



Report of the Task Force on the Regulation of Pharmacy Benefit Managers

NOTE: The NABP Executive Committee accepted all of the recommendations of this Task Force with the exception of Recommendation 5:

- **Upon review of the information pertaining to the Recommendation, the Executive Committee determined that the development of a patient reporting system for collecting consumer concerns regarding Pharmacy Benefits Managers related to the practice of pharmacy to be outside the realm of NABP and that the cost and infrastructure required for NABP to internally develop such a system is prohibitive.**

Members Present:

Patricia Donato (NY), *chair*; Buford Abeldt (TX); Julia Eaton (VT); Suzan Kedron (TX); LuGina Mendez-Harper (NM); Jeffrey Mesaros (FL); Steve Parker (MS); Richard Palombo (NJ); Laura Schwartzwald (MN); Brenda Warren (TN); Cindy Warriner (VA); Stuart Williams (MN).

Others Present:

Hal Wand, *Executive Committee liaison*; Carmen Catizone, Melissa Madigan, Eileen Lewalski, Heather McComas, Cameron Orr, *NABP staff*.

Introduction:

The Task Force on the Regulation of Pharmacy Benefit Managers met October 22-23, 2013, at NABP Headquarters. This task force was established in response to Resolution 109-3-13, Review and Revise the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy Regarding Pharmacy Benefit Managers, which was approved by the NABP membership at the Association's 109th Annual Meeting in May 2013.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing current state laws and regulations addressing the regulation of pharmacy benefit managers (PBMs).
2. Identify activities in which PBMs engage that may be construed to fall under the definition of the Practice of Pharmacy.
3. Review and, if necessary, recommend amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to address appropriate regulation of pharmacy benefit managers.

Recommendation 1: NABP Should Amend the Model Act

The task force recommends that NABP amend the *Model Act*. Revisions are denoted below by underlines and ~~striketroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

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Section 105. Definitions.

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- (x4) “Pharmacy Benefits Manager” means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.
- (y4) “Pharmacy Benefits Processor” means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, but that does not engage in or direct the Practice of Pharmacy.

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Section 105(x4) (and [y4]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that may encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management ~~intervention~~
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment
- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management

- Maintenance of confidential patient information
- Direction or design of the clinical programs for a pharmacy or a group of pharmacies

Background:

As a ground rule for its work, the task force agreed that all discussions and recommendations should remain within the scope of the practice of pharmacy and the protection of public health. Task force members recognized that many concerns surrounding PBMs relate to contractual issues, payment, or coverage, and as such, fall outside the purview of the boards of pharmacy. The group acknowledged the challenges involved in delineating which PBM-related issues fall strictly under the jurisdiction of the boards of pharmacy and expected that areas of ambiguity would arise in its discussions.

The task force then began addressing its charge by reviewing the reports of the 1999 Task Force on Licensing of Pharmacy Benefit Managers and the 2000 Task Force on Model Guidelines for Formulary Development. The task force discussed and ultimately agreed with the existing *Model Act* definitions for Pharmacy Benefits Managers and Pharmacy Benefits Processors that were created by the 1999 task force. The group recommended that the language in the associated Comment section be generalized to avoid the implication that the listed activities always constitute the practice of pharmacy by PBMs. After agreeing that formulary development may involve clinical decision-making and may constitute the practice of pharmacy, the task force recommended that the language related to formularies be broadened to include all aspects of formulary management, not just interventions. Finally, in recognition that many PBMs design the clinical programs for their associated mail order and/or network pharmacies, the task force recommended that direction and design of clinical programs for pharmacies be added to the list of activities that may constitute the practice of pharmacy by PBMs.

Recommendation 2: NABP Should Encourage States to Adopt Existing *Model Act* Language Pertaining to PBMs

The task force recommends that NABP encourage states to adopt existing *Model Act* language pertaining to PBMs.

Background:

After a thorough discussion of the current impact of PBM activities on the practice of pharmacy, the task force affirmed the 1999 task force's recommendation that PBMs engaged in the practice of pharmacy should be licensed and regulated by state boards of pharmacy. The task force supported the other findings and recommendations of both previous task forces.

