Report of the 2006-2007 Committee on Law Enforcement/Legislation

Members Present:
Sheila Mitchell (TN), Chair; George Bowersox (NH); Kim Caldwell (TX); William T. Douglass (WV); Julie Frazier (TN); Kay Hanson (MN); Susan Ksiazek (NY); Cathryn Lew (OR); and Michael Podgurski (PA).

Members Not Present:
Jeanne Furman (MD).

Others Present:
Gary A. Schnabel, Executive Committee Liaison; Carmen A. Catizone, Melissa Madigan, Charisse Johnson, Chris Siwik, and Gertrude “Gg” Levine, NABP staff.

Review of Committee Charge:
The Committee on Law Enforcement/Legislation (Committee) met on January 25-26, 2007, at the Headquarters of the National Association of Boards of Pharmacy (NABP) in Mount Prospect, IL. The members of the Committee reviewed their charge and, proposing no changes, accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists;

2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association; and

3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Committee members then reviewed the report of the 2005-2006 Committee on Law Enforcement/Legislations for background information.

**LE/L Recommendation 1:** The Committee recommends approval of the amendments to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) recommended by the Task Force on Emergency Preparedness, Response, and the US Drug Distribution System, with the following revisions.

The revisions recommended by the Task Force on Emergency Preparedness, Response, and the US Drug Distribution are denoted by underlines and strikethroughs. The recommended revisions by the Committee are denoted by double underlines and double strikethroughs.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article II
**Section 201. Designation**

The responsibility for enforcement of the provisions of this Act is hereby vested in the Board of Pharmacy. The Board shall have all of the duties, powers, and authority specifically granted by or necessary for the enforcement of this Act, as well as such other duties, powers, and authority as it may be granted from time to time by applicable law. In the event of a declared State of Emergency, the Board may waive the requirements of this Act in order to protect the public health, safety, or welfare of its citizens and to facilitate the provision of Drugs, Devices, and Pharmacist Care services to the public.

**Article III**

**Comments**

**Section 201. Comment**

In states where centralized prescription filling or centralized prescription processing are not permitted, states may consider allowing the performance of such activities in a declared State of Emergency.

**Section 303. Comment**

See the NABP Model Rules for Public Health Emergencies for language that addresses the temporary recognition of non-resident pharmacist licensure in the case of a declared State of Emergency issued due to a Public Health Emergency.

**Model Rules for the Practice of Pharmacy**

**Section 2. Personnel**

A. Duties and Responsibilities of the Pharmacist-in-Charge

(2) The Pharmacist-in-Charge has the following responsibilities:

(a) Developing or adopting, implementing, and maintaining:

(i) Developing quality assurance programs for Pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain a Pharmacy Technician Training Manual for the
specific practice setting of which he or she is in charge; he or she shall supervise a training program conducted pursuant to the Pharmacy Technician Training Manual for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy; the Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Pharmacy Technicians successfully completing the Pharmacy’s Technician training program and an objective assessment mechanism; the Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board;

(iii) Establishing policies and procedures for the procurement, storage, security, and disposition of Drugs and Devices; quality assurance programs shall be designed to prevent and detect Drug diversion;

(iv) Establishing policies and procedures for the provision of Pharmacy services;

(v) Implementing an ongoing quality assurance program that monitors performance of the Automated Pharmacy System, which is evidenced by written policies and procedures developed by the Pharmacy;

(vi) Establishing policies and procedures for preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with the established policies and procedures; and

(vii) procedure for the operation of the Pharmacy, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed, in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency; and

(viii) policies and procedures for reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence.

(b) Ensuring that:

(i) Assuring that the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed while maintaining appropriate recordkeeping and security safeguards; and
(ii) Assuring that all Pharmacists and Pharmacy Interns employed at the Pharmacy are currently licensed and that all Certified Pharmacy Technicians and Pharmacy Technicians employed at the Pharmacy are currently registered with the Board of Pharmacy.

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**Section 2 A (2)(n) Comment**
States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

**Model Rules for Public Health Emergencies**

**Section 1. Purpose and Scope**
By the provision of these rules by the Board, the primary purpose of the section is to enable Pharmacists and Pharmacies to assist in the management and containment of a Public Health Emergency or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public.

**Section 2. Definitions.**
(a) “Declared Disaster Areas” are areas designated by the Governor state or federal authorities as those that have been adversely affected by a natural or man-made disaster and require extraordinary measures to provide adequate, safe and effective health care for the affected population.
(b) “Emergency Prescription Drug Order” means a standing Prescription Drug Order issued by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a Public Health Emergency requiring mass Dispensing to expeditiously treat or provide prophylaxis to large numbers of Patients.
(c) “Mobile Pharmacy” means a Pharmacy that is self propelled or movable by another vehicle that is self propelled.
(d) “Public Health Emergency” means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or nongovernmental organizations to resolve.
(e) “State of Emergency” means a governmental declaration, usually issued as a result of a Public Health Emergency, that may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.
(f) “Temporary Pharmacy Facility” means a facility established as a result of a Public
Health Emergency or State of Emergency to temporarily provide Pharmacy
services within or adjacent to Declared Disaster Areas.

Section 3. Emergency Prescription Drug Order

(A) For the duration of a State of Emergency issued due to a Public Health
Emergency, a Pharmacist may Dispense a Prescription Drug pursuant to an
Emergency Prescription Drug Order if the Pharmacist:

(1) performs, to the extent possible, a Prospective Drug Regimen Review and
Patient Counseling in accordance with these rules;

(2) reduces the information to a form that may be maintained for the time
required by law or rule, indicates it is an “Emergency Prescription Drug
Order,” and files and maintains the record as required by state and federal law.

Section 4. Public Health Emergency Refill Dispensing

(A) For the duration of the State of Emergency issued due to a Public Health
Emergency in the affected state and in other states engaged in disaster assistance
pursuant to a governmental declaration of the Governor or rule of the Board, a
Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty
(30) day supply, without Practitioner authorization if:

(1) in the Pharmacist’s professional judgment, the Prescription Drug is essential
to the maintenance of the Patient’s life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form
that may be maintained for the time required by law or rule, indicates it is an
“Emergency Refill Prescription,” and maintains the record as required by state
and federal law, as well as state and federal disaster agencies for consideration
for possible reimbursement programs implemented to ensure continued
provision of care during a disaster or emergency; and

(3) the Pharmacist informs the Patient or the Patient’s agent at the time of
Dispensing that the Prescription Drug is being provided without the
Practitioner’s authorization and that authorization of the Practitioner is
required for future refills.

(B) For the duration of the State of Emergency, in an effort to provide patients with
the best possible care in light of limited Drug availability and/or limited
information on patients’ current Drug therapy, a Pharmacist may initiate or
modify Drug therapy and Dispense an amount of such Drug to accommodate a
patient’s health care needs until that patient may be seen by a Practitioner.
Pharmacists performing such activities must utilize currently accepted standards
of care when initiating or modifying Drug therapy. These activities may be
undertaken if:

(1) in the Pharmacist’s professional judgment, the Prescription Drug is essential
to the maintenance of the Patient’s life or to the continuation of therapy;
(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates that drug therapy has been initiated or modified due to a disaster or emergency, and maintains the record as required by state and federal law; and

(3) the Pharmacist informs the Patient or the Patient’s agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner’s authorization and that authorization of the Practitioner is required for future refills.

(C) The Practitioner and Pharmacist shall not incur any liability as a result of the performance of these activities in good faith pursuant to this section.

Section 5. Temporary Recognition of Non-Resident Licensure

(A) When the Governor declares a State of Emergency is declared due to a Public Health Emergency:

(1) a Pharmacist not licensed in this State, but currently licensed in another state, may Dispense Prescription Drugs in areas affected by the Declared Disaster during the time that the State of Emergency exists if:

(a) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system; and

(b) the Pharmacist is engaged in a legitimate relief effort.

(2) a Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(a) the Board can verify current registration or licensure in good standing of the Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; and

(b) the Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern is engaged in a legitimate relief effort.

(3) a Wholesale Drug Distributor not licensed in this State, but currently licensed in another state, may Distribute Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(a) the Board can verify current licensure in good standing of the Wholesale Drug Distributor directly with the state or indirectly via a third-party verification system; and

(b) the Wholesale Drug Distributor is engaged in a legitimate relief effort.

