



August 28, 2020

The Honorable Andrew R. Stolfi Chairman
PBM Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street, N.W. Suite 700
Washington, D.C. 20001-1512

Delivered via email to Jolie Matthews at jmatthews@naic.org

RE: [STATE] PHARMACY BENEFIT MANAGER LICENSURE AND REGULATION MODEL ACT

Dear Chairman Stolfi,

URAC is an independent, non-profit national health care organization focused on improving the quality of care delivered to patients through accreditation, education, and measurement. URAC has unique insight as it relates to the management of drug benefits as we are the premier accreditor of pharmacies and pharmacy benefit managers (PBMs). The largest PBMs in the country, including CVS Caremark, Express Scripts, and OptumRx, currently hold URAC accreditation. In fact, URAC's accredited PBMs account for over 90% of prescriptions filled in the United States. URAC also accredits more than 400 licensed pharmacies as specialty pharmacies across the country. Many of the pharmacies that have achieved URAC Specialty Pharmacy Accreditation are small, independent community pharmacies.

Since the launch of our pharmacy accreditation program over 13 years ago, URAC has garnered unique insight as the leading quality organization for both PBMs and pharmacies. URAC has substantive expertise and data on the following pharmacy and drug benefit management areas: drug utilization review; pharmacy and therapeutics committees; network adequacy; formulary design; dispensing rates and accuracy; drug safety; and transparency. We have shared our independent expertise related to pharmacies and PBMs with NAIC staff and regulators in the past during the development of the existing Health Carrier Prescription Drug Benefit Management Model Act (MDL#22), and would appreciate the opportunity to continue providing our insights in the future.

It is with this perspective that URAC expresses our support for the NAIC's efforts to increase the level of transparency in health care especially efforts focused on improving quality and timeliness of information provided to patients. While we do not have a position on the appropriate manner to elevate oversight of PBMs, we have worked with federal and state policymakers across the country to ensure that oversight does not inadvertently add administrative costs to the health care system and maintains the high-quality care patients demand.

Accreditation is commonly used by state departments of insurance across the country to augment the oversight of health care organizations operating within their state. We believe that accreditation may also serve as a useful tool to support oversight functions of PBMs. The NAIC's Uniform Health Carrier External Review Model Act (I-76) and the Utilization Review and Benefit Determination Model Act (I-73) provide useful references for how the NAIC and subsequent states have utilized accreditation to support enhanced oversight.

Corporate Member Organizations

- America's Health Insurance Plans
- Academy of Managed Care Pharmacy
- American Association of Preferred Provider Organizations
- American Health Quality Association
- American Hospital Association
- American Insurance Association
- American Medical Association
- American Nurses Association
- American Psychiatric Association
- Blue Cross Blue Shield Association
- Case Management Society of America
- National Alliance of Healthcare Purchaser Coalitions
- National Association of Insurance Commissioners
- Pharmaceutical Care Management Association

Harry Feder, MPA
Board Chairperson

Shawn Griffin, M.D.
President and CEO

Should accreditation be incorporated into this Model Act we recommend the following language be included in a new Section 5 (C):

- 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 adopt regulations establishing the licensing application, financial and reporting requirements for pharmacy benefit managers under this Act.
- C. *A pharmacy benefit manager that is accredited by a nationally recognized private accrediting entity that the commissioner has approved shall be deemed as having met the requirements of the relevant sections of this Act.*
 - 1. *The commissioner shall approve nationally recognized private accrediting entities that the commissioner has determined has accreditation standards that adequately and appropriately validate the operations of pharmacy benefit managers.*
 - 2. *The private accrediting entity shall file or provide the state with documentation that the pharmacy benefit manager has been accredited by the entity.*
 - 3. *The commissioner may adopt regulations establishing the process to approve pharmacy benefit manager accrediting entities.*

