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PBM LEGISLATION IN THE STATES

This memorandum outlines the provisions of 2015 SB 103 (Kansas) and provides comparative information on consideration of similar legislation in other states.

Summary—SB 103

SB 103, as introduced, would enact new law and amend the Pharmacy Benefits Manager Registration Act relating to contracts between pharmacies and pharmacy benefits managers (PBMs) and the regulatory authority granted to the Insurance Commissioner.

Definitions (New Section 1; Section 4)

The bill would establish new definitions relating to reimbursements for certain drugs and documentation of pricing associated with those drugs. Among the definitions created would be these:

- "Covered individual" means an individual receiving prescription medication coverage or reimbursement provided by a health insurance policy, government program, or PBM;
- "List" means the list of drugs for which maximum allowable costs have been established;
- "Maximum allowable cost" [MAC] means the maximum amount thata PBM will reimburse a pharmacy for the cost of a drug; and
- "Pharmacy benefits manager" [PBM] means an entity that contracts with third-party pharmacies on behalf of a health plan, as defined in 45 CFR §160.103, as in effect on July 1, 2015, for the third-party pharmacy to provide pharmacy services to such health plans. Such an entity determines reimbursement to pharmacies for the pharmacy services provided.

The definition for a PBM in the Pharmacy Benefits Manager Registration Act (Act) would be deleted and replaced with the above definition. The current definition for a PBM follows:

A person, business or other entity that performs pharmacy benefits management. Pharmacy benefits manager includes any person or entity acting in a contractual or employment relationship for a pharmacy benefits manager in the performance of pharmacy benefits management for a covered entity.

Under existing law, the definition of PBM specifies a number of services associated with the administration of certain pharmacy benefits, including mail service pharmacy; claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals; clinical formulary development and management services; rebate contracting and administration; certain patient compliance, therapeutic intervention, and generic substitution programs; disease management programs involving prescription drug intervention; and the procurement of prescription drugs at a negotiated rate for dispensation to covered individuals and the administration or management of a prescription drug benefits provided by a covered insurance entity for the benefit of covered individuals. [KSA 2014 Supp. 40-3822(d)]

Drug Pricing, Lists and MAC, Appeals Process (New Section 2)

The bill outlines new requirements for PBMs, including:

- Ensuring that all drugs on a list are generally available for purchase by pharmacies in the state from national or regional wholesalers;
- Ensuring that all drugs on the list are not obsolete;
- Making available to each network pharmacy at the beginning of the contract term, and upon contract renewal, the nationally recognized comprehensive data sources utilized to determine the MAC of the PBM:
- Making a list available to a network pharmacy, upon request, in a format that is readily accessible and usable by the pharmacy;
- Updating each list it maintains every seven business days and making the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format; and
- Ensuring that dispensing fees are not included in the MAC.

Additionally, a PBM would be prohibited from placing a drug on a list unless there are at least three therapeutically equivalent, multiple-source drugs, or at least one generic drug available for purchase by network pharmacies from national or regional wholesalers.

Appeals Process

The bill also would require a PBM to establish an appeals process which would permit a network pharmacy to appeal its reimbursement for a drug subject to MAC. The pharmacy would be permitted to appeal a MAC if the reimbursement is less than the net amount that the pharmacy paid to the supplier of the drug. The bill would require an appeal be completed within 30 calendar days of the pharmacy making the claim for which the appeal has been requested. A

PBM would be required to provide, as part of the appeals process, a telephone number at which a network pharmacy may contact the PBM and speak with an individual who is responsible for processing appeals; a final response to an appeal of a MAC within seven business days; and, if the appeal is denied, the reason for the denial and the National Drug Code (NDC) of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the MAC.

If an appeal is upheld, the PBM would be required to make an adjustment on the date that the PBM makes such determination. The PBM would be required to make the adjustment effective for all similarly situated pharmacies in Kansas that are within its network.