(4) the temporary recognition of non-resident licensure or registration shall cease with the termination of the State of Emergency.

Section 6. Temporary Pharmacy Facilities or Mobile Pharmacies

Facilities
(A) Pharmacies located in Declared Disaster Areas, non-resident Pharmacies, and Pharmacies licensed in another state but not licensed in this State, if necessary to provide Pharmacy services during a State of Emergency, may arrange to temporarily locate or relocate to a Temporary Pharmacy Facility or Mobile Pharmacy temporary or mobile Pharmacy facility if such facility the Temporary Pharmacy Facility or Mobile Pharmacy:

1. is under the control and management of the Pharmacist-in Charge or designated supervising Pharmacist;
2. is located within the Declared Disaster Area or affected areas;
3. notifies the Board of its location;
4. is properly secured to prevent theft and diversion of Drugs; and
5. maintains records in accordance with laws and regulations of the state in which the disaster occurred; and
6. ceases the provision of services with the termination of the State of Emergency, unless it is successfully licensed by the Board of Pharmacy in accordance with Article V of this Act.

(B) The Board, in accordance with Board rules, shall have the authority to approve or disapprove Temporary Pharmacy Facilities and Mobile Pharmacies temporary or mobile Pharmacy facilities and shall make arrangements for appropriate monitoring and inspection of the Temporary Pharmacy Facilities and Mobile Pharmacies temporary or mobile Pharmacy facilities on a case-by-case basis. Approval of Temporary Pharmacy Facilities and Mobile Pharmacies temporary or mobile Pharmacy facilities will be based on the need, type, and scope of Public Health Emergency, as well as the ability of the Temporary Pharmacy Facilities or Mobile Pharmacies temporary or mobile Pharmacy facilities to comply with state and federal drug law.

(C) A Temporary Pharmacy Facility wishing to permanently operate at its temporary site must be licensed by the Board of Pharmacy in accordance with Article V of this Act notify the Board in accordance with Article V, Section 503 of these Rules.

(D) Mobile Pharmacies facilities, placed in operation during a State of Emergency, may not operate permanently, unless approved by the Board, only during a State of Emergency and may not be permanently operated.

Comments

Section 1. Comment
States may consider adding the following, more detailed language, which specifically addresses Drug Disposal and reporting requirements in the case of an emergency or disaster, to their emergency rules or guidelines:

Disposal of Prescription Drugs in Pharmacies Affected by a Certain Disasters
1. For Pharmacies that sustain flood and/or fire damage in the Prescription department or other damage resulting in an irrevocable loss of the Drug inventory, the entire Drug...
inventory, including Drugs awaiting pick up by Patients, becomes unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy.

2. For Pharmacies that experience a loss of power for an extended period of time, the Drug inventory must be evaluated for continued product integrity using USP standards. For example, medications with labeling requiring storage at “controlled room temperature” must be kept at between 68°F and 77°F, with brief deviations of between 56°F and 86°F. Medication inventories found to have been stored outside of USP standards become unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy. For Pharmacies with questions on USP product integrity standards, contact USP at 800/227-8772.

Reporting of Theft or Loss of Controlled Substances During an Emergency or Disaster

1. In circumstances of theft by looting, burglary, etc, where evidence or witnesses indicate the medications were taken by someone, the nearest DEA Diversion Field Office must be notified by telephone, facsimile, or brief written message of the circumstances of the theft immediately upon discovery. In addition, the pharmacy must complete DEA Form 106–Report of Theft or Loss of Controlled Substances, found at www.deadiversion.usdoj.gov, to formally document the actual circumstances of the theft and the quantity of controlled substances involved, once this information has been conclusively determined.

2. In circumstances of damage or where drugs were irrevocably lost to flooding or other circumstance, such information must be reported on DEA Form 41 – Registrants Inventory of Drugs Surrendered, found at www.deadiversion.usdoj.gov.

3. The amount stolen or lost may need to be calculated by taking the most recent controlled substances inventory, adding the amount purchased since that date, then subtracting the amount dispensed and distributed since that date. Absent a calculated amount, a best estimate should be reported.

Disposal of Prescription Drugs Irrevocably Lost in an Emergency or Disaster

1. Controlled Substances
   Reverse Distributors, either individually or in concert with other contractors, are equipped to dispose of controlled substances. Contact your primary distributor for their recommendations for a reverse Distributor or contact a reverse Distributor directly.

2. Contaminated Medical Debris
   Non-controlled substance Prescription Drugs and Devices contaminated with flood water or other contaminants should be disposed of using a medical waste transportation, processing, and disposal system vendor. Such vendors must be licensed by the state.

3. Hazardous Debris
   Materials are deemed hazardous if they are ignitable, corrosive, toxic, or reactive. Prescription Drugs considered hazardous include, but are not limited to, epinephrine, nicotine, nitroglycerin, physostigmine, reserpine, selenium sulfide, chloral hydrate, and many chemotherapy agents, such as cyclophosphamide, chlorambucil, and daunomycin. Other hazardous items that might be found in a Pharmacy include paints, varnishes and thinners, alcohol, batteries, mercury thermometers, and blood pressure cuffs. It is recommended that Pharmacies handle all contaminated Prescription medications as
hazardous debris and dispose of it using a hazardous waste collection and disposal company. These companies must be licensed by the state.

4. **Commercial Waste**

   Over-the-counter Drugs and other store shelf material may be disposed of in the commercial waste stream.

**Section 2(b). Comment**

Boards may consider identifying the official who has authority to issue an “Emergency Prescription Drug Order” and reviewing this on a regular basis.

**Section 3(a)(1). Comment**

Although these services are important, in times of a disaster or emergency, it may not be possible to perform a Prospective Drug Review or provide counseling on Dispensed Drugs.

**Section 4(a). Comment**

Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

**Section 4(b)(2). Comment**

Boards should be cognizant that state and federal disaster agencies, to ensure continued provision of care during disasters or emergencies, have programs that consider reimbursement requests for medication providers and may request Board assistance in the dispersal of funds. Records of dispensing will likely be needed for possible reimbursement consideration. In addition, records may also be used for post-event evaluation of care.

**Section 5(a)(1)(i). Comment**

If the information cannot be verified directly by the state Board of Pharmacy in which the non-resident pharmacist is licensed, the NABP Clearinghouse may be utilized to verify that a non-resident pharmacist has not had disciplinary action taken against his or her license.

**Section 6(a). Comment**

Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure that controlled substances may be delivered to and Dispensed from temporary or mobile pharmacy facilities.

**Section 6(a)(3). Comment**

Boards may choose to require “approval” of a Temporary Pharmacy Facility or a Mobile Pharmacy, as opposed to requiring only “notification.” “Notification” may imply that the Board of Pharmacy has approved the location of the Temporary Pharmacy Facility or Mobile Pharmacy.

**Section 6(d). Comment**

Although many states do not allow the permanent or temporary licensure of Mobile Pharmacies, states that do allow the licensure of Mobile Pharmacies may consider implementing special requirements for permanent licensure; for example, a state may limit Mobile Pharmacies to
operation only by nonprofit organizations and only in communities that are medically underserved.

Background:
The Task Force on Emergency Preparedness, Response, and the US Drug Distribution System, which met in November 2006, was charged with developing a “Model Emergency and Disaster Preparedness and Response Plan” for boards of pharmacy to use in emergency and disaster preparedness and response planning efforts. As part of these efforts, the Task Force also recommended revisions to the Model Act, primarily via an additional section titled “Model Rules for Public Health Emergencies.”

The Committee reviewed the proposed amendments submitted by the Task Force and suggested revisions that attempt to clarify as well as strengthen various sections of the newly added Model Rules. The Committee, for example, suggested adding the definitions of “Temporary Pharmacy Facility” and “Mobile Pharmacy” to better clarify the meaning and intent of these entities, and added a comment suggesting states that allow the permanent licensure of mobile pharmacies to also implement specific criteria defining the circumstances in which licensure is allowed. The Committee also suggested revisions to the Model Rules for the Practice of Pharmacy that recognize that the pharmacist-in-charge often adopts, but does not necessarily develop, policies, procedures, and other programs as mandated by the board of pharmacy.

