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Insurance Plans

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June 5, 2018

Senator Jason Rapert
President
National Council of Insurance Legislators
P.O. Box 10388
Conway, AR 72034

RE: NCOIL Pharmacy Benefits Manager Licensure and Regulation Model Act

Dear President Rapert:

I am writing on behalf of America's Health Insurance Plans to respectfully oppose the National Council of Insurance Legislators' (NCOIL) Pharmacy Benefits Manager Licensure and Regulation Model Act ("Model"). We do not endorse this type of legislative approach to regulate private contractual agreements and we have serious concerns about the regulatory overreach that would accompany such a vague and boundless new structure. Most importantly, this proposed Model does nothing to address drug prices, and in fact, may increase drug costs for patients.

AHIP is the national association whose members provide coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers. Our members are committed to providing consumers with affordable products that offer a broad range of robust provider networks of quality, cost-efficient providers.

Health plans regularly use PBMs to assist in the administration of pharmacy benefits. As part of this, health plans privately contract with PBMs to provide access to network pharmacies, negotiate discounts with drug manufacturers and help manage the drug benefit. The Model seeks to insert a wedge between plans and their PBM partners, potentially impacting enrollees and increasing costs for consumers. For example, health plans provide insurance coverage for prescription drugs and are responsible for maintaining an adequate network to provide pharmacy services to enrollees. But this Model places those duties separately on a PBM, which has no contract with an enrollee nor is it providing the services without health plans oversight.

These inherent differences between PBMs and health plans, as well as the role of drug manufacturers as the primary driver of prescription drug costs, makes the proposed Model a misguided approach to addressing a critical issue. Rather than endorsing an unnecessary, costly

and difficult new regulatory scheme, we suggest that NCOIL review other, more measured responses such as those recently enacted in Tennessee[1] and Florida.[2] In these settings, lawmakers have taken a more suitable approach by endorsing reasonable oversight of PBMs.

The changes in the proposed Model will ultimately lead to a breakdown of the existing collaboration between health plans and PBMs, causing substantial harm to consumers. A few examples of this harm include:

- Consumers may be harmed financially at both the pharmacy counter and with an increase to their health plan premiums as costs to dispense medications increase (both for generic and brand drugs);
- Fraud and abuse may increase as health plans and PBMs are restrained from investigating suspicious behavior or correcting even technical mistakes or omissions;
- The value of PBM expertise will be diminished due to efforts in the proposed Model to restrain the ability of PBMs to develop and implement clinically-based services that reduce medication errors, achieve higher rates of medication adherence and improve health outcomes; and
- Duplicative requirements for network adequacy will confuse health plans, PBMs and regulators when trying to address access and availability issues.

In addition to the flaws inherent to the Model, we are deeply concerned about the dramatic departure from what we, as stakeholders, believe the mission of NCOIL to be. As a national organization, NCOIL members have the unique ability to guide the development of state laws through model language. However, there is no national one-size-fits-all approach. It is critical that NCOIL models be limited to providing the framework for state laws and provide flexibility to fit each unique state. Put simply, NCOIL models should construct the frame of the house and leave the details of furniture and curtains to the state. The proposed Model departs from that role.

AHIP and its member companies appreciate the opportunity to engage in a constructive dialogue about these concerns that we believe will hinder the adoption and implementation of the proposed Model at the state level. We offer the following comments and concerns for your consideration. We hope that these will be given consideration by NCOIL members as part of a truly deliberative process that gives meaningful consideration to the views of all stakeholders.

Proposed model legislation ignores cost drivers and increases costs for consumers.

