June 7, 2018

Assem. Kevin Cahill
Chair, Health, Long-Term Care & Health Retirement Issues Committee
National Council of Insurance Legislators

RE: COMMENTS ON THE "PHARMACY BENEFITS MANAGER LICENSURE AND REGULATION MODEL ACT"

Dear Chair Cahill,

I am writing on behalf of the National Community Pharmacists Association to provide comments on the "Pharmacy Benefits Manager Licensure and Regulation Model Act," which would empower state insurance commissioners to regulate and license pharmacy benefits managers doing business in their states. This model act is a step towards greater oversight of a massive, largely unregulated industry.

NCPA represents the interest of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies across the United States. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines. Independent pharmacists are small business entrepreneurs and multifaceted health care providers who represent a vital part of the United States' health care delivery system.

We hope the committee finds our recommendations and comments helpful as it finalizes the model act. We have divided our recommendations and comments by topic.

Definitions

NCPA urges the Committee to make the following two amendments to the model act's definitions:

- Remove the provision that exempts "[h]ealth benefit plans that are self-funded and specifically exempted from regulation by the State by The Employee Retirement Income Security Act of 1974 (ERISA)" from the definition of "health benefit plan."[1] With this overly broad exemption, the model act's protections would not apply to a significant number of beneficiaries who receive health benefits through self-funded employer plans. Under Supreme Court precedent, the model act's provisions, which apply to PBMs, not health benefit plans, are not of the type that run afoul of ERISA.

[1] Section (3)(b)(2)(viii).

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- Amend the definition of "independent pharmacy" to "a pharmacy that is not a pharmacy benefits manager affiliate." Currently, the definition is "a pharmacy that is not in any way affiliated with a pharmacy benefits manager."[2] This broad language may lead to confusion because all pharmacies contract with PBMs. Referencing pharmacy benefits manager affiliate, which is defined in the act,[3] will bring clarity to the definition of "independent pharmacy."

Licensure by Insurance Commissioner

Twenty-nine states currently require some type of licensure for PBMs to do business within their state, and most of those states provide licensing authority to the state's department of insurance. PBMs are involved with almost every aspect of the prescription drug supply chain, including plan designs, formulary design, and contracting with health plans and pharmacies. PBMs control where beneficiaries can access medications and determine what the plan – and the patient – will pay for those drugs. Despite this level of involvement in providing health insurance benefits, there is little regulatory oversight over PBMs' actions. NCPA supports the model act's licensure requirements because they protect beneficiaries by appropriately requiring licensure of PBMs and allowing for oversight of the PBM industry by the Insurance Commissioner.

Network Adequacy Standards

Ensuring that beneficiaries may readily access their prescription drug needs and receive face-to-face pharmacy provider services is the most vital component of any pharmacy benefit program. Several PBMs own automated dispensing facilities that fill and ship prescriptions. PBMs refer to them as "mail-order pharmacies," but these closed environment, robotics-driven assembly lines do not deliver the patient benefits of a traditional pharmacy. Face-to-face consultation between a pharmacist and patient, by far the most effective type of intervention to ensure that patients adhere to their prescribed medication regimen and receive adequate counseling about potential side effects, is replaced in mail-order with impersonal email communication or long waits on phone calls to a toll-free number. PBMs "hard sell" health plans on implementing complex benefit schemes requiring beneficiaries to use PBM-owned dispensing facilities for maintenance or specialty medications. They promise outrageous savings to health plans but often fail to mention the excessive costs and additional patient burden associated with mail-order waste – discontinued prescriptions for which medications are still mailed to the patient for months, temperature-sensitive medications that are left vulnerable to the elements until patients get home, increased potential for lost or stolen medications, et cetera. Mail-order pharmacies do not provide an adequate pharmacy network for patients – quite the opposite. NCPA supports the model act's network adequacy requirements because they will protect the personal, face-to-face interaction

[2] Section (3)(d).
[3] Section (3)(m).

between pharmacist and patient by preventing PBMs from including mail-order pharmacies in their calculations for network adequacy.