**LE/L Recommendation 2:** The Committee fully supports and endorses the recommendation of the Task Force on Emergency Preparedness, Response, and the US Drug Distribution System, which directs NABP to work with state and federal authorities to develop a uniform pharmacist identification card (national ID) that allows pharmacists interested in servicing disaster areas access to such areas during a crises or emergency. Additionally, the Committee recommends that such an identification card, if feasible, incorporate photo, biometric, or other security features that aid in the authentication of the pharmacist’s identity.

Background:
The Committee echoed the concerns expressed by the Task Force that pharmacists attempting to assist in Hurricane Katrina relief efforts in late 2005 were denied access to disaster areas by various state and federal authorities. In an effort to alleviate this problem in the future, the Committee agreed with the development of a uniform identification card, and further suggested that this card incorporate security features, such as a photo, to help in authenticating the pharmacist’s identity.

**LE/L Recommendation 3:** The Committee recommends approval of the amendments to the Model Act recommended by the Task Force on Standardizing Student Pharmacist Experiential Requirements, with the following amendments.
The revisions recommended by the Task Force on Standardizing Student Pharmacist Experiential Requirements are denoted by underlines and strikethroughs. The recommended revisions by the Committee are denoted by double underlines and double strikethroughs.

**Article I**
**Title, Purpose, and Definitions**

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**Section 105. Definitions.**

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(iii) “Pharmacy Intern” means an individual who is:

1. Currently licensed by this State to engage in the Practice of Pharmacy while under the personal supervision of a Pharmacist and is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

2. A graduate of an approved professional degree program of a school or college of Pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who is currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

3. A qualified applicant awaiting examination for licensure or meeting Board requirements for re-licensure; or

4. An individual participating in a residency or fellowship program.

**Comments**

**Section 105(iii). Comment.**

Most Pharmacy Interns are either enrolled in a professional degree program or postgraduate program (residency or fellowship), or have graduated from a board approved professional degree program and are awaiting examination. In some cases, however, boards of pharmacy also designate pharmacists whose licenses have lapsed or been inactive for a significant period of time as “Pharmacy Intern,” allowing these pharmacists to obtain practical experience so that their licenses can be reactivated. Additionally, Boards may grant the “Pharmacy Intern” designation to those Pharmacists seeking practical experience following a period of license suspension or revocation.

Boards of pharmacy may consider limiting the Pharmacy Interns’ duration of registration especially if the boards find that Pharmacy Interns are not successfully progressing toward Pharmacist Licensure in an acceptable and reasonable time frame.

**Section 105(oooo). Comment.**

Preceptors should be appropriately qualified and possess ample experience for the proper instructional training of Pharmacy Interns. It is strongly encouraged that Preceptors pursue continuing professional development for their practitioner-educator role expectations.
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, registration to engage in the Practice Telepharmacy Across State Lines, 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 professional degree programs of Pharmacy, by specifying the examination to be employed (Section 302[b]), by establishing internship 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).

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Section 302. Qualifications for Licensure by Examination.

(a) To obtain a license to engage in the Practice of Pharmacy, an applicant for licensure by examination shall:

(1) Have submitted a written application in the form prescribed by the Board of Pharmacy;

(2) Have attained the age of majority;

(3) Be of good moral character;

(4) Have graduated and received the first professional undergraduate degree from a college or school of Pharmacy that has been approved by the Board of Pharmacy;

(5) Have graduated from a foreign college of Pharmacy, completed a transcript verification program, taken and passed a college of Pharmacy equivalency examination program, and completed a process of communication ability testing as defined under Board of Pharmacy regulations so that it is assured that the applicant meets standards necessary to protect public health and safety;

(6) Have completed an internship pharmacy practice experience program or other program that has been approved by the Board of Pharmacy, or demonstrated to the Board’s satisfaction that experience in the Practice of Pharmacy, which meets or exceeds the minimum internship pharmacy practice experience requirements of the Board;

(7) Have successfully passed an examination or examinations given by the Board of Pharmacy; and

(8) Have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the license.

(b) Examinations.

(1) The examination for licensure required under Section 302(a)(7) of the Act shall be given by the Board at least two (2) times during each year. The Board shall determine the content and subject matter of each examination and approve the site and date of the administration of the examination.

(2) The examination shall be prepared to measure the competence of the applicant to engage in the Practice of Pharmacy. The Board may employ, cooperate, and contract
with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have successfully passed such an examination.

(c) Internship Pharmacy Practice Experience Programs and Other Training Programs.

(1) All applicants for licensure by examination shall obtain practical experience in the Practice of Pharmacy concurrent with or after college attendance, or both, under such terms and conditions as the Board shall determine.

(2) The Board shall establish such licensure requirements for Pharmacy Interns and standards for internship pharmacy practice experiences, or any other experiential program necessary to qualify an applicant for the licensure examination, and shall also determine the qualifications of Preceptors used in practice experience programs.

Section 303. Qualifications for Licensure Transfer.

(a) In order for a Pharmacist currently licensed in another jurisdiction to obtain a license as a Pharmacist by license transfer in this State, an applicant shall:

(1) Have submitted a written application in the form prescribed by the Board of Pharmacy;

(2) Have attained the age of majority;

(3) Have good moral character;

(4) Have possessed at the time of initial licensure as a Pharmacist all qualifications necessary to have been eligible for licensure at that time in this State;

(5) Have engaged in the Practice of Pharmacy for a period of at least one (1) year or have met the internship pharmacy practice experience requirements of this State within the one (1) year period immediately previous to the date of such application;

(6) Have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;

(7) Have presented to the Board proof that any other license granted to the applicant by any other state has not been Suspended, Revoked, or otherwise restricted for any reason, except nonrenewal or for the failure to obtain the required continuing education credits, in any state where the applicant is currently licensed but not engaged in the Practice of Pharmacy; and

(8) Have paid the fees specified by the Board.

(b) No applicant shall be eligible for license transfer unless the state in which the applicant was initially licensed as a Pharmacist also grants licensure transfer to Pharmacists duly licensed by examination in this State, under like circumstances and conditions.

Section 307. Intern/Extern Licensure Pharmacy Practice Experience Program Standards; Pharmacy Intern Licensure.

The Board of Pharmacy shall establish standards for internship pharmacy practice experience programs for the purpose of providing the practice experience necessary for licensure as a Pharmacist. The Board shall grant a Pharmacy Intern license to Pharmacy students in internship programs, authorizing those students to engage in the Practice of Pharmacy under the supervision of a Pharmacist. The Board of Pharmacy shall adopt rules regarding the licensure of Pharmacy Interns and the standards for internship pharmacy practice experience programs.

Comments
Section 302(a)(4). Comment.
It is contemplated that Boards will approve those programs whose standards are at least equivalent to the minimum standards required by the Accreditation Council for Pharmacy Education. This would include college-structured pharmacy practice experience externship programs and continuing education programs. See Comment to Section 213(a)(4) above for further discussion of the Board’s proper role in the accreditation process.

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Section 302(c). Comment.
As college-based pharmacy practice experience programs become uniform under the most recent revision of the ACPE Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007), and when boards of pharmacy are convinced that schools and colleges of pharmacy are meeting these Accreditation Standards and Guidelines and the competency requirements set out by boards, boards should begin to broadly accept and recognize college-based pharmacy practice experience programs completed by students in other jurisdictions and eliminate requirements that such students obtain additional pharmacy practice experience hours in addition to those obtained as part of the college of pharmacy curriculum.

Because of the potential lack of uniformity among non-college-based pharmacy practice experience programs, it is recommended that Boards exercise their prerogative to accept only at their discretion non-college based pharmacy practice experiences completed by interns in other jurisdictions. Because of the continuing lack of uniformity concerning internship programs, it is hoped that these programs will be relatively uniform, as suggested by NABP Bylaws, and that Boards will exercise the prerogative to accept comparable programs of other jurisdictions in their discretion as permitted in Section 306.

Section 302 (c)(1). Comment.
Although boards of pharmacy mandate a specified number of hours of pharmacy practice experiences as a prerequisite to licensure, boards of pharmacy are also encouraged to deem those requirements met if boards find that the college-based pharmacy practice experiences meet or exceed the hourly pharmacy practice experience requirements.

