NABP State Boards of Pharmacy Member Manual

National Association of Boards of Pharmacy
Mount Prospect, IL
www.nabp.pharmacy

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Chapter 1

NABP and You

Chapter Objectives

After completing this chapter, you should be able to answer the following questions:

- What is the mission of the National Association of Boards of Pharmacy (NABP)?
- Who are the members of NABP? What distinguishes the active and associate members?
- Who governs the Association?
- What is the Electronic Licensure Transfer Program (e-LTP)?
- What is the Verified Pharmacy Program (VPP)?
- How does the Multistate Pharmacy Inspection Blueprint Program assist boards of pharmacy?
- How does the NABP Clearinghouse assist boards of pharmacy?
- How does NABP PMP InterConnect support boards of pharmacy, other prescription monitoring program (PMP) administrators, and registered PMP users?
- What examination programs does NABP offer?
- How does CPE Monitor assist boards of pharmacy as well as licensees and registrants?
- What accreditation and verification programs does NABP offer?
- What member services does NABP offer?
- What consumer protection programs does NABP offer?
- What programs and projects are overseen by the NABP Foundation (NABPF)?

The National Association of Boards of Pharmacy® (NABP®) is a 501(c)(3) nonprofit association. Since its inception in 1904, NABP has operated to support the boards of pharmacy as they regulate for the protection of public health. Every program implemented by NABP must meet this charge as stated in the Association’s mission statement:

The National Association of Boards of Pharmacy (NABP) is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP membership is composed of both active members and associate members. The 54 active members include the 50 United States state boards of pharmacy and the boards in the four jurisdictions of District of Columbia, Guam, Puerto Rico, and the Virgin Islands. Active member boards have formally approved the Constitution and Bylaws of the Association and require the use of the NABP Clearinghouse for all candidates for the purpose of transferring licensure both into and out of the state, as provided by the Bylaws of this Association.
Associate members include 10 Canadian provinces, Australia, and The Bahamas. These members provide an international perspective and have the opportunity to participate in district meetings, NABP Interactive Forums, and the NABP Annual Meeting.

The annual membership fee for each board is $250.

The Association is governed by its Executive Committee, made up of four officers – chairperson, president, president-elect, and treasurer – and eight members. The treasurer and president-elect are elected during the Association’s Annual Meeting; the president takes office by progression and then takes the position of chairperson following completion of his or her year-long term as president.

NABP member boards of pharmacy are grouped into eight districts that include all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, 10 Canadian provinces, Australia, and The Bahamas. A district map is in the Appendix. Each of the Executive Committee members represents one of the eight districts.

Executive Committee members are typically nominated by their districts and subsequently elected at the Annual Meeting; districts may nominate up to two candidates when their member seat is open for election. Members are elected on a rotating basis. Nominations may also occur outside the district process. In these cases, individuals must provide written notice to the NABP executive director/secretary after the relevant district meeting, but no later than 45 days prior to the Annual Meeting’s First Business Session. The Executive Committee member term of office is three years, unless the remainder of a term is being fulfilled by another individual.

NABP is here to support the members of boards of pharmacy by providing members with the most current, pertinent information affecting the regulation of pharmacy. Additionally, through its Annual Meeting and Interactive Forums, NABP provides board members an opportunity to network with other state board of pharmacy members throughout the country, as well as the ability to participate in events that guide Association policy.

NABP is a robust organization with a multitude of programs and services designed to support the many facets of the practice of pharmacy. Following is a brief description of each of the programs and services offered by NABP and the NABP Foundation®.

NABP e-Profile Connect

NABP e-Profile Connect is a secure online system that allows authorized board of pharmacy staff to access pharmacy, pharmacist, technician, and facility e-Profile information in support of licensure responsibilities. In addition, some information is available to authorized users at the schools and colleges of pharmacy. The following data and services are available through NABP e-Profile Connect:

- NABP Clearinghouse data may be uploaded and is available in real time.
- Official licensure transfer applications and supporting documentation can be viewed and evaluated.
- License verification information may be accessed.
- North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®) Official Candidate and Summary Score Reports and Score Transfer Reports are available.
- NAPLEX and MPJE eligibility can be easily approved.
- CPE Monitor® data may be accessed, including reports and searches for specific licensees.
- Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification candidate information is available.
- Verified Pharmacy Program® (VPP®) and state inspection reports may be accessed,
and boards may upload state inspection reports.

