# Report of the Task Force to Develop Regulations Based on Standards of Care

**Members Present:**
Andrew Funk (IA), *chair;* Allison Vordenbaumen Benz (TX); Lemrey "Al" Carter (IL); Cindy Fain (AR); Robert Graves (NC); Donna Horn (MA); Kristina Jonas (ID); Donald "Donnie" Lewis (TX); Carrie Phillips (VT); Kristen Snair (AZ); Edmund Taglieri (MA); Donna Wall (IN); Stuart Williams (MN).

**Others Present:**
Bradley S. Hamilton, *Executive Committee liaison;* Maureen Cahill (NCSBN); Ian Marquand (FSMB); Daniel Robinson (AACP), *guests;* Carmen Catizone; Melissa Madigan; Eileen Lewalski; Maureen Schanck; Angelica Alderton, *NABP staff*.

**Introduction:**
The Task Force met on October 9-10, 2018, at NABP Headquarters in Mount Prospect, IL. This task force was established in response to Resolution 114-4-18, Task Force to Develop Regulations Based on Standards of Care, which was approved by the NABP membership at the Association's 114th Annual Meeting in May 2018.

**Review of the Task Force Charge:**
Task force members reviewed their charge and accepted it as follows:

1. Explore the feasibility of transitioning from prescriptive rule-based regulations to a model that defines regulation through a standard of care process.
2. Discuss the necessary tools (eg, peer review committees, enforcement approaches) that boards of pharmacy would need to develop and utilize to achieve this transition.

**Recommendation 1: NABP Should Encourage State Boards of Pharmacy to Review Their Practice Acts and Regulations, Consistent With Public Safety, to Determine What Regulations Are No Longer Applicable or May Need to Be Revised or Eliminated While Recognizing Evolving Pharmacy Practice.**

The task force recommends that NABP encourage state boards of pharmacy to review their practice acts and regulations to determine what regulations are no longer applicable or may

need to be revised or eliminated, while recognizing evolving pharmacy practice and ensuring public protection.

**Background:**
The task force discussed how antiquated regulations can be a barrier to evolving pharmacy practice and, consequently, improved patient care. The task force recommended that boards of pharmacy review their rules for overly prescriptive language. Boards should consider a process for identifying rules that are obsolete or excessively burdensome. Rule waiver and variance requests or pilot project requests were mentioned as possible prompts for boards to review rules for outdated rules, and to assess those rules for their impact on improved pharmacist care delivery and patient safety. During such a review, boards may want to consider evaluating data from pilot projects to determine their challenges and successes. The task force also discussed the possibility of boards making it known to their licensees, where applicable, that rule waivers or pilot projects are an option to advance public health, when warranted. All agreed that whatever approach a board of pharmacy takes, it will need to review current laws and rules for adequate public protection. The task force stressed that the boards of pharmacy should act prudently in protection of the public health and should not regulate to simply promote the profession of pharmacy. It was agreed that a shift in regulation should be grounded, feasible, and justifiable.

**Recommendation 2: NABP Should Encourage State Boards of Pharmacy to Consider Regulatory Alternatives for Clinical Care Services That Require Pharmacy Professionals to Meet the Standard of Care.**

The task force recommends that NABP encourage state boards of pharmacy to consider regulatory alternatives for clinical care services that require pharmacy professionals to meet the standard of care.

**Background:**
The task force members and guests discussed the evolution of health care delivery and pharmacist roles that developed beyond the traditional prescription delivery model. Members determined that pharmacy practice is often segmented into distinct services encompassing such areas as traditional dispensing, drug control and security, and medication therapy management (MTM). With this in mind, the task force members and guests reasoned MTM and similar “cognitive services” may evolve from present requirements to a standards of care-based regulation. That regulatory evolution would not eliminate all existing requirements. For example, the task force members and guests agreed that because of the unique structure of pharmacy practice, pharmacy operations - the storage, preparation, final verification, and delivery of a medication or device to a patient or patient’s agent - are best regulated through more clear-cut and straightforward language. At the present time, the task force members and guests agreed that the majority of pharmacy boards and pharmacists rely upon and prefer this approach.

The task force discussion also included a review of different regulatory approaches that are currently being applied for other professions such as nursing and medicine. Those various models include standards of care-based regulation, right-touch regulation, and evidence-based regulatory models. Nursing and medicine have been traditionally regulated based on one or a combination of the above models. The inclusion of pharmacists in team-based care and gaining the authority to prescribe in a growing number of states, the traditional manner of regulating pharmacy by focusing primarily on pharmacy operations may need to be reviewed when it comes to the provision of clinical services across multiple states.

Several members expressed their concern about adopting a standards of care-based regulation model for all aspects of the practice of pharmacy. Some wondered how the boards of pharmacy can still adequately protect the public if "permissionless innovation" is applied to health care delivery. The task force expressed the need to maintain safeguards for patient care while still allowing pharmacy professionals to practice at the top of their profession.

With "permissionless innovation" as the foundation, the task force learned that the Idaho State Board of Pharmacy adopted changes in the state pharmacy practice act and rules that defines a pharmacist's scope of practice to allow a pharmacist to engage in acts not expressly prohibited by law as long as such acts are consistent with the licensee's education, training, or practice experience, and if performance of the act falls within the accepted standard of care.

