Report of the Task Force on the Regulation of Telepharmacy Practice

* Please note that the Recommendations made by the Executive Committee during the Formal Conference Call on April 19 pertaining to the Task Force on the Regulation of Telepharmacy Practice will be incorporated accordingly and will be noted on the final LE/L Report upon publication.

Members Present:
Lee Ann Bundrick (SC), chair; Freeda Cathcart (VA); Kamlesh “Kam” Gandhi (AZ); Patty Gollner (NE); Mark Hardy (ND); Lisa Hunt (WY); Douglas Lang (MO); Tamara McCants (DC); Joey McLaughlin, Jr (NC); Bradley Miller (TX); Penny Reher (OR); Karen Ryle (MA).

Others Present:
Philip Burgess, Executive Committee liaison; Adam Chesler (Cardinal Health), Ken Simons (FSMB), guests; Carmen Catizone; Eileen Lewalski; Maureen Schanck; Angie Rutkowski, NABP staff.

Introduction:
The Task Force met on October 24-25, 2016, at the DoubleTree by Hilton O’Hare Rosemont, in Rosemont, IL. This task force was established in response to Resolution 112-5-16, Task Force on Telepharmacy Practice, which was approved by the NABP membership at the Association’s 112th Annual Meeting in May 2016.

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

1. Examine the need for the development and adoption of licensing processes that protect the public, retain board of pharmacy jurisdiction for such practices, and allow for the development of practice models that are not unnecessarily restricted.

2. Review existing state laws and regulations addressing telepharmacy and relevant Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) language.

3. Recommend revisions, if necessary, to the NABP Model Act addressing this issue.

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, and the initiation and provision of Pharmacist Care Services. The Practice of 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. Inclusion of or authorization for specific activities, such as the Administration of medications, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the “Practice of Pharmacy,” the Model Act includes the definition of “Pharmacist Care Services” and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

The definition also acknowledges that 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.

Section 105. Definitions.
...

(a4) “Medication Therapy Management” is a distinct Pharmacist Care Service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication or a medical device. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed Pharmacist’s
scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient:

1. performing or obtaining necessary assessments of the patient’s health status;
2. formulating a medication treatment plan;
3. selecting, initiating, modifying, or administering medication therapy;
4. monitoring and evaluating the patient’s response to therapy, including safety and effectiveness;
5. performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
6. documenting the care delivered and communicating essential information to the patient’s other primary care providers;
7. providing verbal education and training designed to enhance patient understanding and appropriate use of his or her medications;
8. providing information, support services and resources designed to enhance patient adherence with his or her therapeutic regimens, such as Medication Synchronization;
9. coordinating and integrating Medication Therapy Management services within the broader health care management services being provided to the patient; and
10. such other patient care services as may be allowed by law.

(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

(c5) “Practice of Telepharmacy” means the Practice of Pharmacy provision of Pharmacist Care Services by registered Pharmacies and Pharmacists located within US jurisdictions through the use of telepharmacy technologies between a licensee telecommunications or other technologies to and patients or their agents at distances that are located within US jurisdictions.²

(d5) “Practice of Telepharmacy Across State Lines” means the Practice of Telepharmacy when the patient is located within a US jurisdiction and the pharmacist is located in a different US jurisdiction.

¹ Objectives of Pharmacist Care Services 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 Services should be provided by all Pharmacists to the extent of their abilities regardless of the practice setting.

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.
“Telepharmacy Technologies” means secure electronic communications, information exchange or other methods that shall meet applicable state and federal requirements.

Valid Patient-Practitioner Relationship” means the following have been established:

1. A patient has a medical complaint;
2. A medical history has been taken;
3. A face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate Practitioner Board; and
4. Some logical connection exists between the medical complaint, the medical history, and the physical examination and the Drug prescribed.

(See comment list.)

Section 105(bb7). Comment.

A Valid Patient-Practitioner Relationship includes a relationship with a consulting Practitioner or a Practitioner to which a patient has been referred, or a covering Practitioner, or an appropriate Practitioner-Board-approved telemedicine Practitioner providing that a physical examination had been previously performed by the patient’s primary Practitioner.

To best protect the public, the issue of a Valid Patient-Practitioner Relationship should be addressed in each jurisdiction’s Medical Practice Act and the Consumer Fraud Protection Act or their equivalent.

A face-to-face physical examination is not required to establish a Valid Patient-Practitioner relationship if:

(a) The prescribing Practitioner is issuing a prescription or dispensing a non-controlled substance legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases Guidance document issued by the United States Centers for Disease Control and Prevention;
(b) The prescription, administration, or dispensing is through a public health clinic or other distribution mechanism approved by the state health authority in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent; or
(c) The prescribing Practitioner is issuing a prescription through a telemedicine practice approved by the appropriate state agency that provides health care delivery, diagnosis, consultation, or treatment by means of audio, video, or data communications. Standard telephone, facsimile transmission, or both, in the absence of other integrated information or data, do not constitute telemedicine practices.
(d) The state allows third-party prescribing of opioid reversal agents, such as naloxone, or other drugs as allowed by state law to a person other than the patient.

