



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

September 1, 2020

The Honorable Andrew R. Stolfi
The Honorable T.K. Keen
Chairs, PBM Regulatory Issues (B) Subgroup
Members of the PBM Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners

Delivered via email to Jolie Matthews @ jmatthews@naic.org

Re: Proposed Draft of the Pharmacy Benefit Manager and Regulation Model Act

Dear Chair Stolfi, Chair Keen, and Members of the Committee:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to review and provide comment on NAIC's proposed Pharmacy Benefit Manager Licensure and Regulation Model Act ("Model"). We look forward to working with NAIC as the Model continues to evolve. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Pharmacy Claw Backs

A. Pharmacy Claw Backs Should Be Prohibited

We appreciate NAIC's inclusion of language to address the practice of pharmacy claw backs and the prohibition of such, as found under subsection 8.B.(12). However, we urge NAIC to include the claw back prohibition among the provisions that a commissioner would be required to adopt, rather than having it as a permissive or optional provision.

As NAIC may be aware, PBMs impose on pharmacies various payment denials or reductions in payment after a prescription drug claim has already been adjudicated. These denials and reductions in payment often take the form of post-adjudication fees and reimbursement claw backs that go directly to payers' bottom lines and lead to increased patient costs at the pharmacy counter. In fact, the federal Centers for Medicare and Medicaid Services (CMS) has recognized the impact and costs of pharmacy reimbursement claw backs and post-adjudication fees on beneficiaries, pharmacies, and on overall government costs. The impacts range from increased beneficiary cost-sharing to less transparency and competition.

In a recent proposed Medicare Part D drug pricing rule, CMS recognized that “when pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, [however] beneficiaries do not benefit from pharmacy price concessions through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug.”¹ CMS estimated in a proposed rule that restructuring pharmacy price concessions would lead to overall beneficiary savings of \$7.1 to \$9.2 billion over 10 years.² CMS further stated that “[g]iven the significant growth in pharmacy price concessions in recent years, when such amounts are not reflected in the negotiated price, it has become increasingly difficult for consumers to know at the point of sale what share, or approximate share, they are paying of the costs of their prescription drugs to the plan...”³ CMS noted that “[v]ariation in the treatment of these price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program.”⁴ CMS added:

Consequently, consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations. The quality of information available to consumers is even less conducive to producing efficient choices when pharmacy price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy.⁵

B. Unsustainable Growth of Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees

Pharmacy reimbursement claw backs and post-adjudication fees are a growing problem that must be addressed at both the state and federal level. In the same proposed Medicare Part D drug pricing rule mentioned above, CMS highlighted the growth of the use of pharmacy reimbursement claw backs and post-adjudication fees. CMS noted the exponential increase in the use of pharmacy reimbursement claw backs and post-adjudication fees in recent years, and stated it expects the growth to continue in the future:

- “The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017. The data also show that much of this growth occurred after 2012.”⁶

¹ CMS, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62154, 62190 (Nov. 30, 2018), available at <https://www.govinfo.gov/content/pkg/FR-2018-11-30/pdf/2018-25945.pdf>. While this evidence is derived from CMS’ experience in the Medicare Part D program, the impact on patient costs is similar for any pharmacy benefit design that claws back pharmacy reimbursement and/or imposes on pharmacies post-adjudication fees. Here, CMS used the term “pharmacy price concessions,” which has the same meaning as pharmacy claw backs and post-adjudication fees.

² Id. at 62192-93.

³ Id. at 62176.

⁴ Id. at 62190.

⁵ Id. At 62176.

⁶ Id. at 62175.

- “Actual pharmacy price concessions have increased from \$229 million in 2013 to \$4 billion in 2017.”⁷

C. Current PBM Marketplace

Prescriptions filled by patients who are paying cash without any form of insurance account for 5-8% of the total volume of prescriptions.⁸ While 92-95% of the prescriptions filled have a payment component coming from Medicare Part D, Medicaid, or a commercial insurance plan, these plans are ordinarily administered by PBMs. The top three PBMs manage about 75% of the volume.⁹ The top six PBMs and plans manage about 95% of the volume.¹⁰ Five of those six PBMs are owned by large national health insurers.¹¹ This business environment makes it very difficult for pharmacies to negotiate equitable business practices and transparency because the PBMs and health insurers have more commercial market power and leverage in the relationship due to their size and scale.

D. Impact of Pharmacy Reimbursement Claw Backs and Post-Adjudication Fees on Pharmacies

The impact of pharmacy reimbursement claw backs and post-adjudication fees on pharmacy entities has been substantial. If all fees were calculated during the claim adjudication process at the point-of-sale, the pharmacy would know exactly what price they are selling the product for and how much it cost them. When fees are applied after point-of-sale and claw backs occur, pharmacies lose control over their own revenues and profitability, creating undue financial risk.

Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs. Dire financial pressures have caused an alarming number of pharmacies to shut their doors. Payers have increasingly reduced reimbursements; in many cases pharmacies dispense prescriptions below cost. Retroactive fees and claw backs often occur weeks or months after a transaction closes, when a payer decides to recoup a portion of the pharmacy’s reimbursement. These fees have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines. Last year alone, pharmacies paid over \$9 billion in reimbursement claw backs and post-adjudication fees. Nationwide, there are now approximately 2,000 fewer pharmacies than just two years ago.¹²

⁷ Id. at 62191.

⁸ PHAST® *Prescription Monthly*, data drawn August 6, 2019.

⁹ Fein, Adam J.; “The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” March 2020; p. 131.

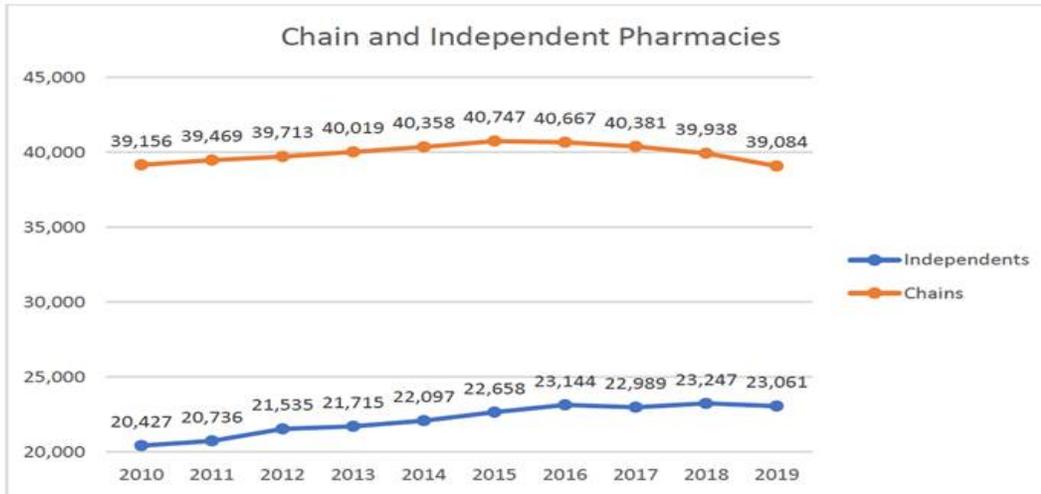
¹⁰ Id.

¹¹ Id. at 131, 136.

¹² Independent data sources confirm that the number of retail pharmacies in the United States dropped by almost 2,000 over the past two years. See IQVIA, DDD – Drug Distribution Data (showing the number of U.S. retail pharmacies dropped from 58,706 in December 2017 to 56,788 in December 2019); National Council for Prescription Drug Programs, dataQ (showing 995 pharmacy profiles closed in 2018 and 695 pharmacy profiles closed in 2019).

A study commissioned by the PBMs' own trade association, the Pharmaceutical Care Management Association (PCMA), recognizes that retail community pharmacies, and particularly chain pharmacies, are in trouble.¹³ PCMA concludes there are fewer chain pharmacies now than a decade ago, and a net loss of 1,583 chain pharmacies over the past three years.¹⁴ PCMA's chart from the study shows an accelerating decline in chain pharmacies since 2015.¹⁵ While PCMA does not suggest why chains are closing pharmacies, in a recent Supreme Court filing, PCMA agreed it is "undisputed" that "reimbursements below cost are approximately 10% of prescriptions filled."¹⁶

Figure 1. Growth Trend of Pharmacies from 2010-2019



The epidemic of pharmacy closures is reducing access to vital healthcare services, especially in rural areas where options are already limited. Recent polling by Morning Consult confirmed that pharmacies are considered the most accessible part of the healthcare delivery system. However, that accessibility is increasingly threatened as more pharmacies go out of business. A recent study published in the *Journal of the American Medical Association* found that pharmacy closures led to a significant drop in medication adherence for older adults taking cardiovascular medications.¹⁷

Pharmacies should not be subject to fees or price concessions applied retroactively after a prescription drug claim has been adjudicated at the point-of-sale. Reforming pharmacy post-adjudication fees by prohibiting claw backs will lower out-of-pockets costs for beneficiaries, lead to greater price transparency, and make medicine more accessible, leading to greater adherence, and better health outcomes.

¹³ See https://www.pcmanet.org/wp-content/uploads/2020/03/FINAL_Independent-Pharmacies-in-the-U.S.-are-More-on-the-Rise-than-on-the-Dcline.pdf; Accessed August 10, 2020.

¹⁴ Id.

¹⁵ Id. at Figure 1.

¹⁶ *Rutledge v. Pharmaceutical Care Management Association*, 18-540, 1 App. 341 (petition granted Jan. 10, 2020) (referring to the joint appendix in the case now pending before the Supreme Court of the United States).

