# Report of the Task Force on the Regulation of Pharmacist Care Services

**Members Present:**

Joel Thornbury (KY), *chair;* Allison Benz (TX); Reginald "Reggie" Dilliard (TN); Kamlesh "Kam" Gandhi (AZ); John Marraffa, Jr. (NY); Dennis McAllister (AZ); Lenora Newsome (AR); Phyllis Stine (TX); Ellen Vick (NC).

**Others Present:**

Hal Wand, *Executive Committee liaison*; Robert Braylock, PharmD/MBA Candidate (University of Findlay College of Pharmacy) *guest;* Carmen Catizone; Eileen Lewalski; Maureen Schanck; Angie Rutkowski, *NABP staff.*

**Introduction:**

The Task Force met on September 9-10, 2015, at the Westin O'Hare, in Rosemont IL. This task force was established in response to Resolution 111-6-15, Task Force on the Regulation of Pharmacist Care Services, which was approved by the NABP membership at the Association's 111th Annual Meeting in May 2015.

**Review of the Task Force Charge:**

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

1. Review existing state laws and regulations pertaining to the provision of pharmacist care outside of the traditional pharmacy setting.
2. Review, and if necessary, recommend revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to assist boards of pharmacy in the oversight and regulation of pharmacist care services outside of the traditional pharmacy setting.

**Recommendation 1: NABP Should Amend the *Model Act.***

The task force recommends that NABP amend the *Model Act*. The amendments recommended by the task force are denoted by underlines and ~~strikethroughs~~.

# National Association of Boards of Pharmacy Model State Pharmacy Act

## Article I

# Title, Purpose, and Definitions

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## Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders~~,; the accepting, processing, or Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling;~~ and the provision of ~~those acts or services necessary to~~ Pharmacist Care Services. ~~in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice, the ordering, conducting, and interpretation of appropriate tests, and the recommendation and Administration of immunizations; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records.~~ The ~~p~~Practice of ~~p~~Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.
(See comment list.)

## Section 104. Comment.

The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms "must perform" and "is responsible for" intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

Pharmacy is a dynamic profession and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the State Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

NABP recognizes that protection of the public health should extend across state borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the "Practice of Pharmacy."

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## Section 105. Definitions.

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(u4) "Pharmacist Care Services" is the provision by a Pharmacist of patient care activities within this state or into this state, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[1]

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(x4) "Pharmacy" means any place within this State where Drugs are Dispensed and Pharmacist Care is provided and any place outside of this State where Drugs are Dispensed and Pharmacist Care is provided to residents of this State.

(See comment list.)

(y4) "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.

(See comment list.)

## 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
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services

[1] Objectives of Pharmacist Care include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist Care should be provided by all Pharmacists to the extent of their abilities regardless of the practice setting.

- 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

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(d5) "Practice of Telepharmacy" means the provision of Pharmacist Care by registered Pharmacies and Pharmacists located within US jurisdictions through the use of telecommunications or other technologies to patients or their agents at distances that are located within US jurisdictions.[2]

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(k5) "Primary Care" is the first level of contact of individuals, the family, and the community with the health care delivery system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process. (Areas of Primary Care where Pharmacists provide Pharmacist Care include, but are not limited to, the following: chronic disease management; smoking cessation; maternal and child health; immunizations; family planning; self-care consulting; Drug selection under protocol; treatment of common diseases and injuries; nutrition; and general health education and promotion.)

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**Section 301. Unlawful Practice.**

(a) Except as otherwise provided in this Act, it shall be unlawful for any individual, whether located in or outside this State, to engage in the Practice of Pharmacy in this State unless currently licensed to practice under any facet of the provisions of this Act.

(b) The provision of Pharmacist Care services to an individual in this State, through the use of telecommunications, the Internet, or other technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.[3]

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[2] The "Practice of Telepharmacy" is deemed to occur within the jurisdiction in which the patient is located and the jurisdiction(s) in which the pharmacist and, if applicable, pharmacy are located; therefore, such practice will be subject to the Pharmacy practice regulations of all jurisdictions' Boards of Pharmacy.