Compensation – prohibited practices

NCPA supports the model act's provisions allowing the insurance commissioner to review and approve PBM compensation programs to ensure that the programs are fair and reasonable to provide an adequate pharmacy benefits manager network. PBMs' opaque compensation practices have a direct negative impact on locally owned community pharmacies in the form of "underwater" reimbursements – in which the amount a pharmacy pays for the medication is more than what the PBM reimburses them for the prescriptions they dispense. Community pharmacists' primary concern has always been the health of their patients. However, there is a limit to the number of underwater reimbursements pharmacies can withstand. Eventually, these under-reimbursements will run community pharmacies out of business, further limiting patient access to local pharmacy services.

NCPA supports the provisions protecting patient access to pharmacy services by prohibiting PBMs from requiring accreditations and certifications beyond the requirements of the State Board of Pharmacy. PBMs have no place interfering in the regulatory aspect of pharmacists and pharmacies operating in the state. PBMs are simply middlemen that have been employed to reduce administrative costs for insurers, validate patient eligibility, administer plan benefits, and negotiate costs between pharmacies and health plans. State boards of pharmacy already have the necessary requirements for pharmacies in place to serve and protect the residents of their states. Additional accreditation and certification requirements implemented by PBMs beyond those mandated by a state board of pharmacy are often used to create narrow networks that inhibit patient access to qualified, trusted pharmacy providers and are well beyond the scope of appropriate PBM practices.

NCPA also supports the provision prohibiting a PBM from reimbursing an independent pharmacy less than it reimburses a PBM affiliate. This will help to minimize the conflicts of interest that occur when PBMs own pharmacies. NCPA urges the committee to remove the language limiting the application of the provision to generic products only.[4]

Pharmacist Provision of Information to Patients

Often community pharmacists are forced to sign take-it-or-leave-it contracts from PBMs with multiple contract provisions or requirements embedded in lengthy provider manuals that include overly broad confidentiality requirements and non-disparagement clauses, as well as requirements that pharmacies charge insured patients what the PBM says at point of sale. This

[4] Section (6)(b)(4).

has the effect of chilling a range of pharmacist communications with patients and others for fear of retaliation by the PBM. While they dislike these provisions and the negative impact they have on communicating with patients, independent pharmacists cannot negotiate these clauses out of PBM contracts, so they sign the contracts anyway to continue filling prescriptions and providing care for patients whose pharmacy benefits are managed by the PBM. Violation of any of these provisions or others may lead the PBM to terminate the contract with the pharmacy and remove the pharmacy from the PBM's networks, resulting in the inability of the pharmacy to continue to serve a significant percentage of its customers and potentially causing access problems for patients. NCPA supports the model act's provisions that protect pharmacy patients by preventing PBMs from prohibiting a pharmacist or pharmacy from, or penalizing them for, providing information to their patients regarding the options that patient has in paying for prescription medications. **Twenty-four states have passed similar laws.**

Enforcement and rules

NCPA supports the model act's provisions allowing the insurance commissioner to adopt rules and set penalties and fines for violations of the act. This enforcement authority is necessary to ensure all parties comply with its requirements.

Maximum allowable cost lists

NCPA urges the committee to make the following changes to the provisions addressing maximum allowable cost (MAC) lists:

- The act should require MAC lists to be updated no fewer than every seven days. The current language requires an update within seven days from an increase of 10% or more in the pharmacy acquisition cost from 60% or more of the pharmaceutical wholesalers doing business in the state. Calculating such a change can lead to confusion, which can be avoided by requiring an update every seven days.
- When a MAC appeal is upheld, the applicable change in the maximum allowable cost should be made effective retroactively to the date of the original claim and should apply to all similar claims. This will ensure that the pharmacy is reimbursed at the appropriate rate.
- Provisions should be added that address generic effective rate (GER) reimbursement. Under a GER reimbursement methodology, a PBM retroactively manages MAC lists by defining an average discount off the Average Wholesale Price (AWP) for all generic drugs. GER is becoming a more common standard and a way for PBMs to avoid existing laws addressing MAC lists. The model act should address GER to ensure PBMs cannot skirt protections in state codes.

