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MEMORANDUM

To: Special Committee on Federal 340B Drug Program

From: Office of Revisor of Statutes

Date: Thursday, December 9, 2021

Re: Selected legislative and legal topics relating to pharmacy benefits managers

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This memorandum addresses three topics relating to pharmacy benefits managers:

I. 2021 House Bill No. 2260.
II. 2021 House Bill No. 2383.
III. *Rutledge v. Pharmaceutical Care Management Association*.

I. 2021 House Bill No. 2260

HB 2260 was introduced during the 2021 regular legislative session on February 8, 2021, by the Committee on Health and Human Services. The bill was referred to the same committee and remains alive for consideration by the 2022 legislature. The committee did not hold a hearing on the bill.

The bill would prohibit a pharmacy benefits manager (PBM) from disparately treating any pharmacy or pharmaceutical services provider based on the pharmacy or provider's designation as a 340B covered entity. PBMs would be prohibited from imposing or requiring different terms for 340B covered entities than those imposed or required for other pharmacies or providers. Prohibited disparate terms would include, but not be limited to:

1) The exclusion of 340B-eligible or 340B covered entities from provider networks.
2) Reimbursing 340B-eligible or 340B covered entity for a lesser amount than a PBM affiliate for the same services.
3) Assessing any fee, chargeback, participation requirement or other adjustment based on designation as a 340B covered entity.

HB 2260 would prohibit a PBM from discriminating against a 340B covered entity in any way that interferes with a person's choice to receive a covered drug from the 340B covered entity. A PBM would be limited in the amount that it could collect as a cost-share amount from a pharmacy, pharmacist, or covered person.

Oversight, administration, and enforcement of the bill would be placed under the commissioner of insurance, who would have the authority to adopt rules and regulations to do so.

II. 2021 House Bill No. 2383

HB 2383 was introduced during the 2021 regular legislative session on February 12, 2021, by the Committee on Insurance and Pensions. The bill was referred to the same committee and remains alive for consideration by the 2022 legislature. The committee did not hold a hearing on the bill.

The bill would restructure the legal environment governing PBMs in Kansas. Current law requires PBMs to register with the commissioner of insurance to do business in the state. The bill would replace that requirement by instead requiring PBMs to apply for and receive licensure. A PBM license could be revoked, suspended, or limited, a licensee could be censured or placed under probationary conditions, or an application for licensure or renewal could be denied for a variety of conduct relating to fraud, misrepresentation, violation of state or federal law or rules and regulations, consumer complaints, and failure to provide required information to the commissioner of insurance.

HB 2383 includes anti-retaliation provisions that protect any pharmacy or pharmacist who provides information requested by the commissioner in relation to any complaint or concern. The commissioner of insurance to establish fines and other penalties as enforcement.

Each PBM must submit to the commissioner of insurance an annual transparency report containing data from the prior calendar year relating to covered entities and plan sponsors doing business in Kansas.

Pharmacies and pharmacists under contract with a PBM would be able to decline to provide covered drugs, devices, or services if the pharmacy or pharmacist is reimbursed less than the acquisition cost of the drug, device, or service. The pharmacy or pharmacist may provide the customer with adequate information were the drug, device, or service may be filled and communicate with the prescriber at the request of the patient to identify alternative treatment options. A PBM would be prohibited from retaliating against a pharmacy or pharmacist for taking any of these actions.

The bill would impose payment and reimbursement requirements and advertisement restrictions on PBMs. First, a PBM shall not reduce a payment to a pharmacy under a reconciliation process to an effective rate of reimbursement. Second, a PBM shall not adjust a claim for services retroactively denied or reduced, except under specified circumstances. Third, a PBM shall not advertise, promote, solicit, represent, propose, or offer to the general public regarding access to pharmacies in a pharmacy network. Finally, the bill would establish requirements for maximum allowable cost lists established and maintained by PBMs.

Provisions of current law relating to PBMs would be amended to conform with the described changes and additions.

III. *Rutledge v. Pharmaceutical Care Management Association*

Rutledge v. Pharmaceutical Care Management Association[1] is a decision by the U.S. Supreme Court relating to state regulation of PBMs. The case was decided on December 10, 2020. Justice Sotomayor delivered the opinion of the Court. She was joined by all other justices except for Justice Barrett, who took no part in the consideration of the case. Justice Thomas wrote a concurring opinion. The Court

[1] 141 S. Ct. 474 (2020).

concluded that the Employee Retirement Income Security Act of 1974 (ERISA) does not preempt a state law regulating PBM reimbursement rates and related procedures, allowing the law to stand.

In *Rutledge,* the Court considered an Arkansas law[2] that regulates the price at which PBMs reimburse pharmacies for the cost of drugs covered by prescription drug plans. The law effectively requires PBMs to reimburse pharmacies at a price not less than acquisition costs in three ways: First, PBMs must update their maximum allowable cost lists when wholesale drug prices increase. Second, PBMs must provide administrative appeal procedures for pharmacies to challenge reimbursement rates. Third, the law allows pharmacies to decline to sell a drug if the PBM will reimburse the pharmacy less than acquisition cost. The law also prohibits a PBM from reimbursing a pharmacy or pharmacist in an amount less than the PBM reimburses a PBM affiliate for providing the same pharmacist services.

Pharmaceutical Care Management Association is a national organization representing PBMs in the United States. The organization filed suit alleging that the Arkansas law is preempted by ERISA. ERISA expressly preempts any state law that "relate to any employee benefit plan."[3] U.S. Supreme Court precedent elaborates that "a state law relates to an ERISA plan if it has a connection with or reference to such a plan."

In *Rutledge,* the Court concluded that the Arkansas law has no connection with or reference to an ERISA plan. According to the Court, ERISA is "primarily concerned with preempting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits." In other ERISA preemption cases, the primary determination has been whether a state law "governs a central matter of plan administration or interferes with nationally uniform plan administration." State regulation that merely increases costs or alters incentives for ERISA plans are permissible.

The Court resolved the arguments presented by the PBMs as follows:

1. The Arkansas law merely sets minimum prices and "does not require plans to provide any particular benefit to any particular beneficiary in any particular way."
2. ERISA does not preempt the required administrative appeal process as a mechanism of enforcement.
3. Allowing a pharmacy to decline to dispense a prescription does not interfere with plan administration by denying benefits; instead, the PBM is responsible because the PBM offered below-acquisition reimbursement.
4. Increased costs associated with state-specific enforcement mechanisms do not implicate ERISA, even if an ERISA plan chooses to limit benefits in response to increased costs.

[2] Ark. Stat. Ann. § 17-92-507.
[3] 29 U.S.C. § 1144(a).