As indicated in the Model Rules for Pharmacy Interns, applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies as delineated in the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007); and (2) not less than 1,740 hours of pharmacy practice experience credit under the instruction and supervision of a Preceptor. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

Section 302 (c)(2). Comment.
Boards of pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007) as a basis for establishment and revision of board standards for pharmacy practice experiences. These Accreditation Standards and Guidelines also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

...
**Section 307. Comment.**

Boards of pharmacy are strongly encouraged to utilize the ACPE *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (effective July 1, 2007) as a basis for establishment and revision of board standards for pharmacy practice experiences. These *Accreditation Standards and Guidelines* also contain additional guidance on the desired behaviors, qualities, and values of preceptors.

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**Model Rules for Pharmacy Interns**

**Section 1. Licensure.**

Every individual shall be licensed by the Board of Pharmacy before beginning his/her internship pharmacy practice experiences in this State. A license to practice Pharmacy as a Pharmacy Intern shall be granted only to those individuals who:

a. are enrolled in a professional degree program of a school or college of pharmacy that has been approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist; or

b. are graduates of an approved professional degree program of a school or college of Pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who are currently licensed by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or

c. are qualified applicants awaiting examination for licensure or meeting Board requirements for re-licensure; or

d. are participating in a residency or fellowship program.

Section 2. Identification.

The Pharmacy Intern shall be so designated in his/her professional relationships, and shall in no manner falsely assume, directly or by inference, to be a Pharmacist. The Board shall issue to the Pharmacy Intern a license for purposes of identification and verification of his/her role as a Pharmacy Intern, which license shall be surrendered to the Board upon discontinuance of internship pharmacy practice experiences for any reason including licensure as a Pharmacist. No individual not properly licensed by the Board as a Pharmacy Intern shall take, use, or exhibit the title of Pharmacy Intern, or any other term of similar like or import.

**Section 3. Supervision.**

A Pharmacy Intern shall be allowed to engage in the Practice of Pharmacy provided that such activities are under the direct supervision of a Pharmacist. A Pharmacist shall be in continuous personal contact with, and actually giving instructions to, the Pharmacy Intern during all professional activities throughout the entire internship pharmacy practice experience period. The Pharmacist shall physically review the Prescription Drug Order and the Dispensed product before the product is Delivered to the patient or the patient’s agent. The Pharmacist is responsible for the work of the Pharmacy Intern.

**Section 4. Change of Address.**

All Pharmacy Interns shall notify the Board immediately upon change of employment and residence residential address.

**Section 5. Evidence of Completion.**

Applicants for licensure as Pharmacists shall submit evidence that they have satisfactorily completed: (1) an objective assessment mechanism intended to evaluate achievement of desired competencies; and (2)
not less than 1,740 hours of internship pharmacy practice experience credit under the instruction and supervision of a Preceptor.

**Comments**

**Section 1. Licensure. Comment.**
The ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007) require schools and colleges of Pharmacy seeking and maintaining ACPE accreditation to incorporate introductory pharmacy practice experiences within their professional curricula, and such experiences must account for not less than 5% of the total curricular length (not less than 300 contact hours). Under the direct supervision of a Preceptor and usually taken throughout the first three academic years of the professional program, these introductory pharmacy practice experiences expose students to and allow students to participate in activities such as processing/Dispensing Medication Orders, conducting Patient interviews, or presenting Patient cases in an organized format.

It is also encouraged that boards of pharmacy allow pharmacy students to be registered as “Pharmacy Interns” as early as initial enrollment in a board-approved professional program as long as the pharmacy student has begun to take professional degree courses.

**Section 3. Supervision. Comment.**
According to the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007), most pharmacy practice experiences must be under the supervision of a qualified Pharmacist Preceptor licensed in the United States. Realizing that in some cases non-Pharmacist Preceptors can also provide valuable learning opportunities, it is hoped that boards of pharmacy recognize these experiences and that schools and colleges of pharmacy ensure, in most cases through faculty, that the desired competencies are being met.

**Section 5. Evidence of Completion. Comment.**
These requirements coincide with the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007). Boards of pharmacy are strongly encouraged to utilize these Standards and Guidelines as a basis for the establishment and revision of board standards for pharmacy practice experiences.

Introductory pharmacy practice experiences, which are not less than 300 contact hours, are in addition to the advanced practice experiences taken during the final professional year, which account for not less than 25% of the curricular length or 1,440 contact hours. The total pharmacy practice experience hour requirement, therefore, is not less than 1,740 hours. Boards may consider moving away from requiring a specific number of contact hours should it be determined that the ACPE Accreditation Standards and Guidelines result in appropriate preparation for students and objective assessment mechanisms demonstrate such.

**Model Standards for Pharmacy Internship Practice Experience Programs**
Section 1. Preceptor.
(a) The Pharmacy Intern, excluding those who are currently enrolled in a professional degree program of a school or college of pharmacy approved by the Board and satisfactorily progressing toward meeting the requirements for licensure as a Pharmacist, shall notify the Board of Pharmacy within two weeks of beginning practice as a Pharmacy Intern, on a form provided by the Board, of the identity of the internship pharmacy practice experience site and of the Preceptor. The Preceptor shall have been engaged in the Practice of Pharmacy for at least two years on a full-time basis immediately prior to serving as a Preceptor.
(b) A Preceptor may be responsible for the training of more than one Pharmacy Intern. The number of Pharmacy Interns engaged in the Practice of Pharmacy at any time is limited to not more than two for each Pharmacist on duty; the number of Pharmacy Interns the Pharmacist can appropriately precept as approved by the Board.

Section 2. Internship Training. Pharmacy Practice Experience Programs.
(a) The Pharmacy at which a Pharmacy Intern is being trained shall provide an environment that is conducive to the learning of the Practice of Pharmacy by a Pharmacy Intern. Pharmacy Practice Experience sites shall meet the standards approved by the Board. It is expected that the Pharmacy Intern will be exposed to all facets of the Practice of Pharmacy in that setting, including but not limited to the following:
(1) Evaluation of Prescription Drug Orders;
(2) Preparation and Labeling of Drugs;
(3) Dispensing of Drugs;
(4) Patient profile update and review;
(5) Drug Regimen Review;
(6) Patient Counseling;
(7) Proper and safe storage of Drugs; and
(8) Allowable use and disclosure of Protected Health Information.
(b) Internship Pharmacy practice experience in non-traditional practice sites (e.g., industry-sponsored programs) must be approved by the Board of Pharmacy prior to granting of internship credit.
(c) When a Pharmacy Intern desires to obtain credit for training received in a state other than this State, he/she the Pharmacy Intern shall abide by all the provisions of the internship pharmacy practice experience rules in that state, and shall provide evidence from that state’s Board of Pharmacy of the number of clock hours of experience actually participated in by the Pharmacy Intern.

Comments

Section 2. Pharmacy Practice Experience Programs. Comment.
Boards of pharmacy are strongly encouraged to utilize the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (effective July 1, 2007) as a basis for the establishment and revision of board standards for pharmacy practice experiences.
Background:
The Task Force on Standardizing Student Pharmacist Experiential Requirements, which met in December 2006, was charged with (1) recommending standardized experiential requirements, taking into consideration the ACPE Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, Standard No. 14, Curricular Core – Pharmacy Practice Experience; and (2) revising the Model Act to reflect the recommended standardized experiential requirements.

The Committee reviewed the recommended revisions of the Task Force and suggested minor changes. For example, the Committee suggested that model language addressing the supervision of pharmacy interns be consistent throughout the Model Act and also incorporated revisions that reflect applications for licensure transfer are no longer restricted to a “written” form.

LE/L Recommendation 4: The Committee fully supports and endorses the recommendation of the Task Force on Standardizing Student Pharmacist Experiential Requirements that boards of pharmacy monitor the implementation of revised the ACPE Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree and, if necessary, consider mandating or continue to mandate requirements for pharmacy practice experiences beyond what is required by college-based pharmacy practice experience programs to ensure that pharmacy practice experience competencies are being met.

Background:
Similar to the Task Force, the Committee also recommended that as school and colleges of pharmacy amend curricula to meet the revised ACPE standards, boards of pharmacy should consider continuing pharmacy practice experience mandates beyond what is required by professional curricula, if needed, to ensure that students become competent entry-level practitioners.

LE/L Recommendation 5: The Committee recommends the following revisions to the Model Act in consideration of proposed revisions submitted by the Food and Drug Administration (FDA).
The revisions recommended by FDA are denoted by underlines and strikethroughs. The recommended revisions by the Committee are denoted by double underlines and double strikethroughs.

