**. To provide better quality care and control costs **BCBSND began efforts in 2015 to establish a specialty network** that included local pharmacies. To participate in the network, pharmacies were asked to seek accreditation. The **specialty network went live in March of 2016 with 47 North Dakota locations in the network.** These local pharmacies met the standards of accreditation and offer local, high quality and competitively priced services to the citizens North Dakota.

[1] North Star Opinion Research, https://www.pcmanet.org/wp-content/uploads/2016/08/pr-dated-06-15-15-final-ny-specialty-pharmacy-summary-memo.pdf.
[2] sPCMA, "The Management of Specialty Drugs"

Allowing this prohibition to become law and limiting accreditation and recertification would be unprecedented. **No other state has enacted language like this and the potential consequences could be disastrous.** The lack of quality pharmacy oversight led to one of the worst outbreaks of meningitis in American history at the New England Compounding Center in 2012. The Wall Street Journal called this, "the worst public health crisis in the U.S. in decades."[3] As a result of insufficient pharmacy oversight, the contaminated drugs killed 64 people and sickened hundreds of others across the United States.[4] It is imperative that PBMs be allowed to require additional accreditation and certification from the pharmacies with which they contract.

The any willing pharmacy requirements included in these two pieces of legislation would mean forced contracting with pharmacies that do not meet even basic quality and performance standards for storing, handling and dispensing specialty drugs, much less the additional quality standards that some PBMs require. The patients who are prescribed specialty drugs deserve the best in clinical care and the included language will limit PBMs in providing that to patients in North Dakota.

SB 2258 and SB 2301 Are in Conflict with the North Dakota Constitution

In Article 1, Section 18 of the North Dakota constitution it states that, "no bill of attainder, ex post facto law, or law impairing the obligations of contracts shall ever be passed."[5] SB 2258 and SB 2301 are an invasion of the State into, and a modification of all current contracts, and dictates how private contracts are negotiated between PBMs and the pharmacies with which they contract. Imagine the chaos that ensues, if the Legislature continues to rewrite contracts on behalf of influential special interest groups.

SB 2258 and SB 2301 Are in Conflict with Federal Law Under ERISA

Both bills impose mandates and restrictions on the relationship between PBMs and their contracted North Dakota pharmacies as well as interfere with how PBMs serve multistate clients, in violation of ERISA. ERISA has one of the most expansive preemption provisions in any federal law, as the Supreme Court has held, even forbidding states from enacting laws in areas that are traditionally seen as under the jurisdiction of states, such as public health.

[3] 'Compound Pharmacy Owners and Employees arrested after Meningitis Outbreak', http://blogs.wsj.com/pharmalot/2014/12/17/compound-pharmacy-owners-and-employees-arrested-for-meningitis-outbreak/
[4] 'Pharmacy Executives Face Murder Charges in Meningitis Deaths,' https://www.nytimes.com/2014/12/18/us/new-england-compounding-center-steroid-meningitis-arrests.html?_r=0
[5] North Dakota Constitution, http://www.legis.nd.gov/constit/a01.pdf

These bills interfere with both design and administration, including claims pricing procedures, the ability to negotiate prices with retail pharmacies in a PBM's network, and the ability to keep proprietary information confidential. ERISA has been interpreted by multiple federal courts of appeals to mean that states cannot interfere with the design and administration of employee welfare benefit plans by imposing requirements on their third party administrators like PBMs (See PCMA v. D.C. and PCMA v. Gerhart[6]). According to PCMA v. Gerhart, states cannot impose mandates and restrictions on a PBM's relationship with ND pharmacies that run "counter to ERISA's intent of making plan oversight and plan procedures uniform."

We respectfully request a veto to both SB 2258 and SB 2301. Both bills, if challenged, are likely to be found contrary to existing federal law. **The recent 8th Circuit opinion PCMA v. Gerhart stated under ERISA, states cannot dictate how plans structure and pay for plan benefits, including prescription drugs. North Dakota is in the 8th Circuit and we would expect a similar ruling if these bills are challenged**. A costly legal challenge will require the tax payers of North Dakota, rather than the bill's proponents, to pay the legal expenses of such a contest.

Finally, the language included in these two bills will jeopardize consumer safety by prohibiting PBMs from ensuring the pharmacies they contract with on behalf of employers and health plans in North Dakota meet important accreditation and recertification standards. And as mentioned the legislation also represents a violation of the constitution of North Dakota and federal law under ERISA.

PCMA joins Blue Cross Blue Shield of North Dakota, the City of Minot, ND REC Benefit Trust, Fargo-Moorhead Home Builders Plan & Trust, Dakota Supply Group, Brandt Holdings, Scheels, Prairie Knights Casino & Resort and many citizens of North Dakota in opposing SB 2301 and SB 2258. We strongly urge you to veto this special interest legislation.

Thank you for your consideration and please let me know if we can provide you with any other information.

Sincerely,

Melodie Shrader
State Affairs

[6] Pharmaceutical Care Management V. Gerhart, No. 15-3292 (8th Cir. 2017)