PCMA

June 6, 2018

The Hon. Kevin Cahill
Chairman
NCOIL Health, Long-Term Care & Health
Retirement Issues Committee
Delivered via email to William Melofchik at wmelofchik@ncoil.org

Re: NCOIL Proposed Pharmacy Benefits Manager Licensure and Regulation Model Act

Dear Chairman Cahill:

The Pharmaceutical Care Management Association ("PCMA") must respectfully state our opposition to the Proposed Pharmacy Benefits Manager Licensure and Regulation Model Act (the "Proposed Model") currently being considered by your Committee. While we have many concerns with the Proposed Model, it is important to highlight some of its more significant flaws, namely, it risks patient safety while potentially increasing the cost of prescription drug care, inappropriately interferes with private sector contracts, and presents an overreach of authority for state Insurance Departments.

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, state employee and retiree plans, and Medicare Part D plans.

First, the Proposed Model would put patient safety at risk in at least two ways. Section 12(d) would expressly put pharmacy profits ahead of patient care by allowing a pharmacy to "decline to provide the pharmacist services to a patient * * * [if the pharmacy] is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services." In other words, it could leave patients stranded at the pharmacy counter, having to go without their medication(s) while they find another pharmacy, potentially interfering with medication adherence. In addition, Section 6(b)(3) would prohibit a PBM from requiring pharmacy credentialing and accreditation standards unless approved by both the Department of Insurance and Board of Pharmacy (BOP). Payers routinely credential health care providers before including them in their networks to verify the providers' ability to comply with contractual provisions and regulatory requirements. Providers throughout the health care system – including PBMs – are routinely accredited by independent organizations such as URAC and The Joint Commission against pre-determined quality standards. Taking those commonly used tools away from PBMs and their clients by exempting pharmacies from such requirements would actually reduce the pharmaceutical care system's ability to "promote, preserve and protect public health, safety and welfare" of the public. By removing these additional tools from PBMs and their clients, it threatens patient safety. Allowing health insurance carriers to enforce high standards for patients can go far in avoiding harmful outcomes to patients, such as the New England Compounding (NECC) disaster in 2012 that resulted in 76 people dying and more than 800 becoming ill with fungal meningitis. Many states have provisions in their insurance codes encouraging – if not requiring – the use of provider credentialing and accreditation, and we urge committee members to check their own state's statutes and/or regulations as they consider the Proposed Model[i].

Second, the Proposed Model will increase prescription drug costs in several ways. For example, Section 6(a)(1) would empower the Insurance Commissioner to review and approve the reimbursement to pharmacies, to determine whether the reimbursement is "fair and reasonable," a very nebulous standard. By guaranteeing

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reimbursement rates at acquisition cost, the state picks winners and losers by not allowing market forces to push pharmacies to shop for the best price. Given the emphasis on guaranteed profits for pharmacies noted above, costs will go up. Section 6(a)(1) would also grant the commissioner the authority to "review and approve the compensation program of a [PBM] with a health benefit plan." Section 6(b)(2) would prohibit PBMs from charging pharmacies certain fees that have long been part of the financial terms of the contracts between PBMs and pharmacies. Section 6(c) would restrict post-adjudication retroactive denial or reduction of pharmacy claims. For example, it would appear to prohibit a PBM from collecting some overpayments that are discovered during an audit, including clerical or recordkeeping errors, such as typographical errors or computer errors. These errors are overpayments to the pharmacy and should be subject to recoupment by the PBM on behalf of its clients. The Proposed Model essentially would become the arbiter of private sector contractual terms, to include but not limited to financial terms determined in a competitive marketplace.

Third, the Proposed Model represents an overreach of regulatory authority for state Insurance Departments, well beyond the intrusion into private contracts highlighted in the previous paragraph. The Proposed Model abdicates legislative authority to the Department of Insurance by granting broad and excessive rulemaking and approval authority, essentially re-defining the entire marketplace delivery of pharmacy benefits and regulating private commercial market contracts between health plans and insurers, pharmacies, and PBMs.
Each piece of the Model Act impedes the delivery of safe and affordable patient care. Collectively, the Model Act ruptures the competitive supply chain, picking winners and losers, while dramatically risking patient safety.

Finally, it is worth noting that Section 12, dealing with PBM reimbursement of pharmacies for dispensing generic drugs, using Maximum Allowable Cost ("MAC") lists, which encourage pharmacies to purchase generic drugs at the most competitive prices, mirrors the provisions of Arkansas Act 900 of 2015. That Act is currently the subject of litigation between PCMA and the state.