Throughout the recent national debate over health care costs and the role of parties that administer prescription drug benefits, we have stressed the need to address prescription drug costs as a critical way of alleviating financial pressures on consumers and ensuring access to affordable health care coverage. Data shows that overall spending on prescription drugs now represents the largest segment of health spending and accounts for more than 23 percent of

[1] Tennessee General Assembly. SB 1852 (2018) – Pharmacy, Pharmacists. Enacted April 27, 2018. Available at http://wapp.capitol.tn.gov/apps/BillInfo/Default.aspx?BillNumber=SB1852&GA=110

[2] Florida Legislature. HB 351 (2018) – Prescription Drug Pricing Transparency. Enacted March 23, 2018. Available at http://www.flsenate.gov/Session/Bill/2018/00351/

commercial premiums.[3] Substantial price increases driven by constantly increasing list prices from pharmaceutical manufacturers pose a threat to state budgets and consumer pocketbooks.

We are disappointed that the proposed Model fails to take advantage of the opportunity to pursue meaningful changes to lower the cost of prescription drugs. Instead, the approach taken by the Model is primarily one of ensuring higher levels of reimbursement for certain pharmacies at the expense of consumers. Independent community pharmacists are an important part of the care continuum. However, it is not appropriate for government to protect any particular business model when Americans are facing higher and higher health care costs.

The approach being considered is based on a fundamental misunderstanding of drug discounts and the way they are negotiated. Rather than relying on draconian, heavy-handed tactics, PBMs contract with their health plan and employer group customers to ensure that drug discounts are administered in a manner that best suits the needs of each purchaser. Some health plans mandate a full pass-through of all discounts to the point of sale (i.e., the patient receives the discount at the pharmacy counter when they pick up their medicine). Other purchasers prefer to have rebates pooled and distributed evenly across all enrollees in that market so that families and employers benefit from lower premiums. In both cases, consumers receive lower cost health care because these discounts are passed on through either lower premiums or lower copays.

Health plans work directly with their PBM partners to manage drug benefits and costs in a way that benefits consumers. Health plans use PBMs to administer the pharmacy benefit because PBMs bring expertise and savings to health plan enrollees. As part of this relationship, health plans audit their contracted PBMs to ensure that they are receiving the appropriate discounts and rebates that are outlined in the contract. PBMs are paid either through administrative fees or a percentage of rebates for the savings that they obtain for the health plan, which is also audited.

When issues arise, we should work collaboratively to address concerns instead of the heavy-handed regulatory approach itemized in the proposed Model. Most importantly, the administration of pharmacy benefits is changing rapidly. New therapies, higher prices and innovative payment and delivery models are evolving in the market. The way that prescription drugs are delivered to patients and paid for will change over time. This model does not allow flexibility to accommodate those changes in the future.

The proposed Model creates an overly broad and unrestrained regulatory structure.

While the proposed Model is at times overly prescriptive and inflexible, it simultaneously establishes a regulatory structure with so few limits and guidance that it will almost certainly result in a massive expansion of regulatory oversight between parties in the health care market. We believe that this is a fundamentally flawed approach to crafting model laws. The complete lack of any limitations on regulatory interventions related to standards and payments for health care services is a harmful and inappropriate approach to crafting laws. Where adopted, the proposed Model gives state regulators virtually unrestricted authority over an entire industry and its reimbursement standards based on undefined and nearly unchallengeable standards.

[3] *Where Does Your Health Care Dollar Go?* America's Health Insurance Plans. May 2018. Available at https://www.ahip.org/wp-content/uploads/2017/03/HealthCareDollar_FINAL.pdf

This is particularly true of Section 9(a) of the Model, which grants a substantial amount of authority to implement new regulatory requirements without restriction. In addition to the identified list of rulemaking areas in subsection (a)(2), subsection (a)(1) also seeks to grant blanket rulemaking authority to regulate any aspect of the PBM industry without specific authority or legislative guidance. Implementation of this proposal by way of such ambiguous requirements and unrestrained authority will almost certainly result in a large number of operational and legal issues. For example, the proposed Model includes standards related to maximum allowable cost (MAC) provisions that have been recently found by a Federal court to be preempted by the Employee Retirement Income Security Act of 1974 (ERISA) and continue to be the subject of ongoing litigation in Arkansas. The vagueness of the Model will require state regulators to implement broad new policy reforms with insufficient guidance and lacking the restraints necessary to ensure effective rulemaking.

The proposed Model's scope and applicability are overly expansive and ambiguous.

At many points, the proposed Model fails to recognize that health plans and PBMs are distinctly separate entities by creating requirements that, while suitable for one, should not be applied to the other. For example, Section 3(L) defines a PBM so broadly that it is likely to include licensed health plans that conduct certain pharmacy benefits internally. Many plans provide either claims processing services or, "Other prescription drug or device services." Our belief is that the Model is intended to regulate stand-alone PBM entities, not internal practices of health plans to execute a basic function of administering benefits. Health plans should not be exposed to duplicative regulatory requirements and the Model should clearly state that health plans are not PBMs.

Additionally, the definitions of "pharmacy benefit manager" – namely the exclusion for fee-for-service Medicaid – and the definition of "health benefit plan" are unclear about the role of Medicaid managed care programs. Enforcing the requirements of the proposed NCOIL Model on Medicaid health plans will result in higher costs for the state and, ultimately, higher taxes. The lack of certainty about the application of these requirements in the Medicaid managed care setting could have a disruptive effect on that segment of the market.

This section should be clarified to exclude health benefit plans and Medicaid managed care plans.

(L)(1) "Pharmacy benefits manager" means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans.

(2) "Pharmacy benefits manager" does not include any:

(i) Healthcare facility licensed in [this State];

(ii) Healthcare professional licensed in [this State];

(iii) Consultant who only provides advice as to the selection or performance of a pharmacy benefits manager; ~~or~~

(iv) Entity that provides claims processing services or other prescription drug or device services for the ~~fee-for-service~~ [State]Medicaid Program only in that capacity~~.~~; <u>or</u>

(v) Health benefit plans as defined in Section 3(B).

We are also concerned that the definition of "independent pharmacy" is overly broad and can be interpreted differently by regulators in different states. For example, are independent pharmacies part of a retail pharmacy chain (which this definition seems to include) or simply a pharmacy that does not have any other affiliated business entities? The definition lacks any reasonable restriction on what is considered an "affiliation" with a PBM and will require substantial investigation and verification from regulators.

The proposed network adequacy provisions are anti-competitive and overly broad.

Many of the provisions in the proposed Model are solely focused on increasing payment rates for pharmacists. These provisions are anti-competitive and will be extraordinarily difficult to enforce. Overly broad provisions will burden state regulators with the task of trying to discern legislative intent for network adequacy with no guidance from the Model and will hinder the compliance of health plans and PBMs.

NCOIL and state legislatures should avoid taking a role in payment negotiations between private parties. However, this Model seeks to increase reimbursement for pharmacies by requiring state regulators to determine whether a rate is "fair and reasonable." The proposed Model sets favorable contractual terms and standards for specific parties, and the potential for anti-competitive behavior is great. The proposed Model inherently relies on network participation as the primary indicator of whether payment rates are sufficient. This is an inappropriate measure of network adequacy which is dependent on outside factors. The proposal creates a strong incentive for individual pharmacies and groups of pharmacies to refuse to contract in order to create an appearance of insufficient access and therefore a justification for higher payment rates. The end result is higher reimbursement for pharmacists and higher costs for consumers.

Furthermore, Section 5 of the Model sets network standards such as "reasonably adequate and accessible," "convenient patient access" and "reasonable distance." These terms are left undefined and are out of step with nationally recognized standards for network adequacy. Health plans and PBMs devote substantial time and resources to creating expansive pharmacy networks, which makes it critical that they are given sufficient ability to demonstrate compliance. As noted in the NAIC Network Adequacy Model Act #22, the standard for insurance regulators to review networks of providers has typically been set at "*accessible without unreasonable travel or delay.*" Vague terms such as "convenient access" were dismissed in broad stakeholder discussions. There are already national standards[4] which have been developed to meet this regulatory guidance.