¹⁷ Qato, Dima M., PharmD, MPH, PhD; Alexander, G. Caleb, MD, MS5; Chakraborty, Apurba, MBBS, MPH; et al.; *JAMA Network Open*; 2019;2(4):e192606. doi:10.1001/jamanetworkopen.2019.2606; April 19, 2019; Accessed August 12, 2020.

II. NACDS Recommended Edits to the Model

A. Addressing Pharmacy Claw Backs

To address the concerns with pharmacy claw backs, we urge NAIC to include a claw back prohibition among the Model's required elements. We recommend establishing the claw back prohibition as a new, separate section in the Model, as opposed to including it under subsection 8.B. Below, we propose to create a new "Section 9," and then to renumber the current Sections 9 and 10 to be Sections 10 and 11, respectively. Current subsections in Section 8.B. would be renumbered accordingly as well, to account for the move and renumbering of current subsection 8.B.(12) as proposed new Section 9.

With respect to the substance of a claw back prohibition, we have provided the recommended edits below. Of note, we suggest using the word "prohibited" in the text of this language to make clear that reductions in payment are prohibited. Moreover, we suggest inserting language that states that the types of reductions that are prohibited are those that are done retroactively. We suggest deleting the secondary reference to "pharmacy benefit manager or covered entity" because it is clear already from the sentence who is prohibited from making or permitting such a reduction.

In lieu of attempting to enumerate all the types of payment reductions that may and do occur, we suggest broadly stating that retroactive reductions shall not occur. Further, we suggest adding language that expressly permits pharmacies to receive a retroactive increase in payment for pharmacist services. We suggest adding this language to allow for the possibility of pharmacy incentive programs that could be implemented in the future.

~~(12)~~ **Section 9.** Clawbacks prohibited.

A pharmacy benefit manager or representative of a pharmacy benefit manager is prohibited from retroactively making or permitting any reduction of payment for pharmacist services by a pharmacy benefit manager or a covered entity directly or indirectly to a pharmacy under during a reconciliation process. The previous sentence shall not prohibit any retroactive increase in payment for pharmacist services to a pharmacy during a reconciliation process pursuant to a written agreement with the pharmacy. to an effective rate of reimbursement, including but not limited to, generic effective rates, brand effective rates, direct and indirect remuneration fees or any other reduction or aggregate reduction of payment;

* * *

B. Potential ERISA Concerns

Beyond pharmacy claw back concerns, we would like to offer recommendations intended to help to minimize potential ERISA preemption challenges.

First, we believe that subsection 3.C.(2) (a), below, could trigger ERISA as it may be read to attempt to specifically exempt ERISA plans from the definition of "covered entity." If so, per the case law, that means it refers to ERISA plans, triggering ERISA preemption.

We suggest deleting subsection (a) which may help to minimize that risk:

Section 3. Definitions

* * *

C. (2) "Covered entity" does not include:

~~(a) A self-funded plan that is exempt from state regulation pursuant to federal law;~~

~~(b) A plan issued for coverage for federal employees; or~~

~~(c) (b) A health benefit plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts.~~

* * *

Second, with respect to the language of subsection 4.A., the contract to which this law applies does not appear to be limited to only contracts between PBMs and pharmacies, which may make it more likely to be successfully challenged under ERISA. It may also be read to apply more broadly to PBM/plan contracts, which is more likely to trigger ERISA preemption. We suggest narrowing the contracts covered by it.

Section 4. Applicability

A. This Act shall apply to a contract or health benefit plan issued, renewed, recredentialed, amended or extended on or after the effective date of this Act.

* * *

Finally, the Subgroup may want to further review the language of subsection 8.B.(2). We find the application and scope of this subsection to be unclear, and as such may be problematic with respect to ERISA:.

Section 8. Regulations

A. The commissioner may adopt regulations regulating pharmacy benefit managers that not inconsistent with this Act.

B. The regulations adopted pursuant to Subsection A may include but are not limited to the following:

* * *

(2) Prohibited market conduct practices;

* * *

III. Conclusion

NACDS thanks NAIC and the Subgroup for your consideration of our recommendations and suggested edits to the Model. We urge you to include a pharmacy claw back prohibition among the mandatory provisions of the Model. We suggest NAIC modify the claw back language to clearly prohibit retroactive payment reductions to pharmacies. We further ask NAIC to include language that would preserve the ability for retroactive (i.e., post-adjudication) pharmacy payments should pharmacy incentive programs be utilized in commercial and managed care contracts in the future.

We also urge you to consider our recommendations regarding potential ERISA implications. If we can provide any further assistance, please do not hesitate to contact Kevin Nicholson, Vice President, Public Policy and Regulatory Affairs, at knicholson@nacds.org or 703-837-4183.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer