HIV+HEP
POLICY INSTITUTE

September 1, 2020

Andrew Stolfi/T.K. Keen
Chair, Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW
Suite 700
Washington, DC 20001

Re: Comments on NAIC Draft Pharmacy Benefit Manager Model Law

Dear Commissioner Stolfi, Deputy Administrator Keen, and PBM Subgroup Members:

Please find the attached comments by the **HIV+HEP Policy Institute** on the draft NAIC Pharmacy Benefits Manager (PBM) Model Law. The **HIV+HEP Policy Institute** is a leading HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. People with HIV and hepatitis rely on medications for their treatment and in the instance of hepatitis C, a cure. Access and affordability to these lifesaving medications are mainly controlled by PBMs.

We are pleased that the NAIC has turned its attention to the important role of PBMs in ensuring access to medications for patients living with HIV, hepatitis, and others who rely on prescription drugs. Our comments on the draft model law seek to improve it by: 1) ensuring greater transparency in the work of PBMs; 2) ensuring greater enforcement in any law that is adopted; 3) establishing that PBMs have a fiduciary relationship with health carriers; and 4) allowing PBMs to pass rebates on to consumers. Many of the proposed revisions align with those recommendations being submitted by the Consumer Representatives to the NAIC.

While most consumers interface with their insurance carriers, access and affordability of prescription drugs is largely controlled by PBMs. The three largest PBMs in the country who control 75 to 80 percent of covered lives[1], decide which drugs are on a plan's formulary. They also establish which tier a drug is placed on. People living with HIV, hepatitis, and many other chronic conditions, frequently must access drugs that PBMs arbitrarily place on specialty tiers. On this tier, patients are required to pay the highest cost-sharing levels, frequently in terms of co-insurance, which can be upwards to 50 percent of the list price of a drug. After placing all

[1] National Academy for State Health Policy, Pharmacy Benefit Manager Model Legislation: Questions and Answers, August 9, 2018, https://www.nashp.org/pharmacy-benefit-manager-model-legislation-questions-and-answers/.

HIV drugs, no matter their list cost, on the highest tier, the State of Florida found this practice to be discriminatory. Other states and the federal government have also stated that placing all drugs to treat a specific health condition on the highest tier to be discriminatory.

Rebates and other price concessions negotiated by the PBMs with drug manufacturers play a significant role in determining not only formularies and tiering but also prior authorization, step-therapy, and other utilization management techniques. These additional access restrictions present substantial barriers for people trying to access their medications prescribed by their providers to best meet patients' medical needs. PBMs also decide whether new and innovative medications are added to formularies and dictate the removal of approved medications from formularies, often done midyear, which force patients to switch from medically stable treatments.

While there has been rightfully great public attention made to the growing problem of high drug prices, PBMs play an increasingly significant role in why we in the United States have high drug prices. PBMs demand substantial rebates from manufacturers and negotiate fees from health insurers which determine drug formularies, cost tiering, and other utilization management techniques. A recent analysis of 2018 spending by the Berkeley Research Group found that health insurers, hospitals, pharmacies, and other health system payers received nearly 50 percent of what was spent on brand medicines in 2018, up from 33 percent five years ago.[2] While some of these rebates are statutorily mandated, the increase has been largely driven by higher rebates negotiated by PBMs. However, these rebates are very rarely passed onto consumers. Instead, the rebates incentivize manufacturers to set high list prices in order to account for the rebates that are expected by purchasers and actors in the drug supply chain.

Drug Channels Institute estimated for 2019 that the gross-to-net bubble—the dollar gap between sales at brand-name drugs' list prices and their sales at net prices after rebates and other reductions—reached $175 billion. This is an increase from $166 billion in 2018 and an increase of $73 billion from just five years ago.[3] PBMs have an important role in creating the gap between list and sales price.

To complicate matters, much of this is being done without any regulation and transparency. Laws aimed to ensure proper licensing and business practices of PBMs are critically important and many states have taken steps to do just that. After a reporting requirement law was passed in Texas, a recent study found that while PBMs received almost $857.5 million from pharmaceutical drug manufacturers, only $16 million was passed on to enrollees, while $177.6

[2] BRG, "Revising the Pharmaceutical Supply Chain: 2013 – 2018," January 9, 2020, https://www.thinkbrg.com/insights/publications/revisiting-the-pharmaceutical-supply-chain-2013-2018/.
[3] Drug Channels Institute, "The Gross-to-net Bubble Hit $175 Billion in 2019: Why Patients Need Rebate Reform," August 4, 2020, https://www.drugchannels.net/2020/08/the-gross-to-net-bubble-hit-175-billion.html.

million was retained by the PBMs as revenue and $663.9 million was passed onto the health issuers.[4]

For all of these reasons, the HIV+Hep Policy Institute strongly supports the NAIC in taking these steps to improve state insurance department regulation of PBMs "to promote, preserve and protect the public health, safety and welfare."