The proposed network adequacy requirement is duplicative and unnecessary.

While we appreciate NCOIL's desire to aid consumers by providing greater access to prescription drugs, the proposed Model fails to take into account that both health plans and PBMs already rely on robust pharmacy networks. In addition, more than 45 states have already

[4] Standards include URAC PBM Standards, Tricare standards for pharmacy networks, as well as regulations passed in multiple states that further define pharmacy and other provider measurements and benchmarks.

enacted some form of network adequacy requirements that apply to health plans. This is the appropriate place to regulate a pharmacy network because health plans are responsible for providing coverage for pharmacy benefits under an insurance contract, not PBMs.

The proposed Model provides insufficient guidance about whether health plans will be required to maintain duplicative and supplementary networks for both the provider and pharmacy side. Section (5)(A)(1) of the Model appears to create additional network requirements that will require health plans to duplicate their existing networks. We do not believe that the Model should or is intended to create new administrative inefficiencies and burdens for health plans.

The proposed Model contains an anti-competitive disincentive for the use of mail-order.

The steps proposed in this bill to increase payment rates for pharmacists and deemphasize the role of mail-order pharmacies is an unwarranted intrusion into private negotiations. Mail-order benefits are a vital and convenient method for patients to acquire their medications. To dismiss mail-order benefits is misguided, particularly with the evolution of drug delivery as certain medications need special handling or instruction. Further, this shift in payment will result in higher costs for consumers, both in potential cost-sharing at the pharmacy counter and through higher premiums. PBMs invite, but do not require, pharmacies to participate in their network or affiliate structure. Pharmacies do so because it benefits them financially and increases the volume of patients that visit their place of business.

The proposed Model is further anti-competitive because it discounts the role of mail-order pharmacy in determining network adequacy. In doing so, the bill seeks to promote one class of provider over another and singles out the use of mail-order pharmacy, which provides consumers with both greater convenience and lower costs. Mail-order services should be a ready-option for consumers and should not be minimized or restricted in the manner outlined in this bill. While not always a replacement for the use of local pharmacy services, mail-order provides patients – particularly those that are sick or homebound – with a vital service that recognizes the complexity of health care needs for different patients.

Contractual interference in the Model threatens free market principles and goals.

Of the parties that will potentially be impacted by the Model, all rely on the ability to negotiate and enter into contractual agreements with other free market actors. As we have stated, we do not believe that the role of NCOIL should be to interfere with these contractual agreements in a manner that dramatically shifts the balance of power between market actors. The relationships between pharmacists, pharmacy service administrative organizations (PSAOs), PBMs and health plans provide benefits to all involved and should be respected by state legislators and NCOIL.

Section 6 of the proposed Model is particularly troubling for the many ways that it eliminates the ability of market participants to negotiate and agree on terms of a contract. For example, Section 6(B)(2) gives regulators authority over which contractual provisions should be held valid by providing the authority to review and approve contractual language. Pharmacists and PBMs often negotiate adjudication fees into contractual language as a means of incentivizing the use of new technologies and infrastructures that benefit both parties. The ability of private parties to negotiate these agreements should not be impeded.

We also believe that the prohibition against tailored accreditation and certification requirements is an unjustified interference with contracts to prohibit the ability of PBMs to develop appropriate standards that meet client needs and ensure patient safety and the quality of pharmacies in their network. This creates a clear conflict of interest as the only waiver of this prohibition requires approval of the state Board of Pharmacy, thereby creating a situation in which pharmacists are ensured of the ability to potentially set qualifications with very little input from the health plans that actually pay for the services. In other words, this would allow the Board of Pharmacy, run by pharmacists, to decide what level of service is sufficient with no oversight or "check and balance" to this authority by the Board over their own industry.