Model Rules for Sterile Pharmaceuticals

Section 1. Purpose and Scope.
The purpose of this section is to ensure positive patient outcomes through the provision of standards for 1) Pharmacist Care; 2) the preparation, Labeling, and Distribution of Sterile Pharmaceuticals by Pharmacies, pursuant to or in anticipation of a Prescription Drug Order; and 3) Product Quality and Characteristics. These standards are intended to apply to all Sterile Pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor’s office). All Compounding Pharmacies and Pharmacists shall practice in accordance with these Rules, the Board’s Good Compounding Practices Applicable to State Licensed Pharmacies, and the current United States Pharmacopeia-National Formulary (USP-NF) chapters on Compounding and sterile pharmaceutical preparations.

**Section 2. Definitions.**

(a) “Beyond-Use Date” means a date determined by a Pharmacist and placed on a prescription label at the time of Dispensing that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(b) “Bioburden” means the total number of microorganism associated with a specific item prior to sterilization.

(c) “Biological Safety Cabinet” means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49.

(d) “Critical Areas” means areas designed to maintain sterility of sterile materials. Sterilized product, container/closures, and equipment may be exposed in critical areas.

(e) “Critical Surfaces” – Surfaces which may come into contact with or directly impact sterilized product or containers/closures.

(f) “Cytotoxic” means a pharmaceutical that has the capability of killing living cells.

(g) “Disinfection” means the process by which surface bioburden is reduced to a safe level or eliminated. Some disinfection agents are effective only against vegetative microbes, while others possess additional capability to effectively kill bacterial and fungal spores.

(h) “Enteral” means within or by way of the gastrointestinal tract or intestine.

(i) “ISO Class 5” means the description of an atmospheric environment characterized by the number of particles within a diameter per cubic foot of air, which contains fewer than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E and the International Organization for Standardization (ISO) Classification.

(j) “Isolator” means a decontaminated unit, supplied with ISO Class 5 or higher air quality that provides uncompromised, continuous isolation of its interior from the external environment (e.g., surrounding cleanroom air and Compounding Pharmacy personnel).

(k) “Parenteral” means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous or intramuscular routes.
the body or administered in a manner other than through the digestive tract, such as
by intravenous or intramuscular injection a sterile preparation of Drugs for injection
through one or more layers of the skin.

(k) “Positive Patient Outcomes” include the cure or prevention of disease, elimination or
reduction of a patient’s symptoms, or arresting or slowing of a disease process so as
to improve the patient’s quality of life.

(lm) “Product Quality and Characteristics” include: sterility, potency, identity, strength,
quality, and purity associated with environmental quality, preparation activities, and
checks and tests.

(mn) “Risk Level” of the Sterile Pharmaceutical means the level assigned to a Sterile
Pharmaceutical by a Pharmacist that represents the probability relative likelihood
probability that the Sterile Pharmaceutical will be contaminated with microbial
organisms, spores, endotoxins, foreign chemicals, or other physical matter.

(no) “Sterile Pharmaceutical” means any dosage form devoid of viable microorganisms,
including, but not limited to, parenterals, injectables, and ophthalmics, any dosage
form of a drug, including but not limited to parenterals (eg injectables, surgical
irrigants, and ophthalmics) devoid of viable microorganisms.

A policy and procedure manual shall be prepared and maintained for the Compounding,
Dispensing, Delivery, Administration, storage, and use of Sterile Pharmaceutical Prescription
Drugs Orders. The policy and procedure manual shall:

(a) The policy and procedure manual shall include a quality assurance program for the
purpose of monitoring patient care and Pharmacist Care outcomes, adverse Drug
reactions, personnel qualifications, training and performance, product integrity,
equipment, facilities, infection control Disinfection, personnel cleansing and
gowning, and guidelines regarding patient education;

(b) The policy and procedure manual shall be current and available for inspection by a
Board of Pharmacy-designated agent;

(c) include a plan designed to prevent microbiological contamination of sterile Drug
products and procedures concerning the validation of any sterilization process;

(d) include training and other requirements for Pharmacy Compounding personnel
involved in aseptic manipulations to ensure adherence to the basic principles of
aseptic technique;

(e) address the management and proper disposal of Cytotoxic and/or infectious waste, if
applicable; and

(f) address how supervisory personnel will monitor the ongoing adherence to procedures
and sound practices.

Section 4. Physical Requirements.
(a) The Pharmacy shall have a designated area with entry restricted to designated personnel for preparing Parenteral products Sterile Pharmaceuticals. This area shall be structurally isolated from other areas with restricted entry or access, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of Drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The Pharmacy preparing Parenteral products Sterile Pharmaceuticals shall have:

1. Appropriate environmental control Devices capable of maintaining at least ISO Class 5 conditions in the workplace where critical objects Critical Areas and Critical Surfaces are exposed and critical activities are performed and providing for appropriate environment control in consideration of the assigned Risk Level of the Sterile Pharmaceutical being prepared according to USP Test and Assays Chapter 797; Furthermore, these Devices are capable of maintaining ISO Class 5 conditions during normal activity all Compounding activities. Examples of appropriate Devices include laminar airflow hoods and zonal laminar flow of High Efficiency Particulate Air (HEPA) filtered air; Use of an Isolator shall also be considered;

2. Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;

3. Appropriate disposal containers for used needles, syringes, etc, and, if applicable, for Cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients’ homes;

4. When Cytotoxic Drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;

5. Temperature-controlled delivery container;

6. Infusion devices, if appropriate.

(c) The Pharmacy shall maintain supplies adequate to ensure an environment suitable for the aseptic preparation of Sterile Pharmaceuticals sterile products.

(d) The Pharmacy shall have sufficient current reference materials related to sterile products to meet the needs of Pharmacy staff.

Section 5. Records and Reports.
In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:

(a) A policy and procedure manual, including policies and procedures for Cytotoxic and/or infectious waste, if applicable; and Maintenance schedules, including a system for cleaning and disinfecting the room and equipment;

(b) Lot numbers of the Components used in Compounding sterile prescriptions;

(c) Compounding records, as described by Good Compounding Practices Applicable to State Licensed Pharmacies, Appendix C, Subpart I;
(dc) Records demonstrating that adequate disinfection (or Sterilization) was performed for the laminar flow hood and supplies used in the aseptic Compounding operation; and

(ed) Dispensing or Distribution records to document who received the Compounded prescriptions.

Section 6. Delivery Service.
The Pharmacist-in-Charge shall ensure the environmental control and stability of all products shipped. Therefore, any Compounded, Sterile Pharmaceutical must be shipped or Delivered to a patient or patient’s agent in appropriate temperature-controlled (as defined by USP Standards) delivery containers and stored appropriately in the patient’s home. Information on appropriate storage shall be provided to the patient or patient’s agent.

If appropriate, the Pharmacist must demonstrate or document the patient’s training and competency in managing this type of therapy provided by the Pharmacist to the patient in the home environment. A Pharmacist must be involved in the patient training process in any area that relates to Drug Compounding, Labeling, Administration, storage, stability, compatibility, or disposal. If appropriate, the Pharmacist must be responsible for seeing that the patient’s competency in the above areas is reassessed on an ongoing basis.

Section 11. Quality Assurance/Compounding and Preparation of Sterile Pharmaceuticals.
There shall be a documented, ongoing quality assurance control program that monitors personnel performance, component verification and usage, Disinfection, sterilization, equipment, and facilities that are appropriate to the Risk Level of the Sterile Pharmaceutical(s) being prepared. Appropriate samples of finished products shall be examined to ensure that the Pharmacy is capable of consistently preparing Sterile Pharmaceuticals meeting specifications.

(a) All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209E and the International Organization of Standardization Classification of Particulate Matter in Room Air (ISO14644-1) for operational efficiency at least every six months. Appropriate records shall be maintained.

(b) There shall be written procedures developed requiring sampling on a frequent basis and special measures taken when microbial contamination is suspected.

(c) If bulk Compounding of sterile solutions is performed using non-sterile chemicals that initially are non-sterile, extensive end-product microbial testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens, and microbes.
(d) Time limits for the completion of each phase of Compounding shall be established to assure the quality of the drug product.

(d) There shall be written justification of the chosen Beyond-Use Dates for Compounded products.