Clearly, it is long past time for state insurance commissioners to regulate PBMs. On behalf of patients across the country who are struggling to access and afford their prescription medications, we thank you for undertaking this process to draft a model PBM law and appreciate the opportunity to provide comments on the draft. We look forward to future deliberations as the NAIC moves forward with this important work.

Should you have any questions or comments, please feel free to contact me at cschmid@hivhep.org or (202) 462-3042. Thank you.

Sincerely,

Carl E. Schmid II
Executive Director

cc: Jolie Matthews

Attachment

[4] "Prescription Drug Cost Transparency, Pharmacy Benefit Managers," https://www.tdi.texas.gov/reports/documents/drug-price-transparency-PBMs.pdf.

Draft: 7/6/20
A new model

Comments are being requested on this draft by Tuesday, Sept. 1, 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, transparency, 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.

C. "Cost--sharing" means any expenditure required by or on behalf of a covered person with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

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

DC. (1) "Covered entity" means:

(a) A nonprofit hospital or medical service corporation, health insurer, health benefit plan or health maintenance organization;

(b) A health program administered by a department or a state in the capacity of a provider of health coverage; or

(c) An employer, a labor union or other group of persons organized in the state that provides health coverage to covered individuals who are employed or reside in the state.

~~(2) "Covered entity" does not include:~~

~~(a) A self-funded plan that is exempt from state regulation pursuant to federal law;~~

~~(b) A plan issued for coverage for federal employees; or~~

~~(c) A health benefit plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts~~.

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

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

GF. "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.

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

IH. "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~~J. "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.

K~~J~~. (1) "Pharmacy benefit manager" means a person, business or entity ~~,~~that, pursuant to a contract or under an employment relationship with a carrier, a self-insurance plan or other 3rd-party payer, either directly or through an intermediary, manages the prescription drug coverage provided by the carrier, self-insurance plan or other 3rd-party payer, including, but not limited to, processing and paying claims for prescription drugs, performing drug utilization review, processing drug prior authorization requests, adjudicating appeals or grievances related to prescription drug coverage, contracting with network pharmacies, controlling the cost of covered prescription drugs, or other prescription drug or device services. ~~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; or

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

L. "Rebate" means any and all payments that accrue to a pharmacy benefits manager or its covered entity client, directly or indirectly, from a pharmaceutical manufacturer, including but not limited to discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a covered entity client.

M. "Aggregate Retained Rebate Percentage" means the percentage of all rebates received from a manufacturer or other entity to a Pharmacy Benefit Manager for prescription drug utilization which is not passed on to Pharmacy Benefit Mangers' health carrier clients. The percentage shall be calculated for each health carrier for rebates in the prior calendar years as follows: a) the sum total dollar amount of rebates received from all pharmaceutical manufacturers for all utilization of covered persons of a health carrier that was not passed through to the health carrier; and b) divided by the sum total dollar amount of all rebates received from all pharmaceutical manufacturers for covered persons of a health carrier.

Section 4. Applicability

A. This Act shall apply to ~~a contract or~~ pharmacy benefit managers that manage prescription drug benefits for a health benefit plan issued, renewed, recredentialed, amended or extended by a covered entity on or after the effective date of this Act~~, including any covered entity that offers pharmacy benefits 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 the pharmacy benefit manager's licensure, any contract it holds with a covered entity 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 obtaining a license from the commissioner under this Act.

B. The commissioner ~~may~~shall 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 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 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 for one (1) year 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.

G. The Commissioner may suspend, revoke, or place on probation a Pharmacy Benefit Manager license under any of the following circumstances:

(1) The Pharmacy Benefit Manager has engaged in fraudulent activity that constitutes a violation of state or federal law:

(2) The Commissions received consumer complains that justify an action under this section to protect the safety and interests of consumers;

(3) The Pharmacy Benefit Manager fails to pay an application fee for the license; or

(4) The Pharmacy Benefit Manager fails to comply with a requirement set forth in this section.

H. If a Pharmacy Benefit Manager, acts without obtaining a license pursuant to this section, it will be subject to a fine of $5,000 per day for the period they are found to be in violation.

I. A pharmacy benefits manager's license may not be sold or transferred to a nonaffiliated or otherwise unrelated party. A pharmacy benefits manager may not contract or subcontract any of its services to any unlicensed nonaffiliated business entity.

