WYOMING LEGISLATIVE SERVICE OFFICE

Issue Brief

PHARMACY BENEFIT MANAGERS: GENERAL INFORMATION, FEDERAL AND STATE REGULATION, AND COMPARISON OF WYOMING AND ARKANSAS PBM STATUTES

May 2021

by
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PURPOSE

Over 20 Wyoming independent pharmacists requested the Joint Labor, Health and Social Services Committee study pharmacy benefit manager (PBM) regulation, specifically the creation of legislation that mimics Arkansas Act 900, passed in 2015 to amend the Arkansas PBM Maximum Allowable Cost (MAC) statute (A.C.A. 17-92-507). This issue brief provides a general overview of the role of PBMs in the prescription drug marketplace, and federal and state regulation of PBM practices. The brief also provides a comparative summary of Wyoming and Arkansas statutes regulating PBM licensure and practices, and presents model PBM legislation developed by the National Council of Insurance Legislators and the National Association of Insurance Commissioners.

PHARMACY BENEFIT MANAGERS: PRESCRIPTION DRUG MARKET INTERMEDIARIES[1]

Pharmacy Benefit Managers (PBMs) are companies that manage prescription drug benefits on behalf of health insurers with the goal of reducing or containing prescription drug costs. PBMs act as intermediaries between the health insurer, drug manufacturers and pharmacies, negotiating

[1] **NCSL,** ***State Policy Options and PBMs,*** **March 17, 2021**; **Prime Therapeutics,** ***Can you follow the money?,*** **March 17, 2017; U.S. Supreme Court,** ***Rutledge v Pharmaceutical Care Management Association,*** **December 10, 2020**; **Wyoming Department of Health,** ***Prescription Drugs in Wyoming: Evaluating State policy options for lowering costs,*** **October 1, 2020**; and Wyoming Department of Insurance, *Wyoming Insurance Topics* report to the Joint Corporations, Elections, and Political Subdivisions Committee, June 3, 2015.

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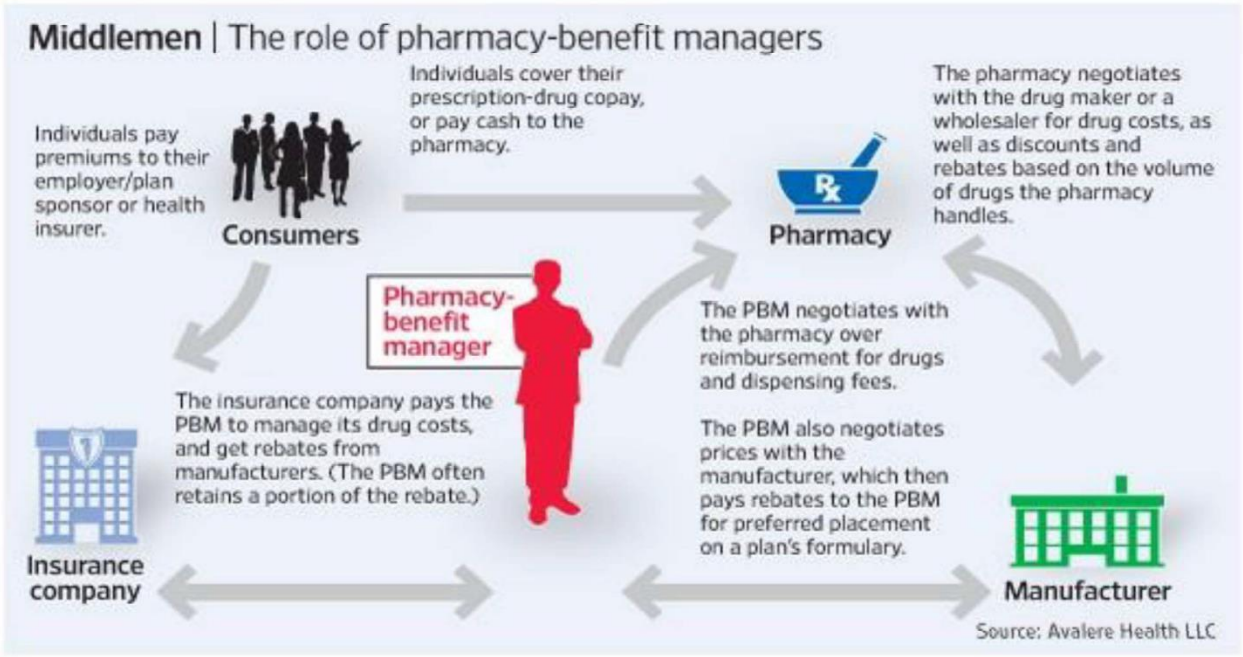
discounts, rebates, and reimbursements. PBMs reimburse pharmacies for the cost of drugs covered by insurer prescription drug plans. The health insurer, in turn, reimburses the PBM.

The amount that PBMs reimburse pharmacies is not necessarily based on the pharmacy acquisition cost, i.e. how much the pharmacy paid to purchase the drug from a wholesaler. Instead, PBMs reimburse contracted pharmacies according to PBM lists specifying the maximum allowable cost (MAC) for each drug. PBMs typically negotiate reimbursements and develop unique MAC lists for each pharmacy network they administer.

Contracts between PBMs and health insurers utilize either a "spread pricing" or "pass-through pricing" model. Under spread pricing, the reimbursement a PBM receives from a health insurer exceeds the PBM's reimbursement to a pharmacy; the difference is the PBM's profit. PBMs may also negotiate brand-name prescription drug rebates from manufacturers, but pass on only part of the rebate to the health insurer. Under a pass-through contract model, PBMs pass through the same discounts and dispensing fees charged by the pharmacy to the health insurer. Since no "spread" is collected, PBMs typically earn income under pass-through contracts by charging administrative fees.

See **Figure 1** for a diagram showing the role of PBMs in the pharmaceutical payment system.

Figure 1. The Role of PBMs



Source: Wyoming Department of Insurance, Wyoming Insurance Topics report to the Joint Corporations, Elections, and Political Subdivisions Committee, June 3, 2015.

REGULATION OF PBMS

PBMs are largely regulated by states rather than the federal government. While no federal law or agency provides specific oversight of PBMs, the Affordable Care Act (ACA) includes transparency requirements for PBMs that manage prescription drug coverage for Medicare Part D prescription drug plans or healthcare exchange plans.[2] PBMs that administer these plans are required to submit information for each contract year to the U.S. Department of Health and Human Services regarding prescriptions provided through retail versus mail order pharmacies; percentage of generic drugs dispensed; the aggregate amount and type of rebates, discounts or price concessions negotiated; the aggregate amount passed through to the plan sponsor; and the aggregate amount of the difference between the reimbursements received by the PBM from the plan sponsor and paid to retail and mail order pharmacies by the PBM.

All 50 states and the District of Columbia have enacted legislation regulating PBMs.[3] State statutes address a variety of issues with PBMs, which can be categorized into twelve areas of regulation:

- Cost-disclosure/gag-clause
- Fiduciary responsibilities
- Maximum allowable cost (MAC) or reimbursement lists
- Network adequacy
- Patient steering
- Pharmacy auditing standards/appeals process
- Pharmacy reimbursement/clawbacks
- Registration/licensure
- Regulatory agency/enforcement
- Reporting/transparency requirements
- Spread pricing
- Utilization management tools

A few states, such as Louisiana and Maryland, regulate PBM practices in all twelve regulation areas. Other states, such as Nebraska, Maryland, and Massachusetts, regulate PBMs in only one or two areas. Most states fall somewhere in between. Wyoming's Pharmacy Benefit Managers Act, enacted in 2016 and amended in 2019, addresses four of the twelve regulatory areas listed above.[4]

See **Appendix A** for a description of the twelve categories of PBM legislation.