- VPP pharmacy e-Profiles.

NABP staff can customize user access for board executive directors by assigning certain responsibilities and functions for use only by designated board staff. Each staff person will be assigned a unique username and password that grants access to the responsibilities assigned by the executive director. Executive directors may contact eProfileAccess@nabp.pharmacy to obtain accounts for new staff members and designate their roles.

**Licensure Transfer**

The impetus for the formation of NABP, uniform reciprocity standards for pharmacists, is the cornerstone of the Association’s operation. Through the Electronic Licensure Transfer Program® (e-LTP™), pharmacists wishing to obtain licensure in additional states can transfer their license with ease. The program screens applicants’ licenses for disciplinary actions and verifies background information. The information is then provided to the boards of pharmacy through e-Profile Connect so they can review the data as part of the decision-making process for licensure transfer approval.

At present, pharmacist licenses are one of the most portable and easily transferred of professional licenses via e-LTP. NABP continues to work with its member boards of pharmacy to enhance the e-LTP process to support the future of pharmacy practice. For a discussion on interstate license portability solutions, see “You Can Take It With You: NABP Enhances Long-Standing Licensure Transfer Model” in the Appendix of this manual.

**Verified Pharmacy Program**

As an extension of NABP’s existing pharmacist license transfer system, Verified Pharmacy Program® (VPP®) provides the capability for boards of pharmacy to share critical licensure and inspection information for pharmacies and other facilities operating in multiple states. For each pharmacy, the program creates e-Profiles through which verified data is made available electronically to the boards through NABP e-Profile Connect, the same platform the boards use for other NABP services. These facility e-Profiles will also contain information to key personnel e-Profiles, including those of the pharmacist-in-charge (PIC) in the state of domicile, as well as any nonresident PICs.

VPP information may be accessed by board staff through the VPP Inspection Sharing Network in the NABP e-Profile Connect. A facility e-Profile includes license verification for all states in which a pharmacy is licensed, any known disciplinary action by a state or federal agency, and any inspection reports that have been provided by a resident state or through VPP.

Over 46 boards recognize VPP or a VPP inspection and/or require that nonresident pharmacies apply to VPP when seeking to obtain or renew licensure.

VPP is also being utilized by third parties, such as FocusScript (formerly United Compounding Management). When third parties utilize VPP inspections, member boards benefit from the increased volume of information available in VPP Inspection Sharing Network. In addition, NABP continues to be in close discussions with the state boards of pharmacy to further develop VPP so that it meets their needs.

**Multistate Pharmacy Inspection Blueprint Program**

The Multistate Pharmacy Inspection Blueprint Program is meant to assist the state boards of pharmacy in continuing to develop their own robust inspection capabilities. The Blueprint Program allows states to ensure their own inspection forms and processes cover minimum requirements agreed upon by the majority of member boards. These requirements are reflected in the blueprint
and focus on general areas of pharmacy and national compounding standards, including United States Pharmacopeia (USP) Chapters <795> and <797>. By becoming a Blueprint state, a state signals that sterile compounding pharmacies that ship product out-of-state are being routinely and consistently inspected by trained inspectors, and that the inspection reports it shares on these facilities reflect this robust, uniform approach. To become a Blueprint state, boards may either utilize the Universal Inspection Form or ask NABP to crosswalk the boards’ inspection forms and processes against the Universal Inspection Form and advise the board of any needed changes.

To further encourage strong oversight of sterile compounding, NABP is providing training opportunities for state board of pharmacy inspectors by way of funding the tuition for one inspector per state each year to attend CriticalPoint, LLC’s Sterile Compounding Inspector Training and certification program. This training program includes a series of preliminary online learning modules, three and a half days of hands-on instruction at a state-of-the-art facility in New Jersey, and a post-test for certification in inspecting for compliance with the standards of USP Chapters <797> and <800>. Also through a grant administrated by NABP, The Pew Charitable Trusts provides funding for both in-state training as well as to support inspectors’ participation in the CriticalPoint training. In one state, in-state training with NABP surveyors was provided to state pharmacy inspectors/compliance officers and included a preliminary educational webinar, onsite observation of sterile compounding inspections, and a follow-up analysis. In addition, participants were presented with an opportunity to practice sterile gowning and garbing for an inspection of a clean room, inspecting for all elements in the universal inspection sterile compounding module, and completing the inspection report.