Failure to Comply (New Section 3)

In the event a PBM fails to comply with one of the requirements outlined above, the bill would provide that the Insurance Commissioner is permitted to suspend or revoke the PBM's certificate of registration required under the Act to transact business in Kansas or the Commissioner could refuse to renew the PBM's certificate of authority. In addition to the permissible actions on the registration of a PBM, the bill further would provide that a PBM violating any provision stated in the bill must incur, in addition to any other penalty provided by law, a civil penalty of up to \$5,000 for every such violation. In the case of a continuing violation, the bill would provide that every day the violation continues must be considered as a separate violation. Finally, the Commissioner, upon finding that a PBM has violated provisions of the bill, would be permitted to impose a penalty within the limits provided for in this section; the penalty must constitute an actual and substantial economic deterrent to the violation for which it is assessed.

Pharmacy Benefits Manager Registration Act (L. 2006, Ch. 154)

The 2006 Legislature enacted registration requirements for PBMs that provide "claims processing services, other prescription drug or device services, or both, to covered persons who are residents of this state." The law requires PBMs to register or renew on an annual basis (registrations expire March 31), submit a renewal form to the Commissioner, and pay a renewal fee of \$140. The Commissioner may revoke or suspend a registrant until the renewal and penalty fee (also specified in the amount of \$140) is paid. The law grants the Commissioner authority to adopt rules and regulations, including requirements relating to the application form, to carry out the act. Any person who as acts as a PBM without being registered is subject to a fine of \$500 for each violation. Moneys received by the Commissioner pursuant to the Act are to be remitted to the State Treasury at least monthly and credited to the Pharmacy Benefits Manager Registration Fund. Finally, the Act contains a severability clause. The Pharmacy Benefits Manager Registration Act has not been amended since its enactment.

States' Consideration of PBM Legislation

Utilizing a legislative database, as well as review of articles and interest group website content, analysis was conducted to determine whether other states have bills similar to 2015 SB 103 pending or have enacted such legislation. The National Conference of State Legislatures maintains a new database for "2015 State Legislation on Prescription Drugs." The following legislation was located using the keyword search term "maximum allowable cost." (Enacted legislation is **noted with boldface type**.)

State	Bill Number	Status	Type/ Summary
Arkansas	S 688	Enacted; Act No. 900	Creates accountability in prescription drug pricing; relates to MAC list used by PBMs, including the wholesaler who sells and distributes prescription pharmaceutical products, including brand-name, generic, and over-the-counter (OTC) pharmaceuticals and that offers regular and private delivery to a pharmacy, provides for affiliates; relates to claims rebilling, Medicaid and employer benefits.
California	A 627	Enacted; Act No. 74	Requires a PBM reimbursing a contracting pharmacy for a drug on a MAC basis to include contract information identifying any NDC pricing compendia or other sources used to determine the MAC for the drugs on the list and to provide for an appeal process. Requires the PBM to provide the most up-to-date cost list or lists used by the PBM in a web-based format. Exempts workers compensation.
Connecticut	S 1052	Adjourned; bill last referred to Appropriations.	Would require certain disclosures from PBMs and establish certain requirements concerning MAC lists.
Florida	H 555/ S 860	Failed; died in committee (see companion bill, S 1049)	Contract requirements for PBMs and pharmacies.
	S 1180	Laid on table; see companion bill, S 1049	Pharmacy Act amendments (veterinarians and compounding); MAC pricing and lists.
	S 1049	Enacted (Chapter No. 2015-127)	Specifies the Pharmacy Act and adopted rules do not prohibit a veterinarian from administering a compounded drug to a patient or dispensing a compounded drug to the patient's owner or caretaker; requires each contract or contract renewal between a PBM and a pharmacy require the PBM to periodically update the MAC pricing information and to maintain a procedure to eliminate certain drugs from the list of those subject to MAC pricing or modify MAC prices to remain consistent with changes in certain pricing data.
Georgia	H 470	Enacted (Act No. 61) [Senate passed substitute bill. H Agree]	Relates to pharmacies and the Pharmacy Audit Bill of Rights; relates to regulation and licensure of PBMs (defines certain terms, imposes certain requirements for the use of MAC pricing by PBMs, provides for enforcement of such requirements); repeals conflicting laws.
Hawaii	H 252	Enacted (Act No. 125)	Requires PBMs to include pharmacy information relating to MAC drug costs, specifies requirements and provisions for listed drugs, specifies additional instructions and requirements to be followed by PBMs, provides for accessible web-based format, provides that PBMs have an appeals process,