[2] 42 U.S. Code 1320b-23 Pharmacy benefit managers transparency requirements
[3] **NCSL, State Policy Options and PBMs, March 17, 2021**
[4] See W.S. 26-52-101 through 26-52-104.

WYOMING AND ARKANSAS PBM STATUTES

Both the Wyoming and Arkansas PBM statutes regulate PBM practices in the four areas of cost disclosure/gag clauses, MAC lists, pharmacy auditing standards/appeals process, and PBM registration/licensure. The Arkansas statutes addressing these four regulation areas, however, are more comprehensive and stringent than the equivalent Wyoming statutes. In addition, the Arkansas PBM statutes go beyond the Wyoming statutes by addressing five additional areas of regulation: network adequacy, pharmacy reimbursement/clawbacks, regulatory agency/ enforcement, spread pricing, and utilization management tools. Unlike Wyoming, the Arkansas statutes explicitly provide the state insurance commissioner with broad regulatory authority over PBM practices and make a violation of the MAC statute a violation of the PBM licensure act, state consumer protection deceptive practices act, and insurance trade protection act. While the Wyoming Insurance Code provides the Wyoming Insurance Commissioner with broad general authority to enforce all provisions of the Code, including the Pharmacy Benefit Managers Act, the statutory enforcement tools provided to the Commissioner are aimed more towards typical insurance investigations. See **Appendix B** for a comparison of current Wyoming and Arkansas statutes.

Wyoming Pharmacy Benefit Managers Act[5]

The 2016 Legislature passed HB 35, sponsored by the Joint Corporations, Elections and Political Subdivisions Committee, enacting Wyoming's first statutes regulating PBMs. House Bill 35 was the product of a 2015 interim working group organized by the Department of Insurance at the request of the Committee. The working group included representatives of PBMs, pharmacies, the Wyoming Pharmacy Association, health insurers, and a Committee member.[6]

The original Act addressed three areas of PBM regulation: PBM licensure by the Department of Insurance, maximum allowable costs, and PBM pharmacy auditing. In 2019, the Legislature passed HB0063 amending the Act to add a fourth area of regulation regarding cost disclosures/gag clauses. A summary of how the Act addresses these four regulatory areas is provided below.

PBM Licensure by the Department of Insurance[7]

The Wyoming Act requires PBMs operating in the State to be licensed by the Department of Insurance and the Department to establish rules for PBM licensure requirements and procedures. The Act specifies that PBM license requirements, "shall only provide for the adequate identification of licensees and the payment of the required licensing fees." To date, the Department has not promulgated rules to establish license requirements.

[5] W.S. 26-52-101 through 26-52-104.
[6] **Appendix 11, Joint Corporations, Elections & Political Subdivisions Committee Minutes, September 8-9, 2015**.
[7] W.S. 26-52-101 and information provided by the Wyoming Department of Insurance, May 2021.

The Department requires PBMs to complete and submit a National Association of Insurance Commissioners (NAIC) Uniform Application for Business Entity License/Registration and a $500 license fee. The license term is one year and must be renewed annually by submission of an NAIC business entity renewal application and a $500 renewal fee. Thirty-four PBMs are currently licensed in Wyoming. See **Appendix C** for a list of current licensees.

The Pharmacy Benefit Manager Act itself only tasks the Department with licensure of PBMs and does not provide specific enforcement mechanisms. The Commissioner of the Department of Insurance, however, has broad enforcement powers and duties over the entire Insurance Code, of which the Pharmacy Benefit Manager Act is a part. With regard to PBM compliance with federal regulations, the Centers for Medicare and Medicaid Services (CMS) directly enforces the provisions of the ACA in coordination with the Department. The Department reports to have heard relatively little about PBMs since passage of W.S. 26-52-101 in 2016. The Department has not received any complaints regarding PBMs in the past five years.

Maximum Allowable Costs (MAC)[8]

The Wyoming Act requires that before placing a drug on a MAC list, a PBM must ensure the drug meets certain national rating requirements and is available for purchase by retail pharmacies in the State from national or regional wholesalers. In setting the MAC reimbursement price for a drug, the Act requires a PBM or insurer to consider "only the price" of that drug and any therapeutically equivalent generic. The PBM must make available to each network provider pharmacy[9] the "sources" utilized to determine the MAC and provide a process for network providers to readily access the MAC list. The PBM is also required to update MAC price information at least once every seven business days to reflect any modification of MAC pricing.

The Act also requires PBMs to establish a process by which a contracted pharmacy can appeal the provider's MAC reimbursement for a drug. A contracted pharmacy has up to ten business days after dispensing the drug to submit an appeal to the PBM and the PBM must respond to the appeal within ten business days. If the PBM upholds the appeal, the PBM is required to make an adjustment to the drug's MAC within one day after the date of the determination and apply the adjustment to all similar situated network pharmacy providers. If the PBM denies the appeal, the PBM must provide to the appealing pharmacy the reason for the denial and the National Drug Code (NDC) number that indicates where the drug is available for purchase in the State from national or regional wholesalers at a price at or below the MAC.

Cost-Disclosure/Gag-Clause[10]

The 2019 Wyoming Legislature amended the Wyoming Act to add statutory language prohibiting PBMs from preventing or penalizing a pharmacy or pharmacist for the disclosure of prescription

[8] W.S. 26-52-104.
[9] W.S. 26-52-102 defines network providers as those pharmacies that provide covered health care services or supplies to an insured or a member pursuant to a contract with a network plan to act as a participating provider.
[10] W.S. 26-52-104(j).

drug cost information to customers or for offering customers a more affordable prescription drug alternative.

Pharmacy Auditing Standards and Appeals Process[11]

The Wyoming Act establishes procedures that PBMs must follow when conducting audits of contracted pharmacies. The Act also regulates what PBMs may consider in audit findings of overpayment to the pharmacy. For example, PBMs may not consider clerical errors, projections or extrapolations, or, with limited exceptions, dispensing fees. PBMs are required to establish a process whereby pharmacies may appeal the audit findings. The Act specifies that recoupment of any overpayments to the pharmacy shall occur after final internal disposition of the audit including the appeals process.

Arkansas PBM Statutes

Arkansas was one of the first states to regulate PBMs through the enactment of several statutes: a maximum allowable cost (MAC) statute, the PBM Licensure Act, and the Pharmacy Audit Bill of Rights. A summary of the three acts follows.

Arkansas Pharmacy Bill of Rights[12]

The Arkansas Legislature enacted the Pharmacy Audit Bill of Rights in 2007. The statute establishes standards for pharmacy audits by managed-care companies, insurance companies, and third-party payors. The audit standards are similar in scope to those addressed by the Wyoming PBM Act, but differ in a number of details, such as the number of days of advance notice required for on-site audits, the use of projections as a basis for overpayment findings, and time allowed for delivery of the final audit report.

Arkansas Maximum Allowable Cost (MAC) statute[13]

The Arkansas statute regulating how PBMs establish and use maximum allowable cost (MAC) lists were enacted in 2013 and amended in 2015 (Act 900)[14], 2018, and 2019. The Arkansas statute provides greater regulatory oversight of PBM MAC lists than Wyoming's statute. Notable differences include:

- To improve transparency, PBMs must include an extensive list of specific costs and prices, including national average drug acquisition cost, average manufacturer price, and average wholesale price, in MAC lists.
- PBMs are required to adjust the MAC equal to or above the pharmacy acquisition cost if a pharmacy appeal is upheld, or if a pharmacy appeal is denied but the pharmacy is

[11] W.S. 26-52-103.
[12] A.C.A. 17-92-1201.
[13] A.C.A. 17-92-507.
[14] The 2015 Act 900 amendments effectively require PBMs to reimburse pharmacies at a price equal to or greater than the pharmacy acquisition cost and allow pharmacies to decline to provide a prescription drug to a patient if the MAC list reimbursement is less than the pharmacy acquisition cost.

unable to obtain the drug from the pharmacy's regular wholesaler at a price below the pharmacy's acquisition cost.

- Pharmacies may decline to provide a prescription drug to a patient if the MAC list reimbursement is less than the pharmacy acquisition cost.
- Violations of the MAC list statute are explicitly stated to be violations of three other state laws: the state PBM licensure act, consumer protection deceptive practices act, and insurance trade protection act.

Following enactment of the 2015 Act 900 amendments to the Arkansas MAC statute, the Pharmaceutical Care Management Association (PCMA), representing the eleven largest PBMs in the country, filed suit, *Rutledge v. Pharmaceutical Care Management Association*, arguing Act 900 is preempted by the Employee Retirement Income Security Act (ERISA) of 1974.[15] ERISA is a federal law that sets minimum standards for most retirement and health plans established by private-sector employers for their employees.[16] In December 2020, the Supreme Court ruled 8-0 that Act 900 is not preempted by ERISA, and states may regulate the price at which PBMs reimburse pharmacies for the cost of prescription drugs without violating ERSA.[17]

Arkansas Pharmacy Benefits Manager Licensure Act[18]

In January 2018, the Arkansas Blue Cross Blue Shield pharmacy network reimbursement model changed from pass-through to spread pricing.[19] The change greatly impacted independent pharmacies in the state who alleged reimbursements under the new model did not cover pharmacy drug acquisition costs and were threatening the pharmacies' financial solvency. Prompted by the independent pharmacy crisis, the Arkansas General Assembly convened an emergency session in March 2018 and passed legislation creating the Arkansas Pharmacy Benefits Manager Licensure Act (A.C.A. 23-92-501 et seq.). The Act was amended in 2019.

The Arkansas PBM Licensure Act requires PBMs to be licensed by the state insurance commissioner. While both Arkansas and Wyoming's basic licensing statutes are similar, Arkansas' law grants the commissioner greater authority to promulgate rules regarding PBM financial standards, financial solvency, maximum allowable cost practices, network adequacy, reporting requirements, rebates, and compensation.[20] The Arkansas Commissioner is also explicitly required to enforce the Act and authorized to examine or audit the books or records of a PBM to determine if the PBM is in compliance with the Act.[21]

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[15] **National Law Review, *Supreme Court rules that Arkansas Act 900, affecting the prices that PBMs pay to pharmacies, is not preempted under ERISA*, December 11, 2020**.
[16] **NCSL, PBMs and Options for State Legislatures webinar, January 28, 2021**.
[17] **U.S. Supreme Court, *Rutledge v Pharmaceutical Care Management Association*, December 10, 2020**.
[18] A.C.A. 23-92-501 et seq.
[19] Information provided by Booth Rand, Managing Counsel, Arkansas Insurance Department, May 2021.
[20] A.C.A. 23-92-509.
[21] A.C.A. 23-92-508.

Unlike Wyoming, PBMs applying for licensure in Arkansas must not only pay the $1000 application fee but also post a $1 million surety bond. In addition, PBMs must attach to their application the following documents:[22]

- Copy of the basic organizational document of the PBM, such as articles of incorporation, articles of association, or partnership agreement, and a copy of the organization's bylaws, rules and regulations.
- Copy of the PBM's standard, generic contract template used for contracts with pharmacies in the state.
- Copy of the PBM's most recent fiscal year-end audited financial statement;
- Description of the projected annual and previous year populations or number of enrollees or beneficiaries in the state to be serviced by the PBM for all healthcare insurers with whom the PBM contracts.
- Policies and procedures which demonstrate the PBM has compliant processes established to adhere to all of the requirements of the Arkansas maximum allowable cost statute (A.C.A. 17-92-507).
- Description or statement explaining how the PBM is in compliance with the anti-gag clause of the Arkansas PBM Licensure Act (A.C.A. 23-92-507).
- Description of each contracted healthcare insurer's network service areas by county and pharmacy directory list.
- If the PBM is engaged in spread pricing for a health benefit plan, an explanation of whether the PBM is assuming risk for payment of the covered prescription benefits of health benefit plans.

The Arkansas PBM Licensure Act further regulates PBM practices by prohibiting PBMs from conducting spread pricing and requiring PBMs to report to the state insurance commissioner on a quarterly basis the aggregate amount of rebates received by the PBM, distributed to healthcare insurers, and passed on to insurer enrollees at the point of sale. PBMs must also report the individual and aggregate amounts paid for pharmacist services by healthcare insurers to the PBM, and by the PBM to pharmacies.[23]

The Arkansas Department of Insurance employs three full-time staff, two investigators and one coordinator, dedicated to PBM regulation.[24]

MODEL PBM LEGISLATION

Two organizations, the National Council of Insurance Legislators (NCOIL) and the National Association of Insurance Commissioners (NAIC), have developed model state legislation for PBM regulation. NCOIL adopted the PBM Licensure and Regulation Model Act in December 2018 and

[22] **Arkansas Insurance Department, Pharmacy Benefits Manager Licensure Application**
[23] A.C.A. 23-92-505.
[24] Information provided by Booth Rand, Managing Counsel, Arkansas Insurance Department, May 2021.

the Drug Pricing Transparency Model Act in December 2019. NAIC created a PBM Task Force which has been working on a PBM Licensure and Regulation Model Act. The Wyoming Department of Insurance has a named representative on the NAIC task force and provided a copy of the October 2020 draft model act. See **Appendix D** for the three model acts.

If you have any further questions, please do not hesitate to contact LSO Research and Evaluation at 777-7881.

APPENDIX A. CATEGORIES OF STATE PBM STATUTES

Category	Description
Cost-Disclosure/ Gag-Clause	Contracts between a pharmacy and a PBM are a common feature in the prescription drug distribution and sales chain. The terms of these arrangements are often proprietary and unknown to consumers and some purchasers, like employers. The terms can include a "gag clause," which restricts pharmacists from informing consumers of lower cost options, such as if a consumer purchases a prescription out of pocket rather than using the drug benefit through their insurance plan. Over two-thirds of states have laws that address this issue.
Fiduciary responsibilities	A fiduciary is a person or entity who holds a legal or ethical responsibility to act in the best interests of their clients. A PBM's clients typically are health plans whose primary stakeholders are plan enrollees. While some states impose fiduciary responsibilities on PBMs, others require PBMs to exercise good faith and fair dealing while performing their contractual duties. More than a quarter of states have this type of legislation in place.
Maximum Allowable Cost (MAC) or Reimbursement Lists	PBMs may choose to establish an upper limit or maximum amount they will reimburse a pharmacy for generic and multi-source drugs. PBMs develop MAC lists using a variety of data, resources and information, and these lists may consist of thousands of products. A state may choose to regulate the frequency MAC lists are updated, such as every 7 days. Another common approach is providing for an appeals process when a pharmacy disputes an amount it was reimbursed. Only a handful of states have not enacted legislation in this area.
Network Adequacy	A pharmacy network is a list of pharmacies or pharmacists that a health plan or PBM has contracted with to provide prescription drug services to their members. Pharmacy network adequacy is often defined as the distance between a patient's residence and where services can be physically accessed. Existing state laws generally set adequacy and eligibility standards for network participation.
Patient Steering	Some PBMs require contracted health plan enrollees to visit affiliated pharmacies, or pharmacies in which they have an ownership interest including retail, mail-order or specialty. Four states—Georgia, Louisiana, Minnesota and Utah—have passed legislation specifically banning this practice.
Pharmacy Auditing Standards/ Appeals Process	Audits on pharmacies by PBMs to detect fraud, waste and abuse are routine; however, some states have implemented laws to ensure pharmacies are audited fairly and are given a process for appeal. Over two-thirds of states have enacted some form of a fair pharmacy audit bill which provides guidelines on when and how pharmacy audits are conducted by PBMs.

Pharmacy Reimbursement/ Clawbacks	In addition to MAC laws, state laws may provide reimbursement standards for pharmacies with which the PBM contracts. For example, a state might prohibit a PBM from denying or reducing the amount they reimburse to a pharmacy or pharmacist for a claim. Clawbacks occur when a health plan enrollee's copayment exceeds the total cost of the drug to their insurer, and the PBM "claws back" some, or all, of the overpayment from the pharmacy. Some states have chosen to prohibit these types of retroactive payments and at least 22 states have enacted some form of clawback legislation.
Registration/ Licensure	States may require PBMs to register or obtain licensure to conduct business, often through the state department of insurance or board of pharmacy. At least thirty states have this type of law.
Regulatory Agency/ Enforcement	Many of the same states that require PBM registration or licensure authorize a specific agency to promulgate rules and regulations. Maine has approached the issue uniquely by requiring insurers that contract with PBMs to monitor the PBM's activities. Most states that opt to give regulatory oversight of PBM business practices to a specific state agency also give that agency the authority to establish and assess fines, impose civil penalties, and suspend or revoke a license of a PBM that is found to be noncompliant.
Reporting/ Transparency requirements	Some states have implemented laws that require PBMs to disclose certain pricing and cost information such as data on rebates, payments and fees collected from drug manufacturers, insurers, and pharmacies.
Spread pricing	Health plans choose contracts with PBMs that commonly use either a spread pricing reimbursement model or pass-through pricing model. In a spread pricing model, the PBM keeps a portion of the amount, or spread, between what the health plan pays the PBM and the amount that the PBM reimburses the pharmacy for a beneficiary's prescription. With a pass-through contract, the PBM passes through the amount charged by the pharmacy to the health insurer. Since no spread is collected, PBMs typically charge an administrative fee. More than a dozen states bar the use of spread pricing models in PBM and health plan contracts.
Utilization management tools	Utilization management tools are used by payers to manage the use and mix of drugs covered under the benefit. A provider might be required to gain prior authorization or approval for a specific treatment before it can be administered. Step therapy, also called "fail first," is when a patient is required to try certain treatments or prescription drugs before switching to a more expensive or non-generic alternative. Non-medical switching occurs when a patient who is stable on one medicine is switched to another for reasons other than clinical purposes. More than half of states have laws that address utilization management policies.

Source: LSO compiled information from NCSL, State Policy Options and PBMs, March 17, 2021

APPENDIX B. COMPARISON OF WYOMING AND ARKANSAS PBM STATUTES

Category of PBM regulation addressed by statute	**Wyoming PBM Act (W.S. 26-52-101 through 26-52-104)**	**Arkansas PBM Licensure Act (A.C.A. 23-92-501 through 23-92-510); MAC statute (A.C.A. 17-92-507); and Pharmacy Audit Bill of Rights (A.C.A. 17-92-1201)**
Cost-disclosure/Gag-clause	PBMs prohibited from preventing or penalizing a pharmacy for disclosing drug cost information or offering customers a more affordable drug alternative. W.S. 26-52-104(j)	Arkansas PBM Licensure Act similarly protects pharmacy cost disclosures to customers, but also states that a PBM contract with a pharmacy shall not prohibit disclosure of information to the state insurance commissioner, law enforcement, or state and federal officials investigating a complaint or conducting a review of the PBM. A.C.A. 23-92-507
Licensure/Registration	PBMs required to be licensed by the state Department of Insurance. W.S. 26-52-101	PBMs required to be licensed by the state insurance commissioner. A.C.A. 23-92-504
Maximum Allow Costs (MAC)	PBM MAC List drugs must meet certain national rating requirements and be available for purchase by Wyoming pharmacies. PBM must consider "only the price" of that drug and any generic when establishing MAC. PBM must make sources utilized to determine MAC and MAC List accessible to network pharmacies. PBM must update MAC list each 7 days. Requires PBMs to establish MAC appeal process and follow certain timelines and procedures. W.S. 26-52-104.	Arkansas MAC statute includes additional requirements for specific costs that must be included in MAC lists. Also requires PBMs to adjust MAC to above pharmacy acquisition cost if (a) pharmacy appeal is upheld, or (b) pharmacy appeal is denied but pharmacy is unable to obtain the drug from the pharmacy's regular wholesaler at a price below acquisition cost. Statute explicitly states that a violation of the MAC statute is a violation of the state PBM licensure act, consumer protection deceptive practices act, and insurance trade protection act. A.C.A. 17-92-507
Pharmacy Auditing Standards/Appeals Process	Establishes standards for PBM audits of pharmacies, regulates what PBMs may consider in audit findings, and requires PBMs to establish an audit appeal process. W.S. 26-52-103.	The Arkansas Pharmacy Audit Bill of Rights was passed in 2007 and amended in 2011. The Bill establishes standards for pharmacy audits by managed-care companies, insurance companies, and third-party payors. A.C.A. 17-92-1201

Category of PBM regulation addressed by statute	**Wyoming PBM Act (W.S. 26-52-101 through 26-52-104).**	**Arkansas PBM Licensure Act (A.C.A. 23-92-501 through 23-92-510); MAC statute (A.C.A. 17-92-507); and Pharmacy Audit Bill of Rights (A.C.A. 17-92-1201)**
Network Adequacy	N/A	PBMs required to provide a reasonably adequate and accessible network for the provision of prescription drugs for a health benefit plan that provides for convenient patient access to pharmacies within a reasonable distance from a patient's residence. A.C.A. 23-92-505
Pharmacy Reimbursement/ Clawbacks	N/A	Regulates PBM reimbursements to pharmacies and allows the state insurance commissioner to review and approve a PBM compensation program to ensure that reimbursements are fair and reasonable. A.C.A. 23-92-506
Regulatory Agency Enforcement	N/A	State insurance commissioner required to enforce the PBM licensure act and authorized to examine or audit PBM books and records to determine if the PBM is in compliance with the act. A.C.A. 23-92-508 Commissioner authorized to issue rules regarding PBM financial standards, financial solvency, MAC practices, network adequacy, reporting requirements, rebates, and compensation. A.C.A. 23-92-509
Spread Pricing	N/A	PBMs prohibited from conducting spread pricing and required to report to the state insurance commissioner on a quarterly basis information regarding the aggregate amount of drug manufacturer rebates received by the PBM, distributed to healthcare insurers, and passed on to insurance enrollees, and the individual and aggregate amounts paid for pharmacist services by the insurer to the PBM, and by the PBM to pharmacies. A.C.A. 23-92-505
Utilization Management Tools	N/A	The Arkansas Prior Authorization Transparency Act was passed in 2015 and amended in 2017 to add provisions limiting the ability of insurance policies to mandate prescription drug step therapy. The step therapy provisions were further amended in 2019 and 2021. A.C.A. 23-99-1114