**NABP Clearinghouse**

The NABP Clearinghouse is a national database of educational, competence, licensure, and disciplinary information on pharmacists practicing in NABP’s member states and jurisdictions. The Clearinghouse also houses information reported by the member boards of pharmacy on actions taken against wholesale distributors, pharmacies, pharmacy owners, technicians, interns, manufacturers, and controlled substance licenses. Information housed in the Clearinghouse is used in determining the acceptability of pharmacists who request transfer of examination scores and licenses into other states or jurisdictions. The Clearinghouse is used to support all the accreditation programs as well. Active member boards agree via the NABP Constitution and Bylaws to submit all final adverse actions in a timely manner to NABP.

NABP can also serve as a board of pharmacy’s reporting agent for the National Practitioner Data Bank. This is as simple as checking a box when submitting actions to the Clearinghouse, thereby reducing extra steps for board staff.

In addition, NABP reports the total number of disciplinary actions reported by the state boards of pharmacy in its newsletter, **Innovations**®, on a quarterly basis. Included in the report are the total number of actions taken by the boards and the bases for actions taken.

**NABP PMP InterConnect**

NABP PMP InterConnect® facilitates the transfer of prescription monitoring program (PMP) data across state lines to authorized users. It allows participating state PMPs across the US to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide.

PMP InterConnect enhances the benefits of state PMPs by providing the means for
The Association coordinated the development of the North American Pharmacist Licensure Examination® (NAPLEX®), which was first given in its earliest form in 1972. The NAPLEX is utilized by all 54 member boards to determine if a candidate for licensure in his or her state has the knowledge and skills necessary to safely and effectively practice entry-level pharmacy.

With practitioners and pharmacy faculty creating the questions, NABP continues to administer a psychometrically sound national examination.

Streamlining the licensing process for both licensure candidates and boards of pharmacy, the NAPLEX Score Transfer Program allows candidates to have their examination scores transmitted to other state(s), in addition to their primary state, if their request is received according to the program guidelines.

Volunteers composed of board members, compliance officers, regulators, and practitioners from participating states write questions for the Multistate Pharmacy Jurisprudence Examination® (MPJE®), which is utilized by 48 member boards of pharmacy. The MPJE, customized for each participating state, combines federal and state-specific law questions to serve as the state law examination in participating jurisdictions.

The Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program documents the educational equivalency of a candidate’s foreign pharmacy education and licensure and/or registration to practice pharmacy. Foreign-educated pharmacists awarded FPGEC Certification are considered to have partially fulfilled eligibility requirements.
for licensure in those states that accept the certification. All 50 states, District of Columbia, Guam, and Puerto Rico require graduates of pharmacy schools that are not based in the US to achieve FPGEC Certification before applying for a license from a state board of pharmacy.

The Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) is a component of the FPGEC Certification process. After their education and pharmacist credentials have been approved, candidates must pass the FPGEE as one of the final steps toward achieving FPGEC Certification.

As with the other NABP examinations, the questions on the FPGEE are developed by volunteers from the boards of pharmacy and faculty of colleges of pharmacy.

**PCOA**

The Pharmacy Curriculum Outcomes Assessment® (PCOA®) is a comprehensive tool for schools and colleges of pharmacy to use as they assess curriculum development and student performance – it remains the only independent, objective, and national test that enables schools and colleges of pharmacy to evaluate their curriculum, measure their students’ knowledge, and compare their results to other schools and colleges throughout the US. The PCOA is required for students nearing completion of the didactic curriculum to meet Standard 24: Assessment Elements of the Accreditation Council for Pharmacy Education’s (ACPE’s) Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016). The PCOA is suitable for students in all professional years, and schools may want to administer it throughout all levels in order to monitor student growth.

**CPE Monitor**

The CPE Monitor® service, a national, collaborative effort between NABP, ACPE, and ACPE-accredited providers, provides a streamlined reporting and compliance verification process for continuing pharmacy education (CPE).

The service allows pharmacists and technicians to easily track their ACPE-accredited CPE credits. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data is sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile.

State boards of pharmacy may access CPE Monitor data through NABP e-Profile Connect to assist them in ensuring that pharmacists and pharmacy technicians have completed state-mandated CPE requirements for relicensure, recertification, or reregistration. Boards of pharmacy may check the status of individual pharmacists and technicians at any time. They also have the option of requesting a report that provides data on all licensees in their jurisdiction, saving board staff the trouble of manually collecting and documenting paper CPE statements for license renewal.