Section 6. Gag Clauses Prohibited

A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies providing prescription drug coverage for ~~health benefit plans~~a covered entity, 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 or pharmacist may provide to a covered person information regarding the covered person's total cost for pharmacist services for a prescription drug.

C. 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.

D. 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 investigating or examining a complaint or conducting a review of a pharmacy benefit manager's compliance with the requirements under this Act.

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~~covered entity 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).

(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 shall require a pharmacy benefit manager to submit a report for the preceding calendar year stating that the pharmacy benefit manager is in compliance with the requirements of the act.

D. Investigate complaints of alleged violations of this Act.

E. The commissioner may impose a penalty of not more than $7,500 on a pharmacy benefits manager for each violation of this law.

Section 8. Transparency

A. Beginning X, 20XX, and annually thereafter, each licensed Pharmacy Benefit Manager shall submit a transparency report containing data from the prior calendar year to the [State Agency]. The transparency report shall contain the following information:

(1) The aggregate amount of all rebates that the Pharmacy Benefit Manager received from all pharmaceutical manufacturers for all covered entities that are clients of the Pharmacy Benefit Manager and for each covered entity of the Pharmacy Benefit Manager;

(2) The aggregate administrative fees that the Pharmacy Benefit Manager received from all manufacturers for all covered entities that are clients of the Pharmacy Benefit Manager and for each covered entity that is a client of the of the Pharmacy Benefit Manager;

(3) The aggregate retained rebates that the Pharmacy Benefit Manager received from all pharmaceutical manufacturers and did not pass through to covered entities;

(4) The aggregate retained rebate percentage as defined in Section 3; and

(5) The highest, lowest, and mean aggregate retained rebate percentage for all covered entity clients and for each covered entity client.

B.~~.~~ A Pharmacy Benefit Manager providing information under this section may designate that material as confidential and proprietary information. Disclosure, however, may be ordered by a court of this State for good cause shown or made in a court filing.

C. Within sixty (60) days of receipt, the [State Agency] shall publish the transparency report of each Pharmacy Benefit Manager on the agency's website in a way that does not violate State trade secrets law.

D. -The state Attorney General may impose civil fines and penalties of not more than $1,000 per day per violation of this section.

Section 9. Business Practices

A. A pharmacy benefit manager has a fiduciary duty to a health carrier client and shall discharge that duty in accordance with the provisions of state and federal law.

B. A pharmacy benefit manager shall perform its duties with care, skill, prudence, diligence, and professionalism.

C. A pharmacy benefit manager shall notify a health carrier in writing of any activity, policy, or practice of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the duties imposed in this section.

D. A pharmacy benefit manager may not require a cover person purchasing a prescription drug to pay a cost-sharing amount greater than the amount the insured would pay for the drug if he or she were to purchase the drug without coverage under a health benefit plan.

E. Any cost-sharing amount shall be attributable toward any deductible or annual out-of-pocket maximums under the covered person's health benefit plan

Section 10. Regulations

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

B. The regulations adopted pursuant to Subsection A may include but are not limited to the following:

(1) Pharmacy benefit manager network adequacy;

(2) Prohibited market conduct practices;

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

(4) Rebates; A pharmacy benefits manager shall remit all rebates received by or on behalf of a pharmaceutical manufacturer, developer or labeler, directly or indirectly, related to the use a prescription drug directly to the covered person at the point of sale to reduce cost-sharing to the covered person associated with the particular prescription drug.

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

(6) Compensation;

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

(8) Medical loss ratio (MLR) compliance;

(9) Affiliate information-sharing;

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

(11) Reimbursement lists or payment methodology used by pharmacy benefit managers;

(12) Clawbacks prohibited. A pharmacy benefit manager or representative of a pharmacy benefit manager may not make or permit any reduction of payment for pharmacist services by a pharmacy benefit manager or a covered entity directly or indirectly to a pharmacy under a reconciliation process to an effective rate of reimbursement, including but not limited to, generic effective rates, brand effective rates, direct and indirect remuneration fees or any other reduction or aggregate reduction of payment;

(13) Affiliate compensation.

(a) “Pharmacy benefit manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefit manager.

(b) A pharmacy benefit manager may not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefit manager reimburses a pharmacy benefit manager affiliate for providing the same pharmacist services; and

(14) Spread pricing prohibited.

(a) “Spread pricing" means the model of prescription drug pricing in which the pharmacy benefit manager charges a health benefit plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefit manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

(b) A pharmacy benefit manager is prohibited from conducting spread pricing in this state.

Drafting Note: Subsection B lists options for a state to consider in adopting regulations to implement the provisions of this Act. Not every option listed will be appropriate for every state.

Section 11. 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 12. 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.