Appendix C. Wyoming Licensed PBMs as of 5/14/2021

PRODUCER TYPE	PRODUCER ID	RESIDENT	NAME	CURRENT STATUS	NPN	MAILING ADDRESS
Firm	15036891	No	ALLUMA LLC	Active	19292399	290 E. JOHN CARPENTER FREEWAY IRVING, TX 75062
Firm	8225	No	AMWINS GROUP BENEFITS LLC	Active	1993001	50 WHITECAP DR NORTH KINGSTOWN, RI 02852-7445
Firm	15033022	No	BENECARD SERVICES, INC.	Active	1989201	3131 PRINCETON PIKE SUITE 103 LAWRENCEVILLE, NJ 08648
Firm	15029934	No	CAREMARK LLC	Active	2225554	9501 E. SHEA BLVD. MC024 SCOTTSDALE, AZ 85260
Firm	15029945	No	CAREMARKPCS HEALTH LLC	Active	6375548	9501 E. SHEA BLVD., MC024 SCOTTSDALE, AZ 85260
Firm	15039093	No	CHANGE HEALTHCARE PHARMACY SOLUTIONS INC	Active	18787102	45 COMMERCE DRIVE SUITE 5 AUGUSTA, ME 04330
Firm	15034639	No	COSTCO HEALTH SOLUTIONS INC	Active	18364018	ATTN: LICENSING, P.O. BOX 35005 SEATTLE, WA 98124
Firm	15030281	No	DST PHARMACY SOLUTIONS INC	Active	7220459	210 W 10TH ST KANSAS CITY, MO 64105-1614
Firm	15030141	No	ELIXIR RX SOLUTIONS LLC	Active	8027577	BAYVIEW CORPORATE TOWER 6451 N. FEDERAL HIGHWAY, SUITE 300 FORT LAUDERDALE, FL 33308
Firm	15030517	No	EMPLOYEE HEALTH INSURANCE MANAGEMENT INC	Active	961351	26711 NORTHWESTERN HWY, SUITE 400 SOUTHFIELD, MI 48033
Firm	15029640	No	ENVOLVE PHARMACY SOLUTIONS INC	Active	16351204	LICENSING 8427 SOUTHPARK CIR STE 400 ORLANDO, FL 32819-9057
Firm	15020762	No	EXPRESS SCRIPTS ADMINISTRATORS LLC	Active	8229376	1 EXPRESS WAY MAIL STOP HQ2E03 SAINT LOUIS, MO 63121-1824
Firm	15029402	No	FAIRVIEW PHARMACY SERVICES LLC	Active	16718225	2550 UNIVERSITY AVE W STE 320N SAINT PAUL, MN 55114-2005
Firm	15039033	No	HEALTHSMART RX SOLUTIONS INC	Active	16470556	222 W. LAS COLINAS BLVD. STE. 500N IRVING, TX 75039

Firm	15020412	No	HUMANA PHARMACY SOLUTIONS, INC	Active	16246295	321 WEST MAIN STREET LOUISVILLE, KY 40202
Firm	15034058	No	INDEPENDENT HEALTHS PHARMACY BENEFIT DIMENSIONS LLC	Active	18049708	511 FARBER LAKE DRIVE BUFFALO, NY 14221
Firm	15034285	No	INGENIORX, INC.	Active	18765355	1831 CHESTNUT ST. MAILDROP MOM905-B502 ST. LOUIS, MO 63103
Firm	15029601	No	MAGELLAN RX MANAGEMENT LLC	Active	17321658	COMPLIANCE, STEPHANIE MCDONALD 8621 ROBERT FULTON DR COLUMBIA, MD 21046
Firm	15029683	No	MAXORPLUS LTD	Active	15861558	320 S POLK ST STE 200 AMARILLO, TX 79101-1436
Firm	15021588	No	MEDIMPACT HEALTHCARE SYSTEMS INC	Active	2751743	10181 SCRIPPS GATEWAY COURT SAN DIEGO, CA 92131
Firm	15032938	No	MERIDIANRX LLC	Active	16676733	ATTN: ENVOLVE PHARMACY SOLUTIONS 7700 FORSYTH BLVD ST. LOUIS, MO 63105
Firm	15025255	No	NAVITUS HEALTH SOLUTIONS LLC	Active	7910070	361 INTEGRITY DR MADISON, WI 53717
Firm	15021473	No	OPTUMRX INC	Active	1915797	ATTN: LICENSING 2300 MAIN ST IRVINE, CA 92614-6223
Firm	15038036	No	PHARMASTAR LLC	Active	18904388	ROBERT TANNER P O BOX 3217 EAU CLAIRE, WI 54702
Firm	15029975	No	PRIME THERAPEUTICS LLC	Active	9111884	1305 CORPORATE CENTER DRIVE EAGAN, MN 55121
Firm	15036983	No	PROCARE PHARMACY BENEFIT MANAGER INC	Active	16971716	1267 PROFESSIONAL PARKWAY GAINESVILLE, GA 30507
Firm	15037465	No	REALRX	Active	19560530	6770 S 900 E SUITE 202 MIDVALE, UT 84047
Firm	15029797	No	SCRIP WORLD LLC	Active	9005338	300 CORPORATE PARKWAY AMHERST, NY 14226
Firm	15035344	No	SOUTHERN SCRIPTS LLC	Active	17862483	411 BIENVILLE STREET NATCHITOCHES, LA 71457

Firm	14217	No	TOWERS ADMINISTRATORS LLC	Active	1904568	99 HIGH STREET FLOOR 28 BOSTON, MA 02110
Firm	15036935	No	TRUE RX MANAGEMENT SERVICES INC	Active	17933961	7 WILLIAMS BROS DRIVE WASHINGTON, IN 47501
Firm	15039742	No	VENTEGRA INC A CALIFORNIA BENEFIT CORPORATION	Active	18559525	450 N BRAND BLVD. SUITE #600 GLENDALE, CA 91203
Firm	15034007	No	WELLDYNERX LCC	Active	9575510	500 EAGLES LANDING DR LAKELAND, FL 33810
Firm	15036364	No	WITHME HEALTH LLC	Active	19237291	400 SOUTH EL CAMINO REAL SUITE 1150 SAN MATEO, CA 94402

Source: Wyoming Department of Insurance

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Manasquan, NJ 08726
7312-201-4133
CHIEF EXECUTIVE OFFICER: Thomas B. Considine

National Council of Insurance Legislators (NCOIL)

Pharmacy Benefits Manager Licensure and Regulation Model Act

Adopted by the Health and Long Term Care Issues Committee and Executive Committee on December 8, 2018
Sponsored by Sen. Jason Rapert (AR)

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Section 1. Title

This Act shall be known as and may be cited as the "[State] Pharmacy Benefits Manager Licensure and Regulation Act."

Section 2. Purpose

(a) This Act establishes the standards and criteria for the regulation and licensure of pharmacy benefits managers providing claims processing services or other prescription drug or device services for health benefit plans.

(b) The purpose of this Act is to:

(1) Promote, preserve, and protect the public health, safety, and welfare through effective regulation and licensure of pharmacy benefits managers;

(2) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the States by the McCarran-Ferguson Act (15 U.S.C. §§ 1011 – 1015), as well as provide for consumer savings, and fairness in prescription benefits.

(3) Provide for powers and duties of the Insurance Commissioner, the State Insurance Department; and

(4) Prescribe penalties and fines for violations of this Act.

Section 3. Definitions

For purposes of this Act:

(a) "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both subdivisions (a)(1) and (2) of this section.

(b) "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including without limitation:

(1) Negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(2) Disbursing or distributing rebates;

(3) Managing or participating in incentive programs or arrangements for pharmacist services;

(4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) Developing formularies;

(6) Designing prescription benefit programs; or

(7) Advertising or promoting services.

(c) "Pharmacist" means an individual licensed as a pharmacist by the State Board of Pharmacy.

(d) "Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy.

(e) "Pharmacy" means the place licensed by the State Board of Pharmacy in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail.

(f) (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]; or

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

Section 4. License to do business – Annual statement – Assessment

(a) (1) A person or organization shall not establish or operate as a pharmacy benefits manager in this State for health benefit plans without obtaining a license from the Insurance Commissioner under this Act.

(2) The commissioner shall prescribe the application for a license to operate in this State as a pharmacy benefits manager and may charge application fees and renewal fees as established by rule.