Task force members noted that boards of pharmacy may not be aware of the work of the previous task forces or the existing provisions in the *Model Act* pertaining to the licensure of PBMs. The task force therefore agreed that NABP should remind its member boards of the existing sections of the *Model Act* addressing PBMs and encourage states that have yet to do so adopt this language in their state pharmacy practice acts.

Recommendation 3: NABP Should Monitor Member States' Initiatives to Regulate the Activities of PBMs as They Relate to the Practice of Pharmacy, Alert Members to

Available NABP Resources to Assist with Regulation Development, and Support the Creation of a State Ombudsman Position for PBM Issues

The task force recommends that NABP monitor member states' activities and initiatives to regulate PBMs in order to determine if an expansion of the boards' authority in these areas is appropriate. The task force further recommends that NABP support the expansion of the authority of state and federal agencies overseeing these activities to ensure that the health and safety of the patient is a primary consideration. Wherever possible, the task force recommends that states institute an ombudsman for PBM issues to assist patients and ensure that their interests and complaints are appropriately received and managed. The task force also recommends that member boards be alerted to the availability of NABP resources to assist in the drafting of rules/regulations pertaining to PBMs.

Background:

The task force acknowledged that the issues identified by the 1999 and 2000 task forces related to patient access, medications excluded from coverage, and formulary changes impacting patient care remain legitimate concerns and although involve payment and coverage they may also relate to the practice of pharmacy. The task force recognized that while PBM contractual and payment issues may impact patient care, they are outside the scope of authority of the boards of pharmacy. To address these continuing challenges, some states are now regulating PBMs through their boards of pharmacy. Notably, PBMs doing business in the state of Mississippi have been regulated by the Mississippi Board of Pharmacy since 2011. Under the Mississippi regulations, PBMs must obtain a license from the Board before operating in the state; the Board also coordinates financial examinations of PBMs.

Task force members discussed the many areas of uncertainty pertaining to this new regulation of PBMs by state boards of pharmacy, including issues related to the scope, purview, and authority of the boards. While it is too early to determine the ultimate outcome of these new efforts, the task force concurred that NABP should actively monitor states' efforts related to PBM regulation and, once this area is more fully evolved, determine if expansion of the boards' authority is warranted. Additionally, NABP should remind any states interested in pursuing new regulations in this area of available NABP resources and support. NABP's Government Affairs staff can assist states with drafting rules and regulations, offer support and education, and testify before legislative committees.

To address unmet patient needs in the area of PBM payment and contractual issues beyond the scope of pharmacy, the task force recommended that states appoint an ombudsman to assist consumers in resolving questions and complaints related to PBM services. Task force members agreed that an ombudsman, ideally, should be positioned within the board of pharmacy because of the board's expertise and primary mission of protecting the public health. However, the task force acknowledged that it may not always be possible to secure an ombudsman position in the board of pharmacy and did not want to exclude the creation of this position within another state agency, provided that oversight is effective.

Recommendation 4: NABP Should Acknowledge That Certain PBM Activities and Medication Therapy Decisions May Impact the Practice of Pharmacy and Require Accountability

The task force recommends that NABP acknowledge that there may be activities and medication therapy decisions implemented through pharmacy benefit plans and PBMs that impact the practice of pharmacy and require accountability.

Background:

The task force reviewed the PBM activities listed in the Comment to Sections 105(x4) and 105(y4) of the *Model Act* and agreed that many of these examples may be the practice of pharmacy by PBMs and may impact patient care. In particular, task force members pointed to prior authorization and formulary decisions as examples of PBM activities that can affect pharmacists' ability to provide patients with needed medications and care. Given the potential effect on public health of these PBM activities, the task force recommended that NABP acknowledge the need for accountability on these issues. By encouraging states to adopt *Model Act* language regarding PBM licensure as described in Recommendation 2, NABP will be supporting accountability and increased oversight of pharmacy practice by PBMs. Additionally, the data-gathering initiative described next in Resolution 5 will further NABP's efforts to protect the public health related to PBM activities.