Article III
Licensing
Introductory Comment to Article III

Article III of the Model Act specifies the requirements for initial licensure of Pharmacists, transfer of licensure, and renewal of licenses and registrations. In each of these areas, the Act sets forth basic Criteria and delegates to the Board the authority for implementing those Criteria. The Board does this by utilizing appropriate administrative enforcement mechanisms and by the issuance of specific rules.

Section 301 establishes the basis for this Article by making it unlawful for any unlicensed Person to engage in the Practice of Pharmacy, and by enabling the Board to exact penalties for unlawful practice.

In the area of initial licensure (Section 302), the Board must implement the Act by approving degree programs of Pharmacy, by specifying the examination to be employed (Section 302[b]), by establishing Pharmacy practice experience standards (Section 302[c]), and by ensuring that all other prerequisites are met by each applicant to whom it issues a license.

The Act also reflects the efforts of NABP to continue uniform standards for transfer of licensure (Section 303).

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 telepharmacy technologies, 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

(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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The fifth and last substantive Article of the Model Act concerns licensure of Pharmacies, Manufacturers, Wholesale Distributors, Repackagers, Third-Party Logistics Providers, and the like. The licensure requirements of this Article will provide a Board with knowledge of all facilities involved in the storage, Distribution, and sale of Drugs or Devices within the state and those located outside the state that are shipping Drugs or Devices into the state. They will permit a Board to verify compliance with federal requirements and better ensure against Drug or Device diversion from the legitimate channels of commerce and provide the necessary data for effective recalls and the dissemination of information.

Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board:

1. persons engaged in the Practice of Pharmacy (including Telepharmacy);
2. dispensing Practitioners and Practitioner’s facilities including those engaged in nonsterile Compounding;
3. persons engaged in the Manufacture or Repackaging of Drugs or Devices;
4. persons engaged in the Wholesale Distribution of Drugs or Devices;
5. persons engaged in Third-Party Logistics Provider activities of Drugs or Devices;
6. pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided;
7. Outsourcing Facilities;
8. Pharmacy Benefits Managers; and
9. Repository Programs

Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

...
(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

(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;
   (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).

7 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.
(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 D 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;
(iii) a process for generating any necessary Medical Orders, including prescription orders, required to initiate allowed activities;
(iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;
(v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
(vi) 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;
(vii) a provision that allows either party to cancel the Agreement by written notification;
(viii) an effective date;
(ix) signatures of all collaborating Pharmacists and Practitioners who are party to the Agreement, as well as dates of signing; and
(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

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

(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 who are providing
care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered Protected Health Information.

(e) Additional Pharmacist Care Services may include but are not limited to the following:

(1) Patient assessment and evaluation;
(2) Assessing health plan and medication eligibility and coverage;
(3) Administering drugs, vaccines, or biologicals;
(4) Performing Peer Review and peer consultations;
(5) Reviewing, selecting, and developing formularies or plan practice guidelines;
(6) Consulting with other health care professionals;
(7) Providing patient referrals;
(8) Performing Medication Therapy Management;
(9) Ordering lab tests
(10) Performing lab test as provided by state and federal law.

Section 10. Practice of Telepharmacy

(a) General Requirements

(1) The Pharmacy shall:
   (i) obtain a resident or nonresident permit issued by the Board prior to engaging in the Practice of Telepharmacy;
   (ii) comply with appropriate federal and state controlled substance laws and rules for each Pharmacy if controlled substances are maintained;
   (iii) maintain additional policies and procedures specific to Telepharmacy.

(b) Remote Dispensing Site Requirements

(1) Shall submit an application to the Board.
(2) The Pharmacist-in-Charge of supervising pharmacy shall be responsible for all operations.
(3) Shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.
(4) The Pharmacist-in-Charge shall oversee monthly inspections, maintenance and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.
(5) A Pharmacist must be designated to be available within ( ) hours, in case of emergency.
(6) Unless staffed by a Pharmacist, a remote dispensing site must be staffed by at least one (1) Certified Pharmacy Technician. All Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates shall be under the supervision of a Pharmacist at the supervising Pharmacy at all times that the remote site is operational. The Pharmacist shall supervise Telepharmacy operations electronically from the supervising pharmacy.
(7) The remote dispensing site and the supervising Pharmacy must utilize a common electronic recordkeeping system that must be capable of the following:
(i) Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site at all times of operations; and

(ii) Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy.

(8) Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, state and federal law.