**CPE Monitor Plans**

In 2018, NABP began offering a choice of two plans to help pharmacists manage their licensing requirements. Both plans, Standard and Plus, are available via the new NABP e-Profile mobile app:

- **Standard Plan:** The Standard plan is free and includes all the basic CPE Monitor features that were in place when the program first began, such as automatic transmission of ACPE-accredited activity from the provider to the e-Profile. Users can view detailed CPE transcripts and monitor their compliance status in all 50 states and the District of Columbia. All CPE
Monitor users are automatically set up with the standard plan upon entering a license in their e-Profile.

**Plus Plan:** The Plus plan gives pharmacists the ability to monitor their CPE credits seamlessly through CPE Monitor. It eliminates the need to manually add and cross-check required types of CPE credits, while automatically tracking their progress in every state where they have a license. The Plus plan costs $29.95 per year; the price remains the same no matter how many licenses a pharmacist has or will add at a later date. The additional features that come with the Plus plan are:

- verify how much CPE credit must be earned to satisfy renewal requirements
- receive alerts when licenses are nearing the end of a CPE cycle
- upload non-ACPE credits to e-Profile
- view consolidated transcripts for each state license
- connect to My CPD to maintain continuing professional development in one place
- connect to P.L.A.N. to easily search for ACPE-approved courses

**Accreditation Programs**

Over the years, advances in technology and distribution, as well as the increase in the use of pharmaceuticals, have created opportunities for new entities in the practice of pharmacy, and with these developments came new concerns for public health and safety. Additionally, boards of pharmacy have seen their resources shrink, causing logistical difficulties in the regulation of these entities. To support the boards of pharmacy and protect public health, NABP developed several accreditation and verification programs to provide uniform standards in three particular areas: wholesale distributors; durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and pharmacies with an internet presence. Several states now require accreditation by the appropriate NABP program as a requisite for licensure of certain entities, thus ensuring public safety and reducing the burden on state boards of pharmacy.

**VAWD**

Established in 2004, the Verified-Accredited Wholesale Distributors® (VAWD®) program helps to protect the public from the threat of counterfeit drugs affecting the US drug supply. The VAWD program provides added protection by ensuring that entities engaged in wholesale distribution are legitimately conducting distribution operations, validly licensed in good standing, and employing security and best practices for safely distributing prescription drugs and devices from manufacturers to pharmacies and other institutions. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, a survey, and screening through the NABP Clearinghouse. Several states require VAWD accreditation as a component of licensure in their state.

**VDIP**

Launched in 2016, the Verified-Accredited Device Integrity Program® (VDIP®) is an extension of VAWD that helps prevent diverted or suspect diagnostic over-the-counter (OTC) medical devices from entering the US medical supply chain. The program accredits distributors of diagnostic OTC medical devices that may be delivered by a pharmacy pursuant to a prescription. Applicants for VDIP accreditation undergo a criteria compliance review, licensure verification, and an on-site survey.
Launched in 2006, the NABP durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program, approved by the Centers for Medicare and Medicaid Services (CMS), is the cost-effective and reliable choice for pharmacies seeking DMEPOS accreditation. Pharmacies accredited through the NABP DMEPOS program are doing their part to help ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS products.

Pharmacy Verified Websites Program

Patients buying medication or obtaining medication-related information or services online must be aware to protect themselves from rogue websites. One easy way for patients to identify a safe online pharmacy is through NABP’s .Pharmacy Verified Websites Program, which was officially launched in 2014. The .Pharmacy Program, which was developed in partnership with a global coalition of stakeholders, addresses a shared concern about illegal online drug sellers distributing products that endanger patient health worldwide.

Verified websites are allowed to use .pharmacy in their web addresses. This means that patients can look for the .pharmacy domain at the end of a web address, as with “.com” or “.biz,” but .pharmacy tells them the site is properly licensed and safe. NABP also provides a list of verified sites on its consumer site, www.safe.pharmacy. Because .pharmacy is a verified domain, companies seeking a .pharmacy domain must have their websites evaluated for compliance with safety standards before they can register a .pharmacy domain. They must meet all applicable regulatory standards, including pharmacy licensure and valid prescription requirements, in the jurisdictions where they are based as well as where they serve patients to become verified.