Currently, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* takes a varied approach to regulation. Prior task forces have addressed a "regulating for outcomes" model, thus *the Model Act* includes language that requires a focus on patient outcomes. Along these lines, the *Model Act* also includes a section on continuous quality improvement programs that, like standards of care-based regulation, is based on a peer review process to assess and improve patient outcomes. The *Model Act* also includes more direct and specific language that defines standards of care and processes that pharmacists must adhere to when providing clinical care services such as MTM, counseling, emergency drug dispensing, drug administration, drug utilization review, and collaborative pharmacy practice, and some states may want to take this approach to the regulation of clinical care services.

The task force noted that the state pharmacy boards are engaged in determining and defining standards of care within the current regulatory environment. State pharmacy boards have not typically engaged in the actual development of clinical standards of care, which are most appropriately developed by standards setting organizations, clinical experts, and other entities recognized by the boards of pharmacy and NABP. This should be taken into consideration when considering regulatory alternatives for the oversight of pharmacist care services.

**Recommendation 3: NABP Should Collaborate With States That May Adopt Standards of Care-Based Regulations to Identify, Monitor, and Disseminate Outcomes.**

The task force recommends that NABP collaborate with states that may adopt standards of care-based regulations to identify, monitor, and disseminate outcomes to member boards of pharmacy.

**Background:**
As states consider adopting standards of care-based regulation for pharmacy, the task force recommended that NABP follow this activity and collaborate with such states regarding their experiences and the impact on patient care. As part of the discussion, members questioned which tools should be used to enforce standards of care-based regulation and how licensees should be held accountable to practice to such standards. It was suggested that NABP and the boards of pharmacy consult with the boards of medicine and nursing to determine effective tools for enforcement and accountability

The task force concluded that if standards of care-based regulation is determined to maintain patient safety, NABP should develop a path forward for boards that are considering taking a similar approach to regulation. The task force realized that the path forward may not be developed for quite some time until metrics-based information, such as number of complaints, incidents of harm, and patient outcomes, becomes available.

**Recommendation 4: NABP Should Develop a Definition of "Standards of Care" Based in Evidence to Be Included in the *Model Act.***

The task force recommends that NABP develop a definition of "standards of care" that is evidence-based to be included in the *Model Act* to foster uniformity.

**Background:**
The task force recommended that NABP include a definition of "standards of care" in the *Model Act* that states can utilize if they choose to adopt this type of regulation. Members noted that in the *Model Act*, under Section 16, Unprofessional Conduct, there currently exists grounds for discipline based on " . . . engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist" With this in mind, there has likely already been discussion and evaluation of pharmacist standards of care by boards of pharmacy, so board members may already be familiar with its application.

There was also discussion among the members as to whether the task force could assume that "standards of care" and "standards of practice" are the same thing. The task force assumed that they were; however, members recommended that NABP clarify whether the terms are interchangeable. As part of the discussion, members learned that the boards of medicine routinely investigate licensees for professional incompetency or failure to act in a manner that harms the patient by violating a standard of care.

**Recommendation 5: NABP Should Monitor the Adoption of the Standards of Care-Based Regulation Model by the States and, if and When Appropriate, Consolidate and Share Information and Tools Obtained From Professional Regulatory Groups and Relevant Stakeholders for Regulating Standards of Care-Based Practice.**

The task force recommends that NABP monitor the adoption of the standards of care-based regulation model and, if and when appropriate, consolidate and share information and tools obtained from professional regulatory groups and relevant stakeholders for regulating standards of care-based practice for states that wish to obtain more information.

**Background:**

Members and guests contemplated how to best assist state pharmacy boards that wish to pursue a standards of care-based regulation model. The task force suggested that barriers to implementing standards of care-based regulation need to be researched and identified. Furthermore, representatives from the Federation of State Medical Boards (FSMB) and the National Council of State Boards of Nursing (NCSBN) explained that the boards of pharmacy, like the boards of medicine and nursing, will have to rely on expert testimony and practice standards established by specialists and/or specialty boards in determining standards of care for pharmacy. Therefore, the task force recommended that NABP collaborate with FSMB and NCSBN as an initial step to develop tools for the boards of pharmacy to use to evaluate licensees to determine adherence to established standards of care.

The task force also recognized that if the pharmacy boards choose to hold licensees accountable to a standard of care, the boards will need guidance on how inspections, inspection forms, board proceedings, hearings, peer reviews, and employer policies and procedures contribute to the establishment of standards of care and how that fits into regulation. A tool kit developed by NABP to assist the boards with standards of care-based regulation can include such information as how to obtain and vet expert witnesses for appropriateness in pharmacy board hearings and how to use the Daubert[1] standard for analyzing expert testimony before admitting it in federal court. This tool kit can also serve as a repository of information to build on and be continuously updated. Task force members concluded that the pharmacy boards adopting standards of care-based regulations will have a greater burden considering the need for peer review processes and expert witnesses. All this information could be disseminated through various NABP communication vehicles.

[1] Daubert vs Merrell Dow Pharmaceuticals 1993.