(b) The commissioner shall issue rules establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers under this Act and not inconsistent herewith.

Section 5. Gag clauses prohibited

Drafting Note: *In addition to the Model language set forth below, States seeking to enact "gag clause" legislation may look to Federal law for guidance. Specifically, S.2553 – The Know the Lowest Price Act of 2018" – and S. 2554 – The Patient Right Know Drug Prices Act."*

(a) In any participation contracts between pharmacy benefits managers and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted, or penalized in any way from disclosing to any covered person any healthcare information that the pharmacy or pharmacist deems appropriate regarding the nature of treatment, risks, or alternatives thereto, the availability of

alternate therapies, consultations, or tests, the decision of utilization reviewers or similar persons to authorize or deny services, the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer.

(b) A pharmacy or pharmacist may provide to an insured information regarding the insured's total cost for pharmacist services for a prescription drug.

(c) A pharmacy or pharmacist shall not be proscribed by a pharmacy benefits manager from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if a more affordable alternative is available.

(d) A pharmacy benefits manager contract with a participating pharmacist or pharmacy shall not prohibit, restrict, or limit disclosure of information to the Insurance Commissioner, law enforcement, or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefits manager's compliance with the requirements under this Act.

Section 6. Enforcement

(a) The Insurance Commissioner shall enforce this Act.

(b) (1) The commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine if the pharmacy benefits manager is in compliance with this Act.

(2) The information or data acquired during an examination under subdivision (b)(1) of this section is:

(A) Considered proprietary and confidential; and

(B) Not subject to the [Freedom of Information Act][1] of this State

Section 7. Rules

(a) The Insurance Commissioner may adopt rules regulating pharmacy benefits managers that are not inconsistent with this Act.

(b) Rules adopted under this Act shall set penalties or fines, including without limitation monetary fines, suspension of licensure, and revocation of licensure for violations of this Act and rules adopted under this Act.

[1] DRAFTING NOTE: State FOIAs have different names in different states, often called Open Records Acts, Public Records Act, Public Records Law, etc. and thus the specific title used in this subsection needs to be tailored accordingly.

Drafting Note: *Although Section 7(a) expressly authorizes rules not inconsistent with this Act, as opposed to those merely implementing it, states may also wish to consider providing the Insurance Commissioner with specific guidance to adopt regulations relating to:*

(1) Pharmacy benefits manager network adequacy;

(2) Prohibited market conduct practices;

(3) Data reporting requirements under State price-gouging laws

(4) Rebates;

(5) Prohibitions and limitations on the corporate practice of medicine (CPOM)[2]

(6) Compensation;

(7) Procedures for pharmacy audits conducted by or on behalf of a pharmacy benefits manager;

(8) Medical loss ratio (MLR) abuses;

(9) Affiliate information sharing;

(10) Lists of health benefit plans administered by a pharmacy benefits manager in this state.

Section 8. Applicability

(a) This Act is applicable to a contract or health benefit plan issued, renewed, recredentialed, amended, or extended on and after _____.

(b) A contract existing on the date of licensure of the pharmacy benefits manager shall comply with the requirements of this Act as a condition of licensure for the pharmacy benefits manager.

(c) Nothing in this Act is intended or shall be construed to be in conflict with existing relevant federal law.

[2] Commissioners may wish to evaluate whether PBMs disregarding of physicians' prescribing practices and substituting their (PBMs') own judgment through the use of mandated step therapy constitutes the practice of medicine

Section 9. Severability Clause

If any provision of this act or the application of this act to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this act are declared severable.

Section 10. Effective Date

This Act is effective immediately.

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CHIEF EXECUTIVE OFFICER: Thomas B. Considine

NATIONAL COUNCIL OF INSURANCE LEGISLATORS (NCOIL)

AN ACT CONCERNING PRESCRIPTION DRUG COSTS

Sponsored by Rep. Tom. Oliverson, M.D. (TX)
Co-Sponsored by Sen. Dan "Blade" Morrish (LA)

Adopted by the Health Insurance & Long Term Care Issues Committee on December 11th, 2019 and by the Executive Committee on December 13th, 2019.

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Section 1. Title

This Act shall be known as the [State] Health Care Cost Transparency Act.

Section 2. Purpose

The purpose of this Act is to promote prescription drug price transparency and cost control.

Section 3. Definitions

"Board of Pharmacy" or "board" means the [State] Board of Pharmacy.

"Commissioner" means the Insurance Commissioner.

"Department" means the Insurance Department.

“Director” means the Medicaid Director.

"Drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; (C) articles, other than food, intended to affect the structure or any function of the body of humans or any other animal; and (D) articles intended for use as a component of any articles specified in this subdivision; but shall not include devices or their components, parts or accessories;

"Health care plan" means any individual, blanket, or group plan, policy, or contract for healthcare services issued or delivered by a healthcare insurer in this state.

"Health carrier" or “Health insurer” means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

“Net spending” means the cost of prescription drugs minus any discounts that lowers the price of the drugs, including, but not limited to, rebates, fees, retained price protections, retail pharmacy network spread, and dispensing fees.

"Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy.

"Pharmacy benefits manager" means any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health care plan offered in the state on behalf of a [HEALTH CARRIER/INSURER].

"Rebate" means any discount or concession which affects the price of a prescription drug to a pharmacy benefits manager or health [CARRIER/INSURER] for a prescription drug manufactured by the pharmaceutical manufacturer.

“Specialty drug” means a prescription drug outpatient specialty drug covered under Medicare Part D program established pursuant to Public Law 108-73, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended from time to time, that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

“Utilization management” means a set of formal techniques designed to monitor the use of, or evaluate the medical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings.

“Wholesale acquisition cost” means, with respect to a pharmaceutical drug or biological product, the manufacturer's list price for the pharmaceutical drug or biological product to wholesalers or direct purchasers in the United States for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pharmaceutical drug or biological product pricing data, not including any rebates, prompt pay or other discounts, or other reductions in price.

Section 4. Disclosure of prescription drug pricing information.

(a)(1) Not later than January 1, 2020, and annually thereafter, each drug manufacturer shall submit a report to the [INSURANCE COMMISSIONER] no later than the fifteenth day of January, April, July, and October with the current wholesale acquisition cost information for the United States Food and Drug Administration approved drugs sold in or into the state by that manufacturer.

(2) The commissioner shall develop a website to contain prescription drug price information submitted pursuant to subsection (a)(1) of this section. The website shall be made available on the [INSURANCE DEPAREMENT’S] website with a dedicated link that is prominently displayed on the home page, or by a separate easily identifiable internet address.

(b)(1) Not more than thirty days after an increase in wholesale acquisition cost of sixty percent or greater over the preceding five calendar years or fifteen percent or greater in the preceding twelve months for a drug with a wholesale acquisition cost of seventy dollars or more for a thirty-day supply, a pharmaceutical drug manufacturer shall submit a report to the [COMMISSIONER OF INSURANCE]. The report shall contain the following information:

(A) Name of the product;

(B) Whether the drug is a brand name or a generic;

(C) The effective date of the change in wholesale acquisition cost;

(D) Aggregate, company-level research and development costs for the prior calendar year;

(E) The name of each of the manufacturer’s prescription drugs that was approved by the federal Food and Drug Administration in the previous five calendar years;

(F) The name of each of the manufacturer’s prescription drugs that lost patent exclusivity in the United States in the previous five calendar years; and

(G) A statement of rationale regarding the factor or factors that caused the increase in the wholesale acquisition cost.

(2) The quality and types of information and data that a pharmaceutical manufacturer submits to the commissioner pursuant to this subsection shall be consistent with the quality and types of information and data that the manufacturer includes in their annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

(3) Within sixty days of receipt, the commissioner shall publish the report on the [INSURANCE DEPARTMENT'S] prescription drug price information website developed pursuant to subsection (a)(2) this section.