Eligible registrants in this global pharmacy community include pharmacies, pharmacy benefit managers, schools and colleges of pharmacy, CPE providers, wholesale drug distributors, pharmaceutical manufacturers, resource sites, professional sites, pharmacy automation distributors, and boards of pharmacy and regulatory agencies.

Information for pharmacies and other organizations that would like to become verified through .pharmacy is available in the Programs section of the NABP website at www.nabp.pharmacy.

VIPPS

NABP’s Verified Internet Pharmacy Practice Sites® (VIPPS®) accreditation program was the first program developed by the Association for the purpose of providing patients with a resource for safe online pharmacy sites. Launched in 1999, the VIPPS program is just as relevant today, with its stringent criteria telling the story of an online pharmacy’s commitment to the safety of patients in the US. Though the core tenants of the program have remained the same, there have, of course, been some changes to the program in the 20 years it has been operating. One major change is the new requirement that pharmacies must first be verified through the .Pharmacy Program before they can apply for VIPPS accreditation. While accredited, they must maintain their active .pharmacy domain. In addition, the .pharmacy web address must either be used as the primary/stand-alone site or redirect to the pharmacy’s primary accredited website.

While there are some similarities between the two programs, there are also several differences. VIPPS accreditation is for those US pharmacies with a web presence
that want to go above and beyond the Pharmacy Program verification and achieve full accreditation. To be VIPPS-accredited, a pharmacy must demonstrate compliance with its resident state's laws and licensing requirements and with each state to which it dispenses pharmaceuticals. Pharmacies displaying the VIPPS Seal must also have demonstrated compliance with VIPPS criteria, including those addressing patient privacy and authentication, and security of prescription orders. Applicants must likewise demonstrate adherence to a recognized quality assurance policy and the provision of meaningful consultation between patients and pharmacists. Several states require VIPPS accreditation for licensure in their state. Finally, VIPPS applicants will undergo an on-site inspection.

Online safety and security challenges will continue to evolve, and NABP will monitor changes to ensure its programs are in the best position to help patients identify safe websites from which to obtain their medication.

**Member Relations and Government Affairs**

In addition to providing support to the boards through its programs and services, NABP can offer support and assistance as boards seek to maintain and develop rules and regulations that protect public health. As the practice of pharmacy increasingly extends across state borders, NABP works with the boards to meet distinct requirements in each of the individual states, as well as provides the boards with a national view of pharmacy practice, standards, disciplinary actions, and regulation. Realizing that no board or state is exactly alike, the NABP Member Relations and Government Affairs department is responsible for working to understand and meet the unique needs of each member board of pharmacy. The department conducts regular outreach to member boards of pharmacy to stay in tune with the emerging issues in that state and ensure that the Association continues to provide resources that are of value to the membership.

NABP offers support to the boards through many services, including:

- Training, education, and tools focused on operational and inspection best practices;
- Education and resources relative to emerging issues;
- Tracking and monitoring critical state and federal legislation that may impact the state boards of pharmacy; and
- Reviewing and providing feedback on proposed legislation and regulations.

Upon request from member boards, NABP can also be available to provide written and/or in-person testimony and to participate in or present during board of pharmacy meetings and deliberations, conference calls, or legislative summits to assist the states with pharmacy practice and regulatory issues.

**Legal Resources**

NABP can serve as a legal resource to boards when appropriate, assisting members in effectively using their resources and protecting the public health. For example, NABP hosts educational forums for board legal counsel. The forums address legal trends in pharmacy practice and administrative law, as well as relevant cases for board attorneys. New members of the boards of pharmacy learn about properly handling conflicts of interest through an annual NABP orientation program. Over the years, NABP has filed several amicus briefs in support of the regulatory and public health protection efforts of the boards of pharmacy. For example, NABP partnered with a board...
of pharmacy and filed a legal brief in federal court in support of state board regulatory powers and immunity protections that the federal government was seeking to abrogate. The Association also educates federal agencies about the critical public health protection role boards of pharmacy perform and provides written commentary when proposed federal regulations seek to nullify or limit key board of pharmacy responsibilities, including licensing authority.

Occasionally, NABP may respond to board inquiries about other states’ laws on a specific subject, such as pharmacy-related licensure requirements.

In addition to providing educational and “friend of the court” support for state boards of pharmacy, from time to time, NABP may interface with Food and Drug Administration (FDA) or Drug Enforcement Administration (DEA) to represent the views of the state boards of pharmacy as determined by resolutions they approve and other Association policy set by the membership.