We urge you to consider the broad implications that the adoption of this sweeping legislation as a national model act would have on the industry and the members we represent. In an era where the rising costs of drugs is the subject of much debate, stripping away tools that protect a patient's safety and access to needed medication and help keep costs lower is not the appropriate public policy. We have attached an appendix that further outlines in more detail some of our concerns with the proposed model act.

We understand that we are at the beginning of an important process and we look forward to continued dialogue on this critical issue.

Sincerely,

Melodie Shrader
Senior Director – State Affairs

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[i] NCSL Sudy: *Accreditation to Approve Health Plans and Providers Process.*
http://www.ncsl.org/research/health/accreditation-to-approve-health-plans-and-provider.aspx

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NCOIL PROPOSED MODEL ACT
APPENDIX TO THE PCMA COMMENT LETTER

A PRESCRIPTION FOR RISKING PATIENT SAFETY WHILE INCREASING COSTS

The NCOIL Model Act inappropriately interferes with private contracts, presents an overreach of authority for the Department of Insurance and unjustly restricts the tools PBMs use to reduce prescription drug costs and maintain high-quality care, leading to higher costs for workers and employers.

SECTION 3 – DEFINITIONS: SOME PROPOSED DEFINITIONS IN THE NCOIL MODEL ACT ARE AT ODDS WITH COMMON USAGE, ARE CONFUSING, AND, AS USED, HAVE THE POTENTIAL TO INCREASE COSTS AND COULD BE MISLEADING

(d) "Independent pharmacy" – not only is this definition vague and confusing, based as it is on the lack of affiliation with a PBM, but it is not consistent with the current usage of this term throughout the industry. The term "independent pharmacy" is typically used today to distinguish a single privately-owned pharmacy (or as many as four under common ownership) from chain pharmacies with four or more retail pharmacies. In common usage, affiliation with a PBM is irrelevant.

- In addition, under the proposed definition, is a pharmacy that is owned by a PBM, for example, an "independent pharmacy" when it is in a network managed by another PBM?
- And what rationale is there for proposing to codify in statute different classes of competitors in a market based solely on their ownership structure? Even in the healthcare industry, what other market participants are treated differently in statute based on ownership? Are independent hospitals regulated any differently than those owned by large multi-state corporations? Are physician-owned medical practices regulated any differently than those owned by hospitals?

(e) "Maximum Allowable Cost List" – the definition is not limited to its use for reimbursement for generic drugs only, which is its common usage in the marketplace today. At a minimum, this could create some confusion. Read literally, it could create the potential for application of the MAC concepts in Section 12 to reimbursement for brand-name drugs as well as generic, including such cost-drivers as the guaranteed profit for pharmacies on every prescription (§12(b)(4)(A)(i)(b))

(k) "Pharmacy acquisition cost" – defined simply as the listed invoice price, it fails to account for off-invoice adjustments, such as rebates, volume discounts, prompt-pay discounts, etc., that are part of the pricing terms and can significantly lower the actual cost to the pharmacy.

- In fact, the definition of a "Rebate" in (q) expressly acknowledges that pharmacies receive these off-invoice adjustments either directly, or indirectly when purchasing through a pharmacy services administrative services organization.
- This is a particularly egregious omission, as the term is only used substantively once in the draft, in §12(b)(4)(A)(i)(b), permitting a pharmacy to appeal its reimbursement on a particular prescription if the reimbursement is below the "pharmacy acquisition cost." The implication is that the pharmacy is losing money on that prescription and therefore entitled to appeal, although its actual net cost may be significantly lower, even lower than the reimbursement, and the pharmacy could actually be earning a profit.

(p) "Pharmacy services administrative organization" – simply stated, akin to pharmacy buying groups, these organizations (often owned by wholesalers) work for and "help" their independent pharmacy members, not PBMs or other third party payers.

SECTION 4 – LICENSE TO DO BUSINESS: NCOIL PROPOSED MODEL ACT IGNORES EXISTING REGULATIONS

The Model Act requires PBMs to be licensed to do business in a state, ignoring any other state requirements such as the requirement to be registered as a Third Party Administrator.

- Health Insurers design the pharmacy benefit and are appropriately regulated by a state's Department of Insurance.
- The NAIC recently spent two years contemplating the regulation of PBMs. Upon conclusion of its review, the NAIC acknowledged that the responsible entity, the health carrier, is the appropriate place to impose regulations on the prescription benefit that the carrier offers.

SECTION 5 – PBM NETWORK ADEQUACY: NCOIL PROPOSED MODEL ACT SETS A MARKET FAVORITISM PRECEDENT

The Model Act requires the Department of Insurance to regulate the PBMs pharmacy network without providing the necessary standards with which the network is to be evaluated.