(e) There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits. Intervals shall be based on the type of operations performed and shall increase as the Risk Level increases.

(g) There shall be policies and procedures on the retraining or recertification of trained Pharmacy Compounding personnel in various aspects of aseptic behavior. The training program shall include a demonstration of ongoing competency. Training to ensure skills such as aseptic technique, cleanroom behavior, and knowledge of the hazards posed by contaminated drugs shall be conducted.

(h) Operators shall wear sterile gowning components if they conduct Pharmacy Compounding Personnel shall wear sterile garb if conducting one or more aseptic manipulation of sterilized equipment or product.

(i) An effective Disinfection program shall be implemented, including adequate provisions for preventing emergence of unsafe levels of sporeforming organisms.

(j) A system shall be in place for monitoring Pharmacy Compounding personnel and environmental conditions.

(j) A system shall be in place for maintaining any equipment or Devices used to control aseptic conditions.

Section 12. Pharmacist Care Outcomes.
There shall be a documented, ongoing quality assurance control program that monitors patient care and Pharmacist Care outcomes, including but not limited to the following:

(a) routine performance of Prospective Drug Regimen Review and patient monitoring functions by a Pharmacist, as defined in the Rules of the Board;

(b) patient monitoring plans that include written outcome measures and systems for routine patient assessment (examples include infection rates, rehospitalization rates, and the incidence of adverse Drug reactions);

(c) documentation of patient training as specified in Section 10; and

(d) appropriate collaboration with other health care professionals.

Comments

Section 2.(g) Comment.
Some disinfection agents are effective only against vegetative microbes, while others possess additional capability to effectively kill bacterial and fungal spores.

Section 2.(i) Comment.
For example, “ISO Class 5” means an atmospheric environment which contains fewer than 100 particles 0.5 microns in diameter per cubic foot or air.

Section 2.(n) Comment.
According to the USP Chapter 797 (27th Revision of the USP), the three Risk Levels of low, medium, and high are intended to guide the health care professional in determining the appropriate breadth and depth of care procedures necessary in the to ensure a safe Compounding process. Correspondingly, based upon the assigned Risk Level, health care professionals are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the Risk Level assigned to the Sterile Pharmaceutical.

Although Boards may consider referencing USP Chapter 797, Boards should also recognize that USP (per October 2005) is working to update this chapter in consideration of recommendations received from its internal expert committees as well as comments received from the professional community.

Section 5. Comment.
Boards may consider exempting lot number documentation for institutions that have an adequate mechanism in place to recall products. Such mechanisms may include bar coding and other technologies that may contain the necessary information that is effectively needed to recall products.

Appendix C
Good Compounding Practices Applicable to State Licensed Pharmacies

The following Good Compounding Practices (GCPs) are meant to apply only to the Compounding of Drugs by State-licensed pharmacies.

Subpart A – General Provisions and Definitions
The procedures contained herein are considered to be the minimum current Good Compounding Practices for the preparation of Drug products by State-licensed Pharmacies for Dispensing and/or Administration to humans or animals. Compounding Pharmacists and Pharmacies shall practice in accordance with these Good Compounding Practices, the Board’s Rules for Sterile Pharmaceuticals, and the current United States Pharmacopeia-National Formulary (USP-NF) chapters on Compounding and sterile product preparation. The following definitions from the NABP Model State Pharmacy Act apply to these Good Compounding Practices. States may wish to insert their own definitions to comply with State Pharmacy Practice Acts.
“Compounding” means the preparation of Components into a Drug product (i) as the result of a Practitioner’s Prescription Drug Order or initiative based on the Practitioner/patient/Pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding includes the preparation of very limited amounts of Drugs or Devices in anticipation of receiving Prescription Drug Orders based on routine, regularly observed prescribing patterns.

“Manufacturing” means the production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a Drug or Device or the Labeling or relabeling of the container of a Drug or Device for resale by pharmacies, Practitioners, or other Persons.

“Manufacturing” means the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, and is the making by chemical, physical, biological, or other procedures of any articles that meet the definition of drug or drugs. The term includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package to further the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

“Active Ingredients” refer to chemicals, substances, or other Components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

“Added Substances” mean the ingredients necessary to prepare the Drug product but are not intended or expected to cause a human pharmacologic response if administered alone in the amount or concentration contained in a single doses of the Compounded Drug product. The term “added substances” is usually used synonymously with the terms “inactive ingredients,” “excipients,” and “pharmaceutic ingredients.”

“Component” means any Active Ingredient or Added Substance intended for use in the Compounding of a Drug product, including those that may not appear in such on the product Label.

Based on the existence of a Pharmacist/patient/Practitioner relationship and the presentation of a valid Prescription Drug Order or Medical Order, Pharmacists may Compound, in reasonable and justified quantities, Drug products that are commercially available in the marketplace as long as they are slightly different from the FDA-approved product based upon and there is a specific, documented medical need for the need for this variation for a particular patient.

Pharmacists shall receive, store, or use Drug substances for Compounding that are Components of FDA-approved drugs and that have been made in an FDA-registered facility. If this requirement cannot be met, Pharmacists shall procure a
Certificate of Analysis for each lot purchased. Pharmacists shall also receive, store, or use Drug Components in Compounding prescriptions that meet official compendia requirements.

The Pharmacist shall notify customers if they may be affected by a product found to have a defect or an out-of-specification result.

Compounding includes the preparation of Drugs or Devices in anticipation of receiving Prescription Drug Orders or Medical Orders based on routine, regularly observed prescribing patterns. Pharmacists may Compound Drugs in very limited quantities, prior to receiving a valid Prescription Drug Order or Medical Order based on a history of receiving valid prescriptions. Prescription Drug Orders or Medical Orders that have been generated solely within an established Pharmacist/patient/Practitioner relationship, and provided that they maintain the prescriptions on file for all such products Compounded at the Pharmacy (as required by State and Federal law). The Compounding of inordinate amounts of Drugs in anticipation of receiving prescriptions without any historical basis is considered Manufacturing.

A Pharmacist may not Compound a Drug that appears on the FDA List of Drugs Withdrawn or Removed from the Market for Safety Reasons only if the prescriber and pharmacist ensure that the Drug product will not harm the patient and is in the patient’s best interest, or A Pharmacist may not Compound a Drug that appears on the FDA List of Drug Products that Present Demonstrable Difficulties in Compounding that adversely affect the safety or effectiveness of the Drug unless approved by the Board.

Pharmacists shall not offer Compounded Drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a Practitioner to Administer to an individual patient, in very limited quantities. Compounding pharmacies/Pharmacists may advertise or otherwise promote the fact that they provide prescription Compounding services, in accordance with State law, as well as applicable federal laws.

Pharmacists engaged in the Compounding of Drugs shall operate in conformance with applicable State law regulating the Practice of Pharmacy.

Subpart B – Organization and Personnel
As in the Dispensing of all prescriptions, the Pharmacist has the responsibility and authority to inspect and approve or reject all Components, Drug product containers, closures, in-process materials, Labeling, and the authority to prepare and review all Compounding records to assure that no errors have occurred in the Compounding process. If errors have occurred, the Pharmacist is responsible for conducting a full investigation. A written record of the investigation shall be made and shall include conclusions and follow-up. The Pharmacist is also responsible for the proper maintenance, cleanliness, and use of all facilities and equipment used in prescription Compounding practice.

All Pharmacists, or other employees such as Pharmacy Technicians, who engage participate in the Compounding of Drugs, including other Compounding Pharmacy personnel who assist the Pharmacist in Compounding, shall be proficient in the art of Compounding and shall maintain acquire the education, training, and/or experience to maintain that proficiency through
participation in seminars, studying appropriate literature, and consulting colleagues, or by becoming certified by a Compounding certification program approved by the Board. Also, every Pharmacist and all Compounding Pharmacy personnel who engage in Drug Compounding must be aware of and familiar with all details of the Good Compounding Practices.

Training of Pharmacists and other Compounding Pharmacy personnel (eg, Pharmacy Technicians) shall be in the particular operations that the employee performs are performed by that individual. Training shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that employees Compounding Pharmacy personnel remain familiar with applicable operations.

Personnel engaged in the Compounding of Drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as a coat/jacket, apron, or hand or arm coverings, shall be worn as necessary to protect Drug products from contamination. For a sterile Compounding operation involving one or more aseptic manipulations, sterile gowns and components are necessary. See the Model Rules for Sterile Pharmaceuticals.