URAC's thirty-year history working closely with federal and state regulators to support oversight of managed care organizations has provided us with a deep understanding and appreciation for the need for transparency and line-of-sight among regulators. This experience coupled with our unique insight into the function of PBMs gives us concern about the proposed language in Section 8 of the Model Act. While we support commissioners having the authority to adopt regulations relevant to licensure, we believe many of the provisions included in Section 8(B) are more appropriately regulated via the health insurance carrier and not the PBM. As PBMs do not serve as the fiduciary administrator of a drug benefit, the carrier in which the PBM is contracted holds the ultimate responsibility for all financial, network, and/or quality requirements. Additionally, while the PBM may be held responsible for these provisions, it is solely as a contracted entity of the carrier. This relationship is appropriately addressed, including many of the provisions included in Section 8(B), in NAIC's Health Carrier Prescription Drug Benefit Management Model Act and the Health Benefit Plan Network Access and Adequacy Model Act. Specifically, Section 10 (Oversight and Contracting responsibilities) of the Health Carrier Prescription Drug Management Model Act states:

- A. A health carrier shall be responsible for monitoring all activities carried out by, or on behalf, of the health carrier under this Act and for ensuring that all requirements of this Act and applicable regulations are met.
- B. Whenever a health carrier contracts with another person to perform activities required under this Act or applicable regulations, the commissioner shall hold the health carrier responsible for monitoring the activities of that person with which the health carrier contracts and for ensuring that the requirements of this Act and applicable regulations with respect to that activity are met.

Corporate Member Organizations

- America's Health Insurance Plans
- Academy of Managed Care Pharmacy
- American Association of Preferred Provider Organizations
- American Health Quality Association
- American Hospital Association
- American Insurance Association
- American Medical Association
- American Nurses Association
- American Psychiatric Association
- Blue Cross Blue Shield Association
- Case Management Society of America
- National Alliance of Healthcare Purchaser Coalitions
- National Association of Insurance Commissioners
- Pharmaceutical Care Management Association
- Harry Feder, MPA**
Board Chairperson
- Shawn Griffin, M.D.**
President and CEO

As such, we recommend that provisions of a PBM license be limited to those components that do not require the sharing of data or contractual terms that may be considered the proprietary information of the insurance carrier. The provisions as written in Section 8 would require the PBM to share health carrier data and financial information that it may or may not have the authority to share. Further, this approach is a departure from common practices to license other managed care entities.

We recommend that the NAIC and regulators approach PBM licensure in a similar manner to the approach to license and regulate utilization review organizations under the Utilization Review and Benefit Determination Model Act or in a manner specified in the Uniform Health Carrier External Review Model Act.

We believe that submission of specific information in order to be licensed in much the same way that utilization review organizations must register with the state is an appropriate construct for PBM licensure. However, we believe it is critical for regulators to acknowledge that the PBM is serving as a contracted entity with the health carrier and the health carrier bears ultimate responsibility for the delivery of the drug benefit. Therefore, information and data owned by the health carrier should not be expected to be reported by the PBM. This type of information, owned by the carrier but generated through the activity of their contracted PBM, includes much of the information listed in Section 8 (B) specifically: network adequacy, rebates, compensation, reimbursement lists or payment methodology, and clawbacks. Given this, URAC cautions the NAIC's adoption of Section 8(B) of the current draft of the Pharmacy Benefit Manager and Regulation Model Act.

In closing, URAC has extensive knowledge of the interplay between PBMs and its contract pharmacies given our role evaluating the deployment of key PBM functions regulated by the proposed rule, including required disclosures, appeal processes, and pharmacy network management. URAC stands ready to be of assistance and an expert resource to the NAIC in its ongoing efforts to increase pharmacy transparency and access.

Should you have any questions or if there is anything URAC can do to provide assistance, please do not hesitate to contact Aaron Turner-Phifer, Vice President of Government Relations and Policy at aturner-phifer@urac.org or by phone at 202-326-3957.

Sincerely,

Shawn Griffin, M.D.

Shawn Griffin, M.D.
President and CEO

Corporate Member Organizations

- America's Health Insurance Plans
- Academy of Managed Care Pharmacy
- American Association of Preferred Provider Organizations
- American Health Quality Association
- American Hospital Association
- American Insurance Association
- American Medical Association
- American Nurses Association
- American Psychiatric Association
- Blue Cross Blue Shield Association
- Case Management Society of America
- National Alliance of Healthcare Purchaser Coalitions
- National Association of Insurance Commissioners
- Pharmaceutical Care Management Association
- Harry Feder, MPA
Board Chairperson
- Shawn Griffin, M.D.
President and CEO