(c) A manufacturer shall notify the commissioner in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. The manufacturer shall provide the written notice within three calendar days following the release of the drug in the commercial market. A manufacturer may make the notification pending approval by the U.S. Food and Drug Administration (FDA) if commercial availability is expected within three calendar days following the approval.

(d) The commissioner may adopt regulations to implement the provisions of this section.

Drafting Note: *States may wish to raise or lower the percentages and dollar amount set forth in Section 4(b)(1) depending upon each state's economic environment as it relates to prescription drug prices.*

Section 5. Disclosure of pharmacy benefit management information.

(a)(1) Not later than February 1, 2020, and annually thereafter, each pharmacy benefits manager shall file a report with the commissioner. The report shall contain the following information for the immediately preceding calendar year:

> (A) The aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical manufacturers;
>
> (B) The aggregated dollar amount of rebates, price protection payments, fees and any other payments collected from pharmaceutical manufacturers that were passed to health [CARRIERS/INSURERS];
>
> (C) The aggregated dollar amount of rebates, price protection payments, fees and any other payments collected from pharmaceutical manufacturers that were passed to enrollees at the point of sale; and
>
> (D) The aggregated dollar amount of rebates, price protection payments, fees and any other payments collected from pharmaceutical manufacturers that were retained as revenue by the pharmacy benefit manager.

(2) Reports submitted by pharmacy benefit managers shall not disclose the identity of a specific health benefit plan or enrollee, the prices charged for specific drugs or classes of drugs, or the amount of any rebates or fees provided for specific drugs or classes of drugs.

(3) Within sixty days of receipt, the commissioner shall publish the report on the [INSURANCE DEPARTMENT'S] prescription drug price information website developed pursuant to subsection (a)(2) of section (4) of this Act. For any pharmacy benefit manager with fewer than five (5) clients, the commissioner shall aggregate all the collected data and publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's internet website. The data from all of the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any pharmacy benefit manager.

(b) The commissioner may adopt regulations to implement the provisions of this section.

Section 6. Disclosure of health [CARRIER/INSURER] spending information.

(a)(1) Not later than February 1, 2020, and annually thereafter, each health [CARRIER/INSURER] shall submit a report to the commissioner. The report shall contain the following information for the immediately preceding calendar year:

(A) The names of the twenty-five most frequently prescribed prescription drugs across all plans;

(B) Percent increase in annual net spending for prescription drugs across all plans;

(C) Percent increase in premiums that were attributable to prescription drugs across all plans;

(D) Percentage of specialty prescription drugs with utilization management requirements across all plans;

(E) Premium reductions that were attributable to specialty drug utilization management.

(2) Within sixty days of receipt, the commissioner shall publish the report on the [INSURANCE DEPARTMENT'S] prescription drug price information website developed pursuant to subsection (a)(2) of section (4) of this Act. The commissioner shall aggregate all the collected data and publish the aggregated data from all reports for that year required by this section in an appropriate location on the department's internet website. The data from all of the reports must be published in a manner that does not disclose or tend to disclose proprietary or confidential information of any health [CARRIER/INSURER].

(b) Reports submitted by [CARRIERS/INSURERS] shall not disclose the identity of a specific health benefit plan or the prices charged for specific drugs or classes of drugs.

(c) The commissioner may adopt regulations to implement the provisions of this section.

Section 7. Severability

If any provisions of this Act or the application of this Act to any person or circumstances is held invalid, the invalidity shall not affect other provisions or applications of this Act which can be given effect without the invalid provision or application, and to this end, the provisions of this Act are declared severable.

Section 8. Effective Date

This Act is effective immediately.

Adopted by the Health Insurance and Managed Care (B) Committee - TBD
Adopted by the Regulatory Framework (B) Task Force – TBD
Adopted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup – Oct. 29, 2020

Draft: 10/29/20
A new model

Comments are being requested on this draft on or before Dec. 22, 2020. Comments should be sent by email only to Jolie Matthews at jmatthews@naic.org.

[STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT

Table of Contents

Section 1. Short Title

This Act shall be known and may be cited as the [State] Pharmacy Benefit Manager Licensure and Regulation Act.

Section 2. Purpose

A. This Act establishes the standards and criteria for the licensure and regulation of pharmacy benefit managers providing claims processing services or other prescription drug or device services for health benefit plans.

B. The purpose of this Act is to:

(1) Promote, preserve, and protect the public health, safety and welfare through effective regulation and licensure of pharmacy benefit managers;

(2) Promote the solvency of the commercial health insurance industry, the regulation of which is reserved to the states by the McCarran-Ferguson Act (15 U.S.C. §§ 1011 – 1015), as well as provide for consumer savings, and fairness in prescription drug benefits;

(3) Provide for powers and duties of the commissioner; and

(4) Prescribe penalties and fines for violations of this Act.

Section 3. Definitions

For purposes of this Act:

A. "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

(1) Receiving payments for pharmacist services;

(2) Making payments to pharmacists or pharmacies for pharmacist services; or

(3) Both paragraphs (1) and (2).

B. "Commissioner" means the insurance commissioner of this state.

Drafting Note: Use the title of the chief insurance regulatory official wherever the term "commissioner" appears.

C. "Covered person" means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health benefit plan.

D. "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of [physical, mental or behavioral] health care services.

E. "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insurance company, a health maintenance organization, a hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

Drafting Note: States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

F. "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including, but not limited to:

(1) Negotiating rebates, discounts or other financial incentives and arrangements with drug companies;

(2) Disbursing or distributing rebates;

(3) Managing or participating in incentive programs or arrangements for pharmacist services;

(4) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(5) Developing and maintaining formularies;

(6) Designing prescription benefit programs; or

(7) Advertising or promoting services.

G. "Pharmacist" means an individual licensed as a pharmacist by the [state] Board of Pharmacy.

H. "Pharmacist services" means products, goods, and services or any combination of products, goods and services, provided as a part of the practice of pharmacy.

I. "Pharmacy" means the place licensed by the [state] Board of Pharmacy in which drugs, chemicals, medicines, prescriptions and poisons are compounded, dispensed or sold at retail.

J. (1) "Pharmacy benefit manager" means a person, business or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides claims processing services or other prescription drug or device services, or both, to covered persons who are residents of this state, for health benefit plans.

(2) "Pharmacy benefit manager" does not include:

(a) A health care facility licensed in this state;

(b) A health care professional licensed in this state;

(c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; or

(d) A health carrier to the extent that it performs any claims processing and other prescription drug or device services exclusively for its enrollees.

Section 4. Applicability

A. This Act shall apply to a contract or health benefit plan issued, renewed, recredentialed, amended or extended on or after the effective date of this Act, including any health carrier that performs claims processing or other prescription drug or device services through a third party.

Drafting Note: States may want to consider adding language to Subsection A above or Section 10—Effective Date providing additional time for pharmacy benefit managers to come into compliance with the requirements of this Act.

B. As a condition of licensure, any contract in existence on the date the pharmacy benefit manager receives its license to do business in this state shall comply with the requirements of this Act.

C. Nothing in this Act is intended or shall be construed to conflict with existing relevant federal law.

Section 5. Licensing Requirement

A. A person may not establish or operate as a pharmacy benefit manager in this state for health benefit plans without first obtaining a license from the commissioner under this Act.

B. The commissioner may adopt regulations establishing the licensing application, financial and reporting requirements for pharmacy benefit managers under this Act.

Drafting Note: States that are restricted in their rulemaking to only what is prescribed in statute may want to consider including in this section specific financial standards required for a person or organization to obtain a license to operate as a pharmacy benefit manager in this state.