[3] NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy Across State Lines within the scope of the "Practice of Pharmacy" and requires an independently practicing pharmacist located outside this State to ~~register to Practice Telepharmacy Across State Lines, rather than~~ obtain full licensure for providing Pharmacist Care services from outside the State to patients within the State. ~~Pharmacists located outside this State who are providing Pharmacist Care services from a Pharmacy or nonresident Pharmacy licensed in this State need not register with this State to Practice Telepharmacy Across State Lines.~~

(1) Licensed Pharmacies located outside this State that provide Pharmacist Care services to individuals in this State must be licensed within this State under Article V of this Act.
(2) Pharmacists located outside this State who are providing Pharmacist Care services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.

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# Model Rules for the Practice of Pharmacy

## Section 5. Pharmacist Care Services

(a) Prospective Drug Utilization Review (DUR)[4]

A Pharmacist shall review the patient record and each Prescription Drug Order for:

(1) known allergies;
(2) rational therapy contraindications;
(3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
(4) reasonable directions for use;
(5) potential or actual adverse Drug reactions;
(6) Drug-Drug interactions;
(7) Drug-food interactions;
(8) Drug-disease contraindications;
(9) therapeutic duplication;
(10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(11) abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(b) Patient Counseling[5]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:
(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;

[4] Pharmacists should be permitted to use computer software, if available, to accomplish this review.

[5] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(3) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(4) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

(c) Medication Adherence Monitoring Services and Intervention Programs

Medication Adherence Monitoring Services and Intervention Programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix E for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)

(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

(i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(ii) the types of decisions that the Pharmacist is allowed to make may include:

(A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;

(B) a detailed description of the methods, procedures, decision criteria, and plan the Pharmacist is to follow when conducting allowed activities; and

(C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the Agreement, documentation shall occur on the prescription record, patient profile, a separate logbook, or in some other appropriate system.

(iii) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(v) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

(vi) a provision that allows either party to cancel the Agreement by written notification;

(vii) an effective date; and

(viii) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.

Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(3) Initiation of the Collaborative Pharmacy Practice Agreement

The Collaborative Pharmacy Practice Agreement must be coupled with a medical order from the Practitioner to initiate allowed activities for any particular patient.

(4) Documentation of Pharmacist activities

Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals providing care to that patient and who are authorized to received it. Documentation of allowed activities shall be considered Protected Health Information.

(5) Review

At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year.

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## Section 14. Provision of Pharmacist Care <u>Services</u> Outside of a Licensed Pharmacy.

~~(a) A Pharmacist providing Pharmacist Care services outside the premises of a licensed Pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:~~

(a) In order for a Pharmacist to provide~~ing~~ Pharmacist Care Services outside the premises of a licensed Pharmacy an applicant, shall:

(1) Register/license with the Board(s);

(2) Have appropriate security and protections in place, similar to or equivalent to those in place for a licensed pharmacy, ~~shall maintain the~~ records or other patient-specific information in such activities shall be maintained in a readily retrievable form; and ~~in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:~~

(3) Follow the patient care process approved by the Board[6].

~~(1) provide accountability and an audit trail;~~
~~(2) be provided to the Board upon request;~~
~~(3) be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and~~
~~(4) secure from unauthorized access and use.~~

## Background:

As health care evolves and pharmacists move beyond the community pharmacy as the epicenter of pharmacist care, the task force agreed that state boards of pharmacy should regulate the expanded function of and services provided by pharmacists. The task force further agreed that the practice of pharmacy can occur outside of the pharmacy and in settings that would not have been previously recognized as an acceptable setting for practice. These settings could include, but are not limited to a person's residence or mobile office. Members also discussed how current regulations do not adequately define these activities or provide the necessary regulatory framework to protect the public from harm due to incompetence or non-pharmacist personnel errors in such a way as to not create barriers to such practices. Specific examples mentioned were pharmacists that work in team-based care settings and those involved in medication therapy management outside of a traditional pharmacy. As automation is streamlining the prescription filling process, the pharmacist may routinely step outside the pharmacy by becoming more involved in over-the-counter recommendations and providing diagnostic laboratory testing and may also include limited prescriptive authority in collaboration with physicians and other providers. This may occur particularly when the pharmacy is located near a clinic where the pharmacist is the patient's next point of contact. Members discussed how the boards must grapple with maintaining patient protection and pharmacist accountability with the evolving

[6] It is anticipated that Boards use the *Pharmacists' Patient Care Process* approved in May 2014 by the Joint Commission of Pharmacy Practitioners.

responsibility assumed by pharmacists for cognitive services provided beyond what is associated with the dispensing of prescription drugs.