- It is inappropriate for the Insurance Commissioner to review private sector pharmacy reimbursement provided for in negotiated contracts with retail pharmacies. It is particularly inappropriate to be reviewing reimbursement against such a nebulous "standard" as "fair and reasonable."

SECTION 6 – COMPENSATION – PROHIBITED PRACTICES: NCOIL PROPOSED MODEL ACT PUTS PATIENT SAFETY AT RISK

The Model Act prohibits PBMs from requiring pharmacy credentialing and accreditation standards unless approved by both the Department and Board of Pharmacy (BOP) *(Accreditation – Section 6(b)(3))*

- Credentialing and accreditation are the foundational requirements that health plans, employers and their PBMs use to validate pharmacy providers prior to enrollment and network contracting.
- State licensure evaluations by the BOP do not include measures to validate a pharmacy's ability to comply with contractual provisions and regulatory requirements, such as inventory control for claim payment audits, quality management, liability, patient compliance and adherence, safety, clinical programs, etc.
- Accreditation is a designation that demonstrates a pharmacy's commitment to safety by adhering to required, proper patient care standards that must be met to ensure appropriate dispensing of highly complex specialty drugs.
- Specialty pharmacies are held to a higher standard of care and plan sponsors have the right to require accreditation to ensure that pharmacies dispensing to their beneficiaries meet such higher standards.
- Insurance plans and other payers routinely use credentialing to validate and approve facilities and practitioners to be in their networks as participating providers of healthcare services, across the healthcare system. This is not a unique requirement for pharmacies.

- It is inappropriate for the BOP to be regulating PBM's accreditation and credentialing requirements as decisions made regarding these issues could benefit the Board's members directly. The Federal Trade Commission has warned about such antitrust concerns.

SECTION 6 – COMPENSATION – PROHIBITED PRACTICES, AND SECTION 7 – GAG CLAUSES: NCOIL PROPOSED MODEL ACT UNNECESSARILY REGULATES PRIVATE CONTRACTS

The Model Act unnecessarily inserts state government into free-market business-to-business transactions by regulating compensation paid in private contracts. *(Compensation – Section 6(a))*

- Allowing the Insurance Commissioner to approve compensation paid by a health plan to a PBM and the reimbursement the PBM will pay to a pharmacy is a broad overreach of government regulation.
- This bill has broad applicability – with the Department becoming the arbiter of what is "fair and reasonable" compensation, inserting government pricing standards into the competitive marketplace.

The Model Act requires Department approval of private contract terms related to network pharmacy fees. *(Fees – Section 6(b)(2))*

- For decades, pharmacies have agreed to contractual arrangements in which—for access to a PBM's health plan and employer clients' members and other services—they pay a fee. This allows pharmacies convenient and timely access to the business of hundreds of millions of consumers.
- This provision could prohibit the future use of performance-based contracting for pharmacies, which promotes affordable, quality care from all health care providers (doctors, hospitals and pharmacists). Performance based incentives are either added to or taken from the pharmacy reimbursement, not the patient's cost sharing. You cannot measure pharmacy quality performance until after they have performed something to measure. It is not unreasonable to expect pharmacists to participate in value-based purchasing arrangements common in the rest of the health care system.
- This legislation would allow for unwarranted interjection of the Department of Insurance into confidential financial relationships in private sector contracts.
- No state should pass a law that impacts transactions between two private sector entities to the financial benefit of one contracting party.

The Model Act places restrictions on retroactive denial or reduction in a claim after adjudication. *(Claims Adjudication – Section 6(c))*

- This restriction fails to contemplate clerical or recordkeeping errors, such as a typographical or computer error uncovered by a PBM during a post-adjudication audit. These errors should be subject to recoupment by the PBM on behalf of its clients, even if not considered to be fraudulent.

The Model Act allows a pharmacy to inform a patient about the costs of a pharmacist's services. *(Gag Clauses – Section 7)*

- As an industry, PCMA believes the patient should NEVER pay more in cost sharing than the pharmacy's submitted price (cash price).

SECTION 9 – RULES: NCOIL PROPOSED MODEL ACT GRANTS EXCESSIVE RULEMAKING AUTHORITY

The Model Act grants the Department broad and excessive rulemaking authority to essentially re-define the entire marketplace delivery of pharmacy benefits and regulate private commercial market contracts between health plans and insurers, pharmacies, and PBMs.