Only personnel authorized by the responsible Pharmacist shall be in the immediate vicinity of the Drug Compounding operation. Any Person shown at any time (either by medical examination or Pharmacist determination) to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a Drug product being Compounded shall be excluded from direct contact with Components, Drug product containers, closures, in-process materials, and Drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products(s) being Compounded. All personnel who normally assist the Pharmacist in Compounding procedures shall be instructed to report to the Pharmacist any health conditions that may have an adverse effect on Drug products.

Subpart C – Drug Compounding Facilities
Pharmacies engaging in Compounding shall have a specifically designated and adequate area (space) for the orderly placement of equipment and materials to be used to Compound medications and to prevent mix-ups or contamination between Components, containers, labels, in-process materials, and finished Drug products. The Drug Compounding area for sterile products shall be separate and distinct from the area used for the Compounding or Dispensing of non-sterile Drug products. The area(s) used for the Compounding of Drugs shall be maintained in a good state of repair and be of suitable construction and location to facilitate cleaning, maintenance, and proper operation. Adequate space and appropriate material flow shall be provided.

Bulk Drugs and other materials used in the Compounding of Drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration as specified on the Compounded Drug’s label.

Adequate lighting, heating, ventilation, and air conditioning shall be provided in all Drug Compounding areas to avoid contamination or decomposition of Components. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects.
that could contribute contamination to any Compounded Drug product. Adequate washing facilities, easily accessible to the Compounding area(s) of the Pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-use towels.

The area(s) used for the Compounding of Drugs shall be maintained in a clean and sanitary condition. Sewage, trash, and other refuse in and from the Pharmacy and immediate Drug Compounding area(s) shall be held and disposed of in a safe, sanitary, and timely manner.

**Sterile Products/Radiopharmaceuticals**

If sterile (aseptic) products are being Compounded, conditions set forth in the NABP Model Rules for Sterile Pharmaceuticals must be followed.

If radiopharmaceuticals are being Compounded, conditions set forth in the NABP Model Rules for Nuclear/Radiologic Pharmacy must be followed.

**Special Precaution Products**

The Compounding area should be designed, arranged, used, and maintained to prevent cross-contamination. Equipment and Compounding areas should be thoroughly cleaned promptly after use, and special precautions should be taken to meticulously clean equipment and Compounding areas after Compounding Drug products that contain allergenic Components (eg, sulfonamides or penicillins).

**Subpart D – Equipment**

Equipment used in the Compounding of Drug products shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. The types and sizes of equipment will depend on the dosage forms and the quantities Compounded. Equipment used in the Compounding of Drug products shall be of suitable composition so that surfaces that contact Components, in-process materials, or Drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the Drug products beyond that desired which they purport or are represented to possess.

Equipment and utensils used for Compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the Drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the Compounding of sterile Drug products, cleaning, sterilization, and maintenance procedures as set forth in the NABP Model Rules for Sterile Pharmaceuticals must be followed.

Previously cleaned equipment and utensils used for Compounding Drugs must be protected from contamination prior to use. Immediately prior to the initiation of Compounding operations, they must be inspected by the Pharmacist and determined to be suitable for use.

Equipment shall be properly maintained to prevent malfunctions that would alter the drug product’s safety, identity, strength, quality, or purity. Equipment shall be subject to maintenance
and there shall be cleaning schedules and descriptions of the methods, equipment, and materials used in cleaning and maintenance operations. There shall be methods of reassembling equipment to assure proper cleaning and maintenance.

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems shall be routinely inspected, calibrated (if necessary), or checked to assure proper performance, as per manufacturer instructions.

**Subpart E – Control of Components and Drug Product Containers and Closures**

Components, Drug product containers, and closures, used in the Compounding of Drugs shall be handled and stored in a manner to prevent contamination. Bagged or boxed Components of Drug product containers and closures used in the Compounding of Drugs shall be stored off the floor in such a manner as to permit cleaning and inspection.

A report of analysis containing the identity, strength, and quality and purity shall be obtained for each component used in the Compounding of Drug products. A report of analysis for Drug product containers and closures shall also be obtained. At a minimum, a visual identification performed on each component product container and closure shall also be conducted against established specifications.

Compounded Drug products should be packaged in containers meeting USP standards. The container used depends on the physical and chemical properties of the Compounded Drug products. Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the Compounded Drug beyond the desired result that which it purports or is represented to possess. Container-Drug interaction should be considered with substances such as phenolic Compounds and sorptive materials (eg, polypeptides and proteins).

Changes to these procedures shall be reviewed and approved by the appropriate organizational units and by a representative from the Continuous Quality Improvement Program.

Components, Drug product containers, and closures for use in the Compounding of Drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the Compounded Drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the Drug, sterilized and processed to remove pyrogenic properties to ensure that they are suitable for their intended use.

Drug product containers and closures intended for the Compounding of sterile products must be handled, sterilized, stored, etc, in keeping with the NABP Model Rules for Sterile Pharmaceuticals. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for Drug product containers and closures used in the preparation of sterile pharmaceuticals, if these processes are performed by the Pharmacist, or under the Pharmacist’s supervision following the NABP Model Rules for Sterile Pharmaceuticals.
Components, Drug product containers, and closures shall not be used for Compounding operations for which they are unsuitable.

**Subpart F – Drug Compounding Controls**

There shall be written procedures for the Compounding of Drug products to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the Components, their amounts (in weight or volume), the order of Component addition, and a description of the Compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the Drug, shall be listed. These written procedures shall be followed in the execution of the Drug Compounding procedure.

Components for Drug product Compounding shall be accurately weighed, measured, or subdivided as appropriate to ensure that the Compounded Drug product will be formulated with the intent to provide 100% of the Labeled or established amount of active ingredient. The Compounding Pharmacist should:

(a) check and recheck these operations at each stage of the process to ensure that each weight or measure is correct as stated in the written Compounding procedures,
(b) observe the finished Drug product to ensure that it appears as expected, and
(c) record the various compounding steps completed at the time of performance, and
(d) investigate any discrepancies and take appropriate corrective action before the Drug product is dispensed to the patient.

If a Component is removed from the original container to another (eg, a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the:

(a) Component name;
(b) weight or measure;
(c) lot number; and
(d) expiration date or Beyond-Use Date.

To ensure the reasonable uniformity and integrity of Compounded Drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product being Compounded (eg, Compounding of capsules). Such control procedures shall be established to monitor the output and to validate the performance of those Compounding processes that may be responsible for causing variability in the final Drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) tablet or capsule weight variation;
(b) adequacy of mixing to ensure uniformity and homogeneity;
(c) clarity, completeness, or pH of solutions.

Rejected in-process and finished materials shall not be used for Compounding operations for which they are unsuitable.
Assurance of sterility in a Compounded sterile Drug product is mandatory. Appropriate written procedures designed to prevent microbiological contamination of Compounded Drug products shall be established and followed. Such procedures shall include validation of any sterilization process.

**Subpart G – Continuous Quality Improvement Program**

Each Compounding Pharmacy shall implement a Continuous Quality Improvement Program (CQIP) intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this document. Emphasis on the CQIP should be placed on maintaining and improving the quality of systems and the provision of patient care. The CQIP should ensure that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions are performed. The CQIP should adhere to the provisions set out in the NABP Model Rules for the Practice of Pharmacy.

A CQIP shall be documented through written policies and procedures and shall include the following:

1. Consideration of all aspects of the preparation and dispensing of products as described in the NABP Model Rules for Sterile Pharmaceuticals and the *USP-NF* Chapter 797, Pharmaceutical Compounding-Sterile Preparations;
2. Description of specific monitoring and evaluation activities;
3. Specification of how results are to be reported and evaluated;
4. Collection of complaints, returns, or recalls that impact the identity, strength, quality, and/or purity of Compounded Drug products;
5. Identification of appropriate follow-up mechanisms when action levels or thresholds are exceeded; and
6. Delineation of the individuals responsible for each aspect of the CQIP.

In developing a specific plan, focus should be on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. Appropriate, provided that Compounding of Drug products with these attributes are appropriate. Proper evaluation of environmental monitoring might include, for example, the trending of an indicator such as settling plate counts.

