



Report of the Task Force on the Definition of a Patient-Pharmacist Relationship

***NOTE: The NABP Executive Committee accepted the recommendations of this task force with the following exception:**

Recommendation 3 – The Executive Committee recognizes that pharmacy regulation is continuously changing and appreciates the spirit of the recommendation. However, the Executive Committee does not support the adoption of a Code of Ethics into the *Model Act* at this time.

Members Present:

Dennis Wiesner (TX), *chair*; Sabrina Beck (NE); Fiona Karbowicz (OR); Sam Lanctin (NB); Leo Lariviere (RI); Dennis McCallister (AZ); Jeff Mesaros (FL); Steve Saxe (WA); Deena Speights-Napata (MD); Christian Tadrus (MO); Cindy Warriner (VA); Tim Koch (AR); Donna Wall (IN).

Others Present:

Susan Ksiazek, *Executive Committee liaison*; Ralph Loomis, Federation of State Medical Boards (FSMB); Carmen Catizone; Melissa Madigan; Eileen Lewalski; Maureen Schanck; Angelica Rutkowski, *NABP staff*.

Introduction:

The Task Force met on September 18-19, 2017, at NABP Headquarters in Mount Prospect, IL. This task force was established in response to Resolution 113-2-17, Definition of a Patient-Pharmacist Relationship, which was approved by the NABP membership at the Association's 113th Annual Meeting in May 2017.

Review of the Task Force Charge:

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

1. Review existing state laws and regulations that address the patient-pharmacist relationship.
2. Examine information related to the definition of patient relationships with pharmacists concerning the pharmacist's role in patient care services, such as, but not limited to disease state manager and patient care advocate.

3. Recommend, if necessary, amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to include a definition of a patient-pharmacist relationship.

Recommendation 1: NABP Should Not Amend the *Model Act* to Include a Definition of Patient-Pharmacist Relationship at this Time.

After extensive review and deliberation, the task force members recommend that NABP should not amend the *Model Act* to include a definition of “patient-pharmacist relationship” at this time.

Background:

The task force members deliberated about what constitutes a valid “patient-pharmacist relationship.” They noted that the “pharmacist-patient relationship” is presently assumed and implicitly defined by standards of care that for the most part are related to the dispensing of a prescription. Members reviewed state laws and rules for guidance and examples of current usage of such a definition. “Pharmacist-patient relationship” is currently used by a handful of states in limited circumstances as required for access to controlled substance usage information and for providing care in home health care settings. The members agreed that if a definition is adopted by states, it should be defined as a “patient-pharmacist relationship,” as per the NABP resolution, to keep the patient as the primary focus of the relationship.

While attempting to define “patient-pharmacist relationship,” the task force members questioned when a “patient-pharmacist relationship” begins, ie, if it can be assumed to occur with the presentation of a prescription, when asked about an OTC product? Also, they asked if the relationship is between the patient and the pharmacist on duty, the pharmacy, or the entire chain, if applicable. They learned from the FSMB representative, Dr Ralph Loomis, that the “patient-physician relationship” begins when a physician assumes care. As health care evolves to recognize the patient as the center of team-based care, a multi-disciplinary approach to patient care will become the standard, with the pharmacist as an integral component. Dr Loomis explained that, in the future, a team-based care commission comprised of various regulatory boards will regulate their corresponding health care providers and their involvement in patient outcomes. However, members countered that the environment of a physician versus a community pharmacist, in particular, varies considerably because a physician setting allows for the mutual consent of a patient-physician relationship to be easily identified. Further, although there are potential environments today where patient-pharmacist relationships are being formulated, the members pointed out that these opportunities are not widespread.

The task force deliberation lead to a request for input from Dale Atkinson, NABP outside legal counsel. He explained that a patient-pharmacist relationship is one that is currently implied and not explicit. He noted that the potential for liability exists with an implied relationship and that a definition may delineate the liability further. Atkinson questioned the role of the patient in

establishing the relationship. Therefore, the discussion also included conversation about how the patient might consent to the relationship. Would consent always be implied or must it be explicitly stated? Along these lines, the termination of a “patient-pharmacist relationship” was also discussed. How might the relationship be terminated and when? Also discussed was the responsibility associated with the relationship, considering factors such as transient patients and if a minimal amount of activity is still expected of a pharmacist as the patient transitions through various levels of health care. In addition, the task force members also asked more general questions, ie, “Will a definition of ‘patient-pharmacist relationship’ improve patient care?” and “Will it address deficiencies in responsibility, accountability, and continuity of care?”

Some members suggested that a definition could serve to enhance patient care by acknowledging the pharmacist’s obligation to the patient beyond an encounter involving prescription dispensing. A stated definition could also provide pharmacists with credibility to practice at the top of their profession, while giving boards of pharmacy regulatory authority to hold pharmacists accountable beyond product-focused care.