- Not only is this unprecedented, it is clear government overreach into private marketplace contracting to excess. Government agencies should not have the unfettered ability to re-define private marketplace contracts through rulemaking -- especially related to compensation and other financial terms of private contracts.
- Additionally, this legislation allows for overly punitive penalties and establishes new legal remedies that are not afforded to other entities – creating legal uncertainties that have the potential to increase costs for consumers.

SECTION 11 – ANNUAL REPORT: NCOIL PROPOSED MODEL ACT ADDS UNNECESSARY REGULATORY BURDENS

The Model Act requires pharmacy benefit managers (PBMs) and their health plans/insurer clients in a state to provide the Department of Insurance with proprietary pricing information from their private market contracts.

- The Commissioner of Insurance will collect volumes of proprietary data at the individual claim level; however there is no stated purpose for the data collection.
- This additional layer of regulatory reporting adds an unnecessary, costly and punitive burden for no benefit to the regulator or the consumer.

SECTION 12 – MAXIMUM ALLOWABLE COSTS LISTS: NCOIL PROPOSED MODEL ACT GUARANTEES PROFIT FOR SPECIAL INTEREST

The Model Act reduces the effectiveness of a PBMs' MAC lists (Maximum Allowable Costs), which encourage pharmacies to purchase generic drugs at the most competitive prices. In January of 2018 the Eighth Circuit heard the state of Arkansas' appeal of the Arkansas District Court's opinion striking down Arkansas Act 900 of 2015 as preempted by ERISA because the statute interfered with key matters of plan administration. The Maximum Allowable Costs provision of the NCOIL Model Act mirror the provisions of Act 900.

- The Model Act guarantees profit on every transaction at the expense of consumers and plan sponsors. No other businesses are granted such a privileged position in any supply chain.
- The State's employers, who use PBMs to manage their pharmacy benefits, will bear the resulting inflated drug costs.
- The Model Act places restrictions on retroactive denial or reduction in a claim after adjudication. *(Claims Adjudication –Section 6)*
- This restriction fails to contemplate clerical or recordkeeping errors, such as a typographical or computer error uncovered by a PBM during a post-adjudication audit. These errors should be subject to recoupment by the PBM on behalf of its clients, even if not considered to be fraudulent.

- The Model Act obligates a PBM to pay a pharmacy for a service even if they have terminated from the network. *(Pharmacy Termination –Section 6(d)*
- Requiring payments to a terminated pharmacy takes no account of the reasoning behind the termination, especially around patient safety due to fraud, waste, or abuse.

SECTION 12 – MAXIMUM ALLOWABLE COSTS LISTS: NCOIL PROPOSED MODEL ACT RAISES COSTS FOR EMPLOYERS WHILE PROVIDING PROTECTION FOR STATE RUN PROGRAMS

The Model Act differentiates among programs by placing the burden to pay pharmacies a guaranteed profit on PBM-administered benefits only, exempting a state run Medicaid program or state run state employee benefit program. *(Section 12(e))*

SECTION 12 – MAXIMUM ALLOWABLE COSTS LISTS: NCOIL PROPOSED MODEL ACT PUTS ACCESS TO NEEDED MEDICATIONS AT RISK

The Model Act would allow a network pharmacy to decline to dispense a medication to a patient if the reimbursement to the pharmacy is less than their acquisition cost. This will lead to patients going without important medications and endangering their safety. *(Maximum Allowable Costs List – Section 12(d))*

- It would also interfere with medication adherence and the treatment of serious illnesses. Not only does this provision put pharmacy profits ahead of patients, it fails to recognize that overall pharmacy profits on the dispensing of drugs are measured on the dispensing of all drugs, brand and generic, and not on a particular drug.

NCOIL PROPOSED MODEL ACT IGNORES CRITICAL UNREGULATED PLAYER IN THE DRUG SUPPLY CHAIN

The Model Act fails to recognize the critical role Pharmacy Services Administration Organizations (PSAOs) play in pharmacies' compensation and, ultimately, the profitability or lack of profitability for independent pharmacies.

- According to the U.S. Government Accountability Office (GAO) 80% of independent pharmacies are represented by a PSAO. These entities help negotiate and enter into contracts with PBMs on independent pharmacies' behalf; provide inventory and back office functions to improve operations; and negotiate the purchasing price for prescription drug inventories.
- PSAOs do not provide services or work for or "help" PBMs or third-party payers. They work for and "help" their independent pharmacy members.
- Nationally, according to an analysis of NCPDP (National Council for Prescription Drug Programs) data, the number of independent pharmacies actually grew by 2,231 stores from Q1 2010 to Q1 2015 (the most recent year in the analysis), an increase of almost 11%. Chain drugstores, on the other hand, grew by only 1,591 stores, an increase of only 4%.