The task force members recommended amending the *Model Act* by streamlining the definition of the "Practice of Pharmacy" by making it more general and relevant to the evolving practice with room to grow. Tennessee's definition of the practice of pharmacy was cited as an example of an encompassing definition. It was further determined that any specific practice changes or additions can be made to the comment section of the definition rather than cluttering the definition itself with specific examples. The task force further determined that the *Model Act* should be amended to change the definition of "Pharmacist Care" to "Pharmacist Care Services" to make pharmacist clinical services more tangible and to include more than the dispensing of prescription drugs. Along those lines, the task force also opined that the state boards of pharmacy must set standards for licensure of medication therapy management that occurs outside of a pharmacy and recognize that the practice of pharmacy is occurring where the medication therapy management and patient counseling is occurring rather than a pharmacy site-specific location. Furthermore, as pharmacists are beginning to provide more primary care services, the task force recommended that the boards mandate documentation of these services and encounters to increase the accountability of pharmacists.

The task force members also discussed that the pharmacy community should continue to bring attention to pharmacists as medication experts and not just nurses and physicians as being the primary providers of medication therapy management as is portrayed in the media. With the expansion of pharmacist care services, there will be added focus to patient-centered care rather than product-oriented services as is typically associated with the pharmacist role. The task force stressed the prerequisite for achieving provider status in the hope that a payment system for clinical services offered by pharmacists could ensue. This is important as many patients rely solely on their insurance to cover health care costs. With patients receiving coverage for clinical pharmacy services, they will be able to routinely utilize pharmacists care services to better manage their health.

## Recommendation 2: NABP Should Encourage State Boards of Pharmacy to Expand the Scope of Activities That Pharmacists May Delegate to Certified Pharmacy Technicians.

The task force recommends that NABP encourage state boards of pharmacy to expand the scope of activities that pharmacists may delegate to certified pharmacy technicians in order to increase the amount of time for pharmacists to engage in pharmacist care services. This expanded delegation, provided that the certified pharmacy technician is qualified, should be determined by the pharmacist and/or permit holder.

### Background

In order to implement the guidelines of the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process, the task force members concluded that pharmacists must be given more time and the opportunity to meaningfully communicate with patients and members of their health care team. Therefore, task force members determined that pharmacists should be allowed to delegate pharmacy functions to certified pharmacy technicians if the pharmacist is

comfortable with the certified pharmacy technician's competence and experience. The board of pharmacy can still hold the pharmacist and permit holder ultimately responsible for overall pharmacy operations if pharmacy personnel are delegated functions that they are ill equipped to handle. Task force members reiterated that boards should continue to set practice standards and education requirements for pharmacy technicians for added safeguards.

Although technician certification does not ensure full competence for all pharmacy technician functions such as sterile compounding, it does provide a minimum standard. The Arizona State Board of Pharmacy has taken note that there have been fewer cases of pharmacy technician calculation errors since requiring pharmacy technician certification. Other members noted that pharmacist-to-technician ratios are less relevant when the pharmacy technicians are certified. The discussion also focused on the differences between states when it comes to background checks and pharmacy technician licensure requirements. Because of the ongoing problem of drug diversion by pharmacy technicians, the members discussed how pharmacy technician licensure should be made universal among states to ensure traceability of diverters.

As pharmacists begin to engage in functions beyond drug dispensing, the task force members agreed that the state pharmacy boards should allow pharmacists to delegate more advanced functions such as the documentation associated with pharmacist care services, accepting new and refill prescriptions over the telephone, and tech-check-tech verification provided that the pharmacy technician is qualified as determined by the board. Currently, there are several states that have evolved to allow for an extended technician role provided additional education and training is obtained to ensure public protection.