We are further concerned that this limit on the ability of PBMs to ensure safety and quality will have serious unintended and far-reaching consequences for patient health. The standards developed and relied on by PBMs are a way of ensuring a higher level of knowledge, implementation capabilities, quality review, and oversight of dispensing and safety standards. We are uncertain why the Model would seek to eliminate a practice with such clear benefits to patient safety. To disallow PBMs from contracting with pharmacies meeting these higher standards meant to protect consumers is short-sighted and potentially dangerous. Only a few years ago compounding pharmacies were responsible for mishandling certain medications which lead to severe illness and death.

Section 6(B)(4) of the Model creates additional unwarranted contractual interventions by prohibiting differences in payment amounts based on a pharmacy's affiliate status with a PBM. Again, we believe that prices and contractual terms should be set by private parties through negotiation. These determinations are not appropriate for model laws.

The proposed Model also interferes with the ability of PBMs and pharmacies to agree on standards for the retroactive denial or reduction of claims amounts. While we appreciate the interests of NCOIL in ensuring that pharmacists are treated fairly and are not inappropriately denied or reduced payment after providing services, PBMs and pharmacists should be permitted to agree on situations where this may be appropriate. For example, if a pharmacist submits a claim that includes a basic technical error impacting payment, the parties should be permitted to agree that such a mistake warrants a retroactive adjustment.

The proposed "gag clause" prohibition and reporting requirements are overly broad.

Lawmakers, the public and stakeholders have an interest in ensuring that consumers have access to critical information about their health care needs and choices. However, some contractual information is not appropriate for disclosure and lends itself to the possibility of anti-competitive behavior. Many elements of individual contracts with pharmacists are sensitive and their disclosure could lead to price fixing and agreements not to contract. The Model should not encourage this behavior, which is antithetical to a healthy and functioning market. Steps should be taken to ensure that the disclosure of information permitted by Section 7(D) is kept confidential. The goal of the Model in ensuring communication between patients and pharmacists would not be impacted by such a change.

Our concern about overly broad reporting requirements can also be found in Section 11(A)(1), where the regulator is given unlimited authority to mandate reporting requirements as frequently as they want. We appreciate NCOIL's desire for annual reporting of the data elements listed in the section, but the language in subsection (A)(1) creates an unreliable regulatory standard that permits frequent changes with insufficient guidance and timing for health plans and PBMs. Beyond the timing of the annual report, the elements specified in subsection (A)(2) will create a difficult administrative requirement that can result in large volumes of data being provided to regulators that will struggle to mine the data. If PBMs are expected to turn over a record of every single claim that they administer during the calendar year, the information will be of such granular detail that regulators will struggle to make use of it. Additionally, it is a departure from the way that many PBMs currently manage their data for reporting purposes where necessary.

Maximum allowable cost (MAC) provisions are overly prescriptive, unnecessary and potentially unlawful.

The proposed model should seek to provide a high-level structure that provides regulators with the ability to know and understand the role that PBMs play in the market. It should not seek to create inflexible legal requirements such as those contained in Section 12, which are not appropriate for all states. Similar requirements are currently the subject of legal challenges and we are concerned that NCOIL has chosen to rely on provisions of such suspect legality. The inclusion of these provisions is particularly difficult to understand given that a majority of states have already acted to address MAC pricing in some regard. In those states, laws and regulations are varied and tailored to the unique needs of individual states. The provisions of the proposed Model are made unnecessary by those state actions.

AHIP supports access to high-quality pharmacy services and contracts with independent pharmacies throughout the country, as well as mail-order services and larger pharmacy chains. The health care delivery system includes a pivotal role for all of these groups, and we encourage patients to find pharmacy services in a way that best benefits their specific circumstances. However, the provisions in this proposed Model will not further the goal of increasing access or lowering costs for patients. Instead, this Model focuses on increasing reimbursement to certain pharmacies, and inserting administratively burdensome government regulation at the expense of employers, families and consumers.

If you have any questions or would like to discuss the matter further, please contact me at lgassaway@ahip.org or by phone at (202) 861-6365.

Sincerely,

Leanne Gassaway
Senior Vice President, State Affairs