NCOIL PROPOSED MODEL ACT

A PRESCRIPTION FOR RISKING PATIENT SAFETY WHILE INCREASING COSTS

NCOIL PROPOSED MODEL ACT PUTS SAFETY & 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 its acquisition cost. This will lead to patients going without important medications and endangering their safety. *(Maximum Allowable Costs List –Section 12)*

- 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 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)*

- 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.

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. *(Licensure –Section 4)*

- Health Insurers design the pharmacy benefit and are appropriately regulated by a state's Department of Insurance.

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. *(Rules –Section 9)*

- Not only is this unprecedented, it is clear government overreach into private marketplace contracting. 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.

NCOIL PROPOSED MODEL ACT REMOVES FREE MARKET INCENTIVES

The Model Act reduces the effectiveness of a PBMs' MAC lists (Maximum Allowable Costs), which encourage drugstores to purchase generic drugs at the most competitive prices. *(Maximum Allowable Costs List –Section 12)*

- On June 8th 2018 the Eighth Circuit issued an 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 provisions 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 a0re granted such a privileged position in any supply chain.
- This windfall of profits for pharmacies will be at the expense of consumers and plan sponsors.

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. *(Maximum Allowable Costs List –Section 12)*

The Impact of the Recent 8th Circuit Opinion in PCMA v. Rutledge On the NCOIL PBM Model Act

ERISA provides a *"comprehensive system for the federal regulation of employee benefit plans"* [1] and **applies to all employer-based health plans, whether fully insured or self-insured.**[2]

Terms At A Glance
NCOIL – National Council of Insurance Legislators
PBM – Pharmacy Benefit Managers
ERISA – The Employee Retirement Income Security Act of1974, as amended
PCMA – Pharmaceutical Care Management Association (the national association for PBMs)
MAC – Maximum Allowable Cost - PBMs set and regularly update MAC lists at a level that reflects the average acquisition cost of a well-run pharmacy.

The central design of ERISA *"is to provide a single national scheme for the administration of ERISA plans without interference from the laws of several states."* [3]

No state can directly or indirectly interfere with the key matters of plan administration, such as dictating terms of the PBMs contract with its clients.

States simply cannot *"undermine the congressional goal of minimizing the administrative and financial burden on plan administrators – burdens ultimately borne by the beneficiaries."* [4]

The ERISA insurance–savings clause allows states to regulate the business of insurance and does not preempt state *"laws….which regulate [] insurance."* [5] But in order to be "saved" from preemption, a state law must (1) be *"specifically directed toward entities engaged in insurance"* and (2) *"substantially affect the risk pooling arrangement between the insurer and the insured."* [5] **State laws that seek to regulate plan structure and administration** through the regulation of a vender such as the provisions found throughout the proposed NCOIL Model Act **are strictly preempted** and therefore prohibited by ERISA.

In 2015, Arkansas passed Act 900, better known as the Arkansas MAC legislation. PCMA challenged the constitutionality of the law under ERISA, asserting that the law could not be enforced on any ERISA regulated plan including all employer-based health plans, whether fully insured or self-insured.

On June 8, 2018, the Eighth Circuit Court of Appeals, in the case PCMA v. Rutledge, ruled in favor of PCMA in a unanimous 3-judge decision.[6] **The 8th Circuit opinion *"found that Act 900 was preempted by ERISA."*[6]** This ruling means that Act 900 cannot apply to any employer-based health plans, whether a fully insured plan sold in the commercial market or a self-insured plan.

The **MAC provisions in Section 12** of the proposed NCOIL PBM Licensure and Regulation Model **Act mirrors Arkansas Act 900. The proposed NCOIL Model Act and the unconstitutional provisions of Act 900 mandate the following**:

- PBMs reimburse pharmacies at the invoice price for generic drugs, regardless of rebates or discounts received by the pharmacy, or whether other less costly sources of the drugs was available.
- PBMs to update their MAC lists every seven days with specific increases in the pharmacy acquisition costs from wholesalers – data impossible for PBMs to obtain.
- Pharmacies right to refuse to dispense if the acquisition cost of the drug were more than the reimbursement.

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[1] *District of Columbia v. Greater Was. Bd. Of Trade*, 606 U.S. 125, 127 (1992)
[2] *Mitchell Williams Letter to PCMA* dated February 21, 2018
[3] *Gobeille v. Liberty Mutual ins. Co*, 136 S. Ct. 936, 947 (2016)
[4] *Gobeille*, 136 S. Ct. at 944
[5] *Ky. Ass'n of Health Plans v. Miller*, 538 U.S. 329,342 (2003)
[6] *PCMA v. Rutledge*, (June 8, 2018)