(9) A supervising Pharmacy of a remote dispensing site must maintain a video and audio communication system that provides for effective communication between the supervising Pharmacy and the remote dispensing site personnel and patients or caregivers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or Delivery of Drugs. The remote dispensing site must retain a recording of facility surveillance, excluding patient communications, for a minimum of ( ) days.

(i) Adequate supervision by the pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person or entity.

(ii) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed to the public if any component of the communication system is malfunctioning until system corrections or repairs are completed.

(iii) The video and audio communication system used to counsel and interact with each patient or patient’s caregiver must be secure and compliant with state and federal confidentiality requirements.

(10) Unless a Pharmacist is present, a remote dispensing site must not be open or its employees allowed access to it during times the supervising Pharmacy is closed. The security system must allow for tracking of entries into the remote dispensing site, and the Pharmacist-in-Charge must periodically review the provision of access and record of entries.

(11) If Drugs are maintained or dispensed from the remote dispensing site, Drug transfers to the remote dispensing site must comply with applicable state and federal requirements.

(12) A remote dispensing site must display a sign, easily visible to the public, that informs patients that:

(i) this is a remote site
(ii) location of supervising Pharmacy; and
(iii) informs patients that a Pharmacist will counsel the patient using audio and video communication systems each time a new medication is delivered and on a refill, if necessary, at a remote dispensing site.

(13) The remote dispensing site must use Telepharmacy Technology that confirms that the Drug selected to fill the prescription is the same as indicated on the prescription label and Prescription Drug Order.
Background:
The task force members discussed how telepharmacy can provide patients with quality health care that they may not otherwise receive or have difficulty accessing. The task force agreed that residents in urban settings may benefit just as much as those in rural settings from the convenience and accessibility provided by telepharmacy. Members received background information from Kenneth Simons, MD, representative for the Federation of State Medical Boards, who explained that telemedicine is viewed as a tool in the practice of medicine, no different than a stethoscope or CT machine. Dr Simons also explained that the state medical boards are in consensus that the practice of telemedicine occurs where the patient is located. In addition, task force members received an overview from Adam Chesler, PharmD, Cardinal Health, about the various communication technologies that can be utilized in various telepharmacy settings. Members were in agreement that state regulations should not mandate specific telecommunication modalities but rather be drafted broadly to encompass emerging technologies.

Members discussed how Wyoming has had to reevaluate its current telepharmacy rules to be less restrictive in order to provide the appropriate environment for the expansion of telepharmacy practices. Task force members discussed the challenges presented by promulgating telepharmacy regulations based on geographical or distance-related parameters. They agreed that from the practice perspective, such requirements tend to create artificial barriers; however, from the regulatory perspective, monitoring and enforcement of such regulations may become difficult. Members were also informed that North Dakota has seen an increase in telepharmacy permits with no decline in the number of traditional pharmacy locations. Rural communities have also benefitted and grown when telepharmacy services have been established because residents value the health care services afforded to them by a telepharmacy practice in town.

The members reviewed existing Model Act language and recommended amendments that include amending the definition of telepharmacy to recognize that it is the practice of pharmacy both within and across state lines. Furthermore, a definition for telepharmacy technologies was also recommended that is broad and encompassing of future technological developments. The task force briefly addressed, but decided not to discuss kiosks and other similar technologies in detail. The members agreed that the definition of pharmacist care services should include examples of such practices to illustrate the potential of this model and to help grant pharmacists such privileges in each state. The task force members also recommended adding an exemption to the requirement of a face-to-face examination in instances of third-party prescribing. The members also agreed that the existing sections on shared pharmacy services and automated pharmacy systems remain intact and that a new section for telepharmacy be added to the Model Act that specifies, among other things, general requirements for licensure, staffing, supervision of delivery and storage of drugs, and the security of drugs at a remote telepharmacy location.
**Recommendation 2: NABP to Collaborate With Boards of Pharmacy Regarding the Regulation of the Act of Telepharmacy Between Pharmacies and Medical Clinics or Other Facilities Not Regulated by the Board of Pharmacy.**

The task force recommends that NABP collaborate with boards of pharmacy to discuss the regulation of telepharmacy practices that are occurring between pharmacies and medical clinics or other facilities that are not regulated by the board.

**Background:**

The task force members pondered about compounding and drug dispensing that occurs in medical clinics and other facilities not generally regulated by the boards of pharmacy. Although it seemed more beneficial to the task force members to have trained pharmacy technicians involved rather than physicians’ office staff in drug dispensing, the boards of pharmacy have no presumed oversight. One member discussed how oncology clinics are hiring pharmacy technicians to compound and mix chemotherapy under the supervision of a remote pharmacist via telepharmacy technologies. When such pharmacy technician supervision occurs in a remote location that is not under the board of pharmacy purview, there may be insufficient regulations and public protections in place. Task force members discussed how NABP could collaborate with its member boards to determine how best to regulate such circumstances.