The task force discussion also centered on the implications of having a definition of “patient-pharmacist relationship” in the *Model Act*, specifically it was concerned with unintended consequences. Members suggested that if boards of pharmacy define a “patient-pharmacist relationship,” a standard of care may be inferred that pharmacists are not currently in a position to meet, especially in the community pharmacy setting. Payers may then use the patient-pharmacist relationship standard to deny or limit financial reimbursement, which would impact access to care. Would pharmacists need to have access to electronic medical records and care planning records in order to meet the standard of care and be held accountable and liable for patient outcomes? The task force members expressed their concern about possibly creating a universal patient care standard that pharmacists currently are unable to meet in all practice settings. Members also wondered how a “patient-pharmacist relationship” definition would be determined in everyday community pharmacy settings. Would a relationship be defined by having one active prescription on file at a pharmacy, or could a relationship still exist if a patient was dispensed a prescription several years ago?

Members noted that, beyond inspiring pharmacists to practice more patient-centered care, having a definition of “patient-pharmacist relationship” in regulation may also provide payers an avenue to deny claims if pharmacists do not properly document that a relationship exists, again decreasing access to care for many patients. The task force opined that it was not within the scope of its charge to address the impact of defining a patient-pharmacist on the ability to be recognized and reimbursed as a provider; however, access to non-dispensing pharmacy services was viewed by the task force as positively impacting patient safety. Some members suggested that pharmacists’ trade associations are more appropriately positioned to develop and endorse a definition of “patient-pharmacist relationship” to further the profession than regulatory boards and associations like NABP.

Recommendation 2: NABP Should Assist State Boards of Pharmacy in Revising the Current Definition of and Responsibilities for the Provision of “Pharmacist Care Services” Beyond the Current Regulatory Oversight of Pharmacists’ Responsibilities Associated with Dispensing.

After reviewing current language in the *Model Act*, task force members unanimously agreed that NABP should assist state boards of pharmacy in revising the current definition and responsibilities for the provision of “Pharmacist Care Services” beyond the current regulatory oversight of pharmacists’ responsibilities associated with dispensing including, but not limited to, areas such as team-based practice, direct patient care, and other patient-centered services.

Background:

The task force identified that an expanded scope of practice and team-based care will dramatically impact, perhaps necessitate, the need to more formally define the present concept of “pharmacist care services.” The members determined that, in lieu of adding a new definition of “patient-pharmacist relationship” in the *Model Act*, NABP should collaborate with member pharmacy boards to possibly revise the definition of “pharmacist care services” to encompass emerging practices and expand their geographic application. The new definition would not contravene the present definition and associated standards of care but would be utilized to establish the pharmacist’s role in the expanded responsibilities and team-based care when needed. As pharmacists play a key role in team-based care and chronic disease state management, the pharmacist’s individual responsibility will have to be delineated and overseen by the state board of pharmacy in concert with other collaborating health professional regulatory boards.

As members pondered whether the current lack of a definition of “patient-pharmacist relationship” impedes patient care, the task force focused attention on the lack of specific regulatory language to oversee certain pharmacists’ responsibilities, such as those involved in over-the-counter drug recommendations. Members also recognized that nontraditional pharmacy services are not universal from state to state. With this in mind, the task force recommended that the definition of “pharmacist care services” should be reviewed for broader application.

Recommendation 3: NABP to Explore an Alternative Approach to Regulation Based on the Development and Adoption of a Code of Ethics into the *Model Act*.

The task force unanimously recommended that NABP explore an alternative approach to regulation based on the development and adoption of a Code of Ethics into the *Model Act* to support the evolution of pharmacy regulation and address the accountability and responsibility of the pharmacist.

Background:

When the task force members questioned what constitutes a standard of care for pharmacists, a discussion about what place a code of ethics has in the regulation of pharmacy practice

followed. Members learned that Canadian Pharmacy Regulatory Authorities have Codes of Ethics to outline appropriate pharmacist practice. Adherence to the Code by members is made mandatory via legislation in each province. The task force contemplated whether pharmacy regulation in the United States should be based on a standard of care and a code of ethics, which is how the practice of medicine is regulated. Members envisioned that pharmacy regulation will need to evolve beyond dispensing rules as pharmacists become more involved in direct patient care activities, such as team-based care. Task force members expressed that it may also be time to change the philosophy and fundamentals of pharmacy regulation, from detailing what is and is not permitted to determining if appropriate care was given. Members decided that it behooves state pharmacy boards to also incorporate what constitutes professional and unprofessional conduct into pharmacy laws and rules. As pharmacists practice at the top of their profession, boards of pharmacy will have to adapt regulations to encompass the pharmacist as being a primary access point to health care and a key provider for chronic disease state management. Members concluded that a pharmacist code of ethics should move beyond language used by trade associations and should be developed and referenced by pharmacy regulatory boards.