State	Bill Number	Status	Type/ Summary
Hawaii (cont.)	H 252 (cont.)		relates to obsolete drugs, prohibits disclosure to third party.
Kansas	SB 103	In Senate Committee; Interim Study	
Kentucky	S 126	Referred to S Committee	Would amend law to require review of MAC pricing at least every 7 instead of 14 days; require that only certain drugs be subject to MAC; create new law to establish licensure requirements for PBMs.
Maine	H 788	In Committee; Carryover	Would establish requirements for MAC pricing lists and requires PBMs to make disclosure regarding pricing methodology to plan sponsors; would establish an appeals process and provide for financial penalties for violations.
Missouri	S 325	Senate Committee: Be Passed.	Would delineate procedures to be used by PBMs with regard to MAC lists.
	H 780	House action postponed (had been passed with amendments).	Would delineate procedures to be used by PBMs with regard to MAC lists.
Montana	S 211	Enacted (Act No. 431)	Establishes procedures for MAC lists for prescription drugs, requires disclosure of pricing sources, provides an appeals process, relates to PBMs.
Oregon	H 3178	In House Committee	Would modify requirements for PBMs with respect to MAC lists.
Pennsylvania	H 947	Laid on the Table	Would provide for registration of PBMs and for MAC transparency.
Rhode Island	S 92	House Committee Substitute placed on H Calendar	Would regulate providers of pharmacy services as to acceptance or denial of benefits, substitution of drugs, cost limitations, maximum allowable cost rates, grievance procedures, and liability sharing requirements.
	H 5602	H passed Sub bill (amended on H Floor)	Would require that PBMs include in each contract the methodology utilized to determine generic drug pricing and update such pricing reduction every ten calendar days.
South Carolina	S 849	Referred to Senate Committee	Would provide procedures governing MAC reimbursements for generic prescription drugs by PBMs, provide necessary definitions, exempt Department of Health and Human Services in the performance of its duties (Medicaid), provide requirements for placing drugs on MAC lists by PBMs, and provide various requirements of PBMs.
Texas	S 332	Enacted (Act No. 596); Effective 01/01/2016	Relates to use of MAC lists; prohibits a health plan issuer or PBM from including a drug on a MAC list unless the drug meets certain specifications, and requires certain disclosures.
Vermont	H 97	In House Committee – Carryover	Would relates to the MAC for prescription drug reimbursement.

State	Bill Number	Status	Type/ Summary
Vermont (cont.)	S 139	Enacted (Act No. 54)	Creates or amends several provisions relating to health and health care reform; includes PBM provisions relating to MAC lists and reimbursement rates and an appeals process.
Virginia	H 2031	Enacted (Act No. 518)	Relates to health insurance, updating MAC pricing lists, pharmacy benefits contract or provider contract on and after a specified date that provides for the use of MAC as the basis for the amount of reimbursement or payment of claims to a pharmacist or another person, and to an appeals process for resolution of pricing disputes.

Additional state information published by *CQ Rollcall* indicates that, since 2013, 17 states have enacted legislation implementing transparency within MAC lists (including some states listed above): Arkansas, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Michigan, Missouri, New Jersey, New Mexico, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, and Tennessee).

For more information on states' PBM legislation similar to Kansas 2015 SB 103, please contact Melissa Calderwood-Renick, Iraida Orr, or Whitney Howard.