The selection of indicators and the effectiveness of the overall CQIP plan should be reassessed as needed or on an annual basis.

**Subpart H – Labeling Control of Excess Products**

In the case where a very limited quantity of a Compounded Drug product in excess of that to be initially Dispensed in accordance with Subpart A is prepared, the excess product shall be labeled or documentation referenced with the complete list of Components, the preparation date, and the assigned expiration date, Beyond-Use-Date based upon appropriate testing, published data, and/or USP Guidelines. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (eg, in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.
At the completion of the Drug finishing operation, the product shall be examined for correct Labeling.

**Subpart I – Records and Reports**

Compounding Pharmacies shall maintain a Formulation Record and a Compounding Record.

**Formulation Record** – A formulation record lists individually Compounded Drug products, and includes, but is not limited to, the following information:

1. name, strength, and dosage form of the Drug product Compounded;
2. all Components and their quantities, an accurate statement of the weight or measure of each component;
3. equipment needed to prepare the Drug product, when appropriate;
4. mixing instructions, including:
   a. mixing temperatures;
   b. other environmental controls, such as the duration of mixing;
5. other factors pertinent to the replication of the Drug product as Compounded;
6. Beyond-use Date;
7. container, closures, and packaging materials used in dispensing;
8. storage requirements; and
9. Labels and Labeling with appropriate Beyond-use Date and instructions for storage and use; and
10. quality control procedures to include identification of the Person(s) performing and directly supervising or checking each significant step in the Compounding operations.

**Compounding Record** – A Compounding record contains:

1. documentation of the name and strength of the Compounded Drug product;
2. the formulation record reference for the Drug product;
3. the sources and lot numbers of the Components;
4. the total number of dosage units Compounded;
5. the name of the Person who prepared the Drug product;
6. the name of the Pharmacist who approved the Drug product;
7. the name of the Practitioner and the name of the person patient who received and the health care provider who prescribed the Compounded Drug product;
8. the date of preparation;
9. the examination of the Labels, Labeling, and packaging materials for suitability and correctness before dispensing;
10. the prescription number or assigned internal identification number;
11. the Dispensing or Distribution records to document who received the Compounded Prescriptions, if different than the Patient; and
12. the results of quality control procedures (eg, weight range of filled capsules) as described within the pharmacy’s Continuous Quality Improvement Program.

In addition to the formulation record and Compounding record, records shall be maintained for all components, Drug product containers, closures, Labeling, equipment cleaning and
Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Any records required to be maintained in compliance with these Good Compounding Practices shall be retained for the same period of time as each State requires for the retention of prescription files. All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection.

**Comments**

**Subpart A. Comment.**

Boards of Pharmacy should continually monitor compliance with these Good Compounding Practices to distinguish Compounding from Manufacturing, and base their judgment upon including consideration of the following factors:

1. Compounded prescription volume;
2. the existence of a Practitioner/patient/Pharmacist relationship;
3. use of commercial scale equipment;
4. Nature availability of the product (commercially available);
5. whether or not the pharmacy Compounds, in anticipation of receiving Prescription Drug Orders, an inordinate supply of product; and
6. whether the Pharmacy Compounds Drugs for third parties who re-sell to individual patients; or
7. any such other indicators as may be necessary to monitor from time to time to determine compliance and distinguish Compounding from Manufacturing, such as Compounding Drugs that were withdrawn or removed from the market for safety reasons, or Compounding finished drugs from bulk active ingredients that are not components of FDA-approved Drugs.

Additionally, Boards of Pharmacy, in extreme situations as defined by the Board, may permit the Compounding of Products contained on the FDA List of Drug Withdrawn or Removed from the Market for Safety Reasons or on the FDA List of Drug products that Present Demonstrable Difficulties in Compounding. For example, if a determination has been made and documented that other FDA-approved Drug Products have not been able to successfully treat the patient, the Pharmacist can Compound a product that appears on the FDA lists only if documentation of, for example, clinical assessments, benefit to risk analysis, etc, can be provided and the Patient and Practitioner are informed and aware of the benefits to, risks.
**Subpart D. Comment.**
Boards of Pharmacy may consider referencing *USP-NF* Chapter 41 (Weights and Balances), Chapter 1176 (Prescription Balances and Volumetric Apparatus), and equipment manufacturers’ instruction manuals.

**Subpart E. Comment.**
Boards of Pharmacy may consider referencing *USP-NF* Chapter 661 (Containers) and Chapter 671 (Containers-Permeation).

**Subpart F. Comment.**
Boards may consider referencing *USP-NF* Chapter 797 (Pharmaceutical Compounding-Sterile Preparations) and requiring adherence by all Compounding Pharmacists to the Compounding and packaging of sterile product guidelines found within that chapter. However, Boards should also recognize that USP (per October 2005) is working to update this chapter in consideration of recommendations received from its internal expert committees as well as comments received from the professional community.

Boards may consider referencing the following checklist, found in the *USP-NF* Chapter 795 (Pharmaceutical Compounding–Nonsterile Preparations) and requiring its use by the Compounding Pharmacist to ensure the appropriate strength, quality, and purity of the Compounded product:

1. Have the physical and chemical properties and medicinal, dietary, and pharmacological uses of the Drug products been reviewed?
2. Is the quantity and quality of each Active Ingredient identifiable?
3. Will the Active Ingredients be effectively absorbed, locally or systemically according to the prescribed purpose, from the Drug product and route of administration?
4. Are there Added Substances (confirmed or potentially present) from manufactured products that may be expected to cause an allergic reaction, irritation, toxicity, or undesirable organoleptic response from the patient? Are there Added Substances (confirmed or potentially present) that may be unfavorable (eg, unsuitable pH or inadequate solubility)?
5. Were all calculations and measurements confirmed to ensure that the Drug product will be Compounded accurately?

**Subpart I. Comment.**
The objective of documentation is to allow another pharmacist to reproduce the identical prescription at a future date. The formulation record provides a consistent source document for preparing the Drug product (recipe), and the Compounding record documents the actual Components in the Drug product and the person responsible for the Compounding activity.

Normally, the patient’s name and the name of the Practitioner Prescribing the Compounded Drug product are recorded in the Compounding Record at the time of compounding and dispensing. If, however, the Compounded Drug Product is prepared in anticipation of a Prescription Drug Order, a mechanism should be implemented that identifies to whom the previously-Compounding Drug Products have been dispensed.
Background:

In November 2005, NABP convened the Task Force on Standards for Compounding. This Task Force was appointed in response to a resolution which directed NABP to review and revise, where appropriate, the Model Rules for Sterile Pharmaceuticals to reflect applicable standards set forth in USP Chapter 797. The Task Force recommended a variety of amendments, many of which were eventually incorporated into the Model Act. Although two ex officio FDA members attended the Task Force meeting, FDA was unable to formally submit the Agency’s amendments to the Model Act at the time of the Task Force meeting. Subsequently, FDA submitted its formal recommendations in time for this Committee to review.

In addition to the Model Rules for Sterile Pharmaceuticals, FDA also submitted revisions to Appendix C of the Model Act, Good Compounding Practices Applicable to State Licensed Pharmacies. In summary, most of the revisions submitted by FDA attempted to strengthen model language in terms of policy and procedural requirements, quality assurance, and the physical aspects associated with the pharmacy and its equipment. Although the Committee agreed with most of the changes submitted by FDA, the Committee also recommended the preservation of the current Model Act with respect to certain FDA recommended amendments, including: (1) the definition of “Risk Level” as it relates to sterile compounding, so that this section remains consistent with USP Chapter 797; (2) the definition of “Manufacturing,” so it continues to not include compounding within its definition; and (3) the ability to compound products that appear on the FDA List of Drugs Withdrawn or Removed from Market for Safety Reasons, so that it remain allowable in certain circumstances.

LE/L Recommendation 6: The Committee recommends the removal of Appendix B, Computerized Compliance Reports, from the Model Act.

Background:

Appendix B, Computerized Compliance Reports, was initially incorporated into the Model Act in 1994 to give boards of pharmacy direction in implementing requirements for computerized record-keeping reports related to controlled substances. This section provided an example of what information a computer-generated report should contain. With the wide-spread adoption of the use of computers in pharmacies and the fact that pharmacies have been generating such reports for many years, the Committee agreed that an example of such a report in the Model Act was of limited value.