Recommendation 5: NABP Should Collect Data on Patient, Pharmacy, and Board of Pharmacy Concerns Related to Prescription Drug Benefits Via Survey, Provide These Data to the States, and Educate Consumers and Licensees About PBMs Through the AWA Rx E Program

The task force recommends that NABP collect data on patient, pharmacy, and board of pharmacy concerns related to pharmacy benefits via survey and provide this information to the states. Additionally, the task force recommends that NABP utilize the AWA Rx E program to educate patients and licensees about PBMs and the availability of this survey tool to report applicable concerns.

Background:

The task force struggled with how to resolve the ongoing concerns regarding PBM activities within the scope of the authority of the boards of pharmacy. Task force members noted that concrete statistical data documenting consumer concerns with PBMs are necessary to convince legislators to take action on these issues and increase regulatory oversight of PBMs. There is no mechanism currently in place to collect consumer concerns regarding PBMs; therefore, the task force suggested that NABP serve as the conduit to gather this information. NABP staff indicated that there is precedence for the Association to function as a data clearinghouse, as illustrated by NABP's monitoring of rogue Internet drug outlets and collection of licensee disciplinary information. NABP's efforts to collect PBM-related data will provide weight and legitimacy to consumer concerns surrounding PBMs.

The task force discussed several important elements of the proposed data-collection initiative, which included the following:

- **Mission of the program:** The NABP program will operate exclusively as an information-gathering tool, not a dispute-resolution process, and this will need to be explicitly stated to consumers accessing the system. The program will focus solely on concerns related to the practice of pharmacy and will not address coverage or payment issues. The task force stressed that this must be clearly communicated to consumers and

suggested that NABP provide examples of the types of issues to be tracked by the system to enhance consumer understanding of the program.

- **Information sharing and confidentiality concerns:** For this program to have the greatest impact and scope, information will need to be shared between NABP and the boards of pharmacy. The task force recommended that NABP's reporting mechanism be structured to provide consumers with the option to concurrently submit their PBM-related concern to the appropriate state board of pharmacy. Similarly, task force members indicated that boards of pharmacy should share any PBM-related consumer reports with NABP. Consumers will need to authorize this information sharing, or the data will need to be appropriately de-identified prior to being shared with other organizations.
- **Data aggregation:** The program will collect and report PBM data both nationally and by state. This will allow for the identification of any state- or region-specific issues related to PBMs.
- **Participation:** To ensure that the program gathers the most robust data, all states will be highly encouraged to participate.
- **Education and Outreach:** Both NABP and the boards of pharmacy will need to publicize the PBM data reporting system to maximize its reach and utility. Boards of pharmacy will be responsible for informing licensees about the program, and licensees can then in turn communicate the information to consumers via personal interactions and signs posted in pharmacies. NABP will raise awareness about the program through multiple communication vehicles, to include newsletters, electronic news mailings, and the AWARe Web site.
- **Data Analysis and Review:** After the collection of sufficient data, NABP should commission another task force to review and analyze the information and recommend further actions related to PBMs, if warranted.

The task force also addressed the need for education regarding PBMs among both consumers and licensees. Task force members indicated that many patients are unaware that a PBM, not their primary health insurer, administers pharmacy benefits. Additionally, consumers often do not understand their pharmacy benefits and corresponding limitations in medication coverage and access. Pharmacists and their staff also may not be fully aware of PBM operations and how plan restrictions can impact patients' access to medications.

To address these gaps in knowledge, the task force recommended that NABP create educational resources for both consumers and licensees regarding PBMs and their activities. Through the AWARe program, NABP can increase consumers' and licensees' understanding of PBMs, as well as publicize NABP's PBM reporting system. Task force members stressed that any materials intended for a consumer audience should use simple, clear language. NABP can also use various communication outlets, including newsletters and electronic mailings, to raise awareness of the new PBM content available through the AWARe program.