C. A person applying for a pharmacy benefit manager license shall submit an application for licensure in the form and manner prescribed by the commissioner.

Drafting Note: States may want to consider reviewing their third party administrator statute if a state wishes to specify what documents must be provided to the commissioner to obtain a pharmacy benefit manager license in the state.

D. A person submitting an application for a pharmacy benefit manager license shall include with the application a non-refundable application fee of $[X].

E. The commissioner may refuse to issue or renew a license if the commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible or of good personal and business reputation or has been found to have violated the insurance laws of this state or any other jurisdiction, or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.

F. (1) Unless surrendered, suspended or revoked by the commissioner, a license issued under this section shall remain valid as long as the pharmacy benefit manager continues to do business in this state and remains in compliance with the provisions of this act and any applicable rules and regulations, including the payment of an annual license renewal fee of $[X] and completion of a renewal application on a form prescribed by the commissioner.

(2) Such renewal fee and application shall be received by the commissioner on or before [x] days prior to the anniversary of the effective date of the pharmacy benefit manager's initial or most recent license.

Section 6. Gag Clauses and Other Pharmacy Benefit Manager Prohibited Practices

A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacy or pharmacist may be prohibited, restricted or penalized in any way from disclosing to any covered person any healthcare information that the pharmacy or pharmacist deems appropriate regarding:

(1) The nature of treatment, risks or alternative thereto;

(2) The availability of alternate therapies, consultations, or tests;

(3) The decision of utilization reviewers or similar persons to authorize or deny services;

(4) The process that is used to authorize or deny healthcare services or benefits; or

(5) Information on financial incentives and structures used by the insurer.

B. A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.

C. A pharmacy benefit manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the commissioner, law enforcement or state and federal governmental officials, provided that:

(1) The recipient of the information represents it has the authority, to the extent provided by state or federal law, to maintain proprietary information as confidential; and

(2) Prior to disclosure of information designated as confidential the pharmacist or pharmacy:

(a) Marks as confidential any document in which the information appears; or

(b) Requests confidential treatment for any oral communication of the information.

D. A pharmacy benefit manager may not terminate the contract of or penalize a pharmacist or pharmacy due to pharmacist or pharmacy:

(1) Disclosing information about pharmacy benefit manager practices, except for information determined to be a trade secret, as determined by state law or the commissioner; or

(2) Sharing any portion of the pharmacy benefit manager contract with the commissioner pursuant to a complaint or a query regarding whether the contract is in compliance with this Act.

E. (1) A pharmacy benefit manager may not require a covered person purchasing a covered prescription drug to pay an amount greater than the lesser of the covered person's cost-sharing amount under the terms of the health benefit plan or the amount the covered person would pay for the drug if the covered person were paying the cash price.

(2) Any amount paid by a covered person under paragraph (1) of this subsection shall be attributable toward any deductible or, to the extent consistent with section 2707 of the Public Health Service Act, the annual out-of-pocket maximums under the covered person's health benefit plan.

Section 7. Enforcement

A. The commissioner shall enforce compliance with the requirements of this Act.

B. (1) The commissioner may examine or audit the books and records of a pharmacy benefit manager providing claims processing services or other prescription drug or device services for a health benefit plan to determine compliance with this Act.

Drafting Note: States may want to consider including a reference to the cost of examinations in the *Model Law on Examinations* (#390).

Drafting Note: States may want to consider incorporating their existing market conduct examination statutes into this Act rather than relying on the examination authority provided under this section.

(2) The information or data acquired during an examination under paragraph (1) is:

(a) Considered proprietary and confidential;

(b) Not subject to the [Freedom of Information Act] of this state;

(c) Not subject to subpoena; and

(d) Not subject to discovery or admissible in evidence in any private civil action.

C. The commissioner may use any document or information provided pursuant to Section 6C of this Act or Section 6D of this Act in the performance of the commissioner's duties to determine compliance with this Act.

D. The commissioner may impose a penalty on a pharmacy benefit manager or the health carrier with which it is contracted, or both, for a violation of this Act. The penalty may not exceed [insert appropriate state penalty] per entity for each violation of this Act.

Drafting Note: If an appeals process is not otherwise provided, a state should consider adding such a provision to this section.

Section 8. Regulations

The commissioner may adopt regulations regulating pharmacy benefit managers that not inconsistent with this Act.

Drafting Note: This Act is primarily intended to establish licensing standards for pharmacy benefit managers (PBMs). A number of states have enacted statutes or made suggestions that extend into the regulation of pharmacy benefit manager business practices. The provisions below, which are followed by citations to state law where applicable, provide topic areas that states pursuing this Act may wish to consider in their proposed legislation:

(1) PBM network adequacy (Ark. Code 23-92-505 and Okla. Stat. 36-6961) (Also, see provisions in the *Health Carrier Prescription Drug Benefit Management Model Act* (#22) and the *Health Benefit Plan Network Access and Adequacy Model Act* (#74));

(2) Prohibited market conduct practices (Ark. Code 23-92-506; MD. ANN. CODE § 15-1642; N.M. Stat. 59A-61-5 and 59A-61-7; Oregon Rev. Stat. §§ 735.534 through 735.552; and South Carolina Code §38-71-2230(A)(1));

(3) Data reporting requirements under state price-gouging laws;

(4) Rebates (MD. ANN. CODE § 15-1624 and Texas Insurance Code §1369.502);

(5) Prohibitions and limitations on the corporate practice of medicine (CPOM);

(6) Compensation (Ark. Code 23-92-506(b)(5)(A) and N.J.S.A. 17B:27F-8 (New Jersey));

(7) Procedures for pharmacy audits conducted by or on behalf of a PBM (Del. Ins. Code Chapter 33A §§ 3301A – 3310A; MD. ANN. CODE § 15-1629; Oregon Rev. Stat. §§ 735.540 through 735.552; and 40 PA. CONS. STAT. §§ 4511-4514);

(8) Medical loss ratio (MLR) compliance;

(9) Affiliate information-sharing (Ga. Code § 26-4-119 and § 33-64-11(a)(8);

(10) Lists of health benefit plans administered by a PBM in this state (New Hampshire Rev Stat § 402-N:6)

(11) Reimbursement lists or payment methodology used by PBMs (Ark. Code § 17-92-507; Del. Ins. Code Chapter 33A §§ 3321A – 3324A; Kansas Rev Stat §§ 40-3829 - 40-3830; 24-A Maine Rev. Stat. Ann. Chapter 56-C; Colo. Rev Stat. § 25-37-103.5; MD. ANN. CODE § 15-1628.1 and §15-1628.2; N.J.S.A. §17B:27F-2 (New Jersey); and Oregon Rev. Stat. § 735.534 and § 735.536);

(12) Prohibiting clawbacks (Ala. Code § 27-45A-5; MD. ANN. CODE § 15-1628.3; Minn. Stat. 62W.13; N.J.S.A. 17B:27-7 (New Jersey); and Oregon Rev. Stat. § 735.534);

(13) Affiliate compensation (Colo. Rev. Stat. § 10-16-122.3 and Ga. Code § 26-4-119 and § 33-64-11(a)(7));

(14) Prohibiting spread pricing (LA. REV. STAT. ANN § 22:1867 and Va. Code § 38.2-3467(D)); and

(15) Transparency provisions (24-A Maine Rev. Stat. Ann. Chapter 56-C and Texas Insurance Code § 1369.502).

Section 9. Severability

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of this Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

Section 10. Effective Date

This Act shall be effective [insert date]. A person doing business in this state as a pharmacy benefit manager on or before the effective date of this Act shall have [six (6)] months following [insert date that the Act is effective] to come into compliance with the requirements of this Act.

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