PBMs typically establish a MAC list for multi-source generic drugs that includes the amount a PBM will pay for certain drug products. The process PBMs use to determine the drugs and the prices of

the drugs included on the list, however, lacks any degree of transparency. This process is further complicated by the fact that PBMs frequently maintain multiple lists. There is no standardization in the industry for the criteria or methodology used to determine inclusion or pricing of a drug on one of these lists. In most cases, these lists remain entirely confidential to both the PBM's client – the health plan sponsor – and the pharmacy; therefore, there is no way of knowing how or why a health plan sponsor or pharmacy is paying or being paid the PBM-set price for a drug. This gives PBMs the ability to gain significant revenues through questionable business practices.

For example, PBMs will typically use an aggressively low price list to reimburse their contracted pharmacies and a different, higher list of prices when they sell to their clients or plan sponsors. Essentially, the PBMs reimburse low and charge high with their price lists, pocketing the significant "spread" between the two prices, and we can demonstrate the impact this practice has on ever-increasing prescription drug plan costs.

At the federal level, CMS has recognized the fiscal benefits of the type of transparency required by the model act. In their Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule, CMS stated that "updating maximum allowable cost prices for drugs at least every 7 days generally should have a downward pressure on overall drug costs. Therefore we do not agree with the commenters that the requirement will necessarily increase costs."

The model act is not requiring anything that would result in a negative fiscal impact to the health care system or to any state agency or plan. **Of the thirty-eight states with enacted legislation similar to this act, no state has reported a negative fiscal impact.**

Fair pharmacy audit procedures and guidelines

NCPA urges the committee to add language addressing pharmacy audits. Pharmacists understand that audits are a necessary practice to identify fraud, abuse, and wasteful spending, and they are not opposed to appropriate audits to identify such issues. Current PBM audits of pharmacies, however, are often used as an additional revenue source for the PBM. PBMs routinely target community pharmacies and recoup vast sums of money for nothing more than harmless clerical errors where the correct medication was properly dispensed and no financial harm was incurred. In many instances, the PBM not only recoups the money paid to the pharmacy for the claim in question but also recoups for every refill of that claim, even if all other fills were dispensed without error.

In their 2014 Final Call Letter, the Centers for Medicare and Medicaid Services indicated their recognition of abusive pharmacy audit practices occurring within the Medicare Part D program. CMS found that pharmacy audits in the Part D program were not focused on identifying fraud and financial harm but on targeting clerical errors that "may be related to the incentives in contingency

reimbursement arrangements with claim audit vendors." CMS concluded that "full claim recoupment should only take place if the plan learns that a claim should not have been paid under Part D at all; for example, because it is fraudulent." **Forty states have also recognized that abusive practices occurring during pharmacy audits are not limited to the Part D program and have enacted legislation to address these practices.**

A model act of comprehensive PBM regulation should address fair pharmacy audit requirements.

Almost all of the provisions in this model act have been enacted in some form in states across the nation. Ninety-one percent of all prescriptions are covered by insurance, and state legislators realize the need to regulate a PBM industry that touches almost every one of their constituents. Each time a bill is proposed that will protect patients, payers, and pharmacy providers from opaque PBM practices and abuses, the PBM industry has fought against the proposed protections. By adding reasonable regulations on an industry that has contributed to increasing prescription drug benefit costs, this model act will allow community pharmacists to better serve their patients without PBMs imposing unfair and burdensome requirements.

If you have any questions about the information contained in this letter or wish to discuss the issue in greater detail, please do not hesitate to contact me at matthew.magner@ncpanet.org or (703) 600-1186.

Sincerely,

Matthew Magner
Director, State Government Affairs