As a respected national organization, NABP is well positioned to provide such legal support and has done so on a number of occasions.

Publications and Resources

Publications

The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) provides the boards of pharmacy with model language that may be used when developing state laws or board rules. Expert legal commentary accompanies each section. It is available as a free download in the Publications and Reports section of the NABP website at www.nabp.pharmacy.

NABPLAW® Online – State Pharmacy Law and Rules Database, available at nabplaw.pharmacy since 1993, is a comprehensive, national database of laws and regulations specific to pharmacy and provides access to state pharmacy laws and regulations in all 50 states as well as the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and all Canadian provinces and territories. The NABPLAW Online tools allow users to adapt the information to meet specific research requirements.

NABPLAW Online subscriptions may be ordered online at https://nabplaw.pharmacy/signup.php. A variety of short-term and long-term licenses are available for purchase, ranging from one-day to one-year and single-user to multi-user subscription options.

The Survey of Pharmacy Law provides summary data from 53 member boards about topical issues in pharmacy, including prescribing and dispensing authority, pharmacy technicians, the electronic transmission of prescriptions, and patient counseling requirements. The Survey consists of four sections: organizational law, licensing law, drug law, and census data. Executive officers of the boards of pharmacy and final-year pharmacy students from ACPE-accredited schools and colleges of pharmacy receive a complimentary copy.

Innovations, which is published 10 times a year, provides Association news and articles about issues that affect the regulation and practice of pharmacy. It was developed to educate, inform, and communicate the objectives and programs of the Association and its 66 active and associate member boards of pharmacy. All board of pharmacy members receive a complimentary subscription.

The State Newsletter Program, which began in 1980, is one of the educational programs overseen by the NABP Foundation. Published on a quarterly basis, the state
newsletters provide pharmacists in over 30 states with vital information about their state’s pharmacy laws and board of pharmacy regulations.

As part of the State Newsletter Program, the National Pharmacy Compliance News provides important news and alerts from FDA, DEA, and other federal agencies, as well as information about current national developments affecting pharmacy practice.

The State News Roundup provides legislative and regulatory updates compiled primarily from the newsletters of state boards participating in the State Newsletter Program. In addition to keeping board leaders up to date on other states’ legislation and regulation, since 2008 the State News Roundup has provided information on state legislation relating to current task forces as well as any information on current hot topics. All board of pharmacy members receive complimentary email subscriptions.

NABP e-News provides timely educational, regulatory, and Association news on a weekly basis. Members are automatically subscribed to receive the complimentary e-News, which is sent electronically. Others may request to receive e-News by completing the online form on the NABP website.

AWARX® Prescription Drug Safety News, a biweekly electronic newsletter, provides the latest news about prescription drug abuse trends, online pharmacy safety, and medication safety. Members can sign up to receive the electronic newsletter by completing the online form on the NABP website.

.Pharmacy News, launched in 2016, provides regulators and other stakeholders in the online pharmacy community with valuable news they can use to improve their technology knowledge. The monthly electronic newsletter provides information on improving a pharmacy’s online presence, the latest rogue internet drug outlet threats and how they are being addressed, NABP’s .Pharmacy Verified Websites Program, and more. Sign up at www.safe.pharmacy.

**Internet Drug Outlet Identification**

NABP provides several additional resources to help protect the public from illegal online drug sellers and raise awareness about the problem. The Internet Drug Outlet Identification program continues to identify and review websites marketing medications to consumers in order to determine whether the sites are in compliance with state and federal laws as well as NABP patient safety and pharmacy practice standards.

To help consumers make informed choices when buying medicine online, NABP publishes the Not Recommended Sites list. NABP also provides regulators and other stakeholders with pertinent details and news related to internet drug outlets in the Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators. The reports and the Not Recommended List are available on the NABP website at www.safe.pharmacy.

**Electronic Mailbag**

NABP uses the electronic mailbag to communicate in a timely manner with the active and associate member boards of pharmacy. The mailbag, sent to the boards' executive officers each Thursday, consists of an email message with important memos, news releases, reports, or other documents attached, typically in a pdf format. Information included in the mailbag pertains to the protection of public health, NABP programs, upcoming meetings, surveys, and other information of importance and interest to the boards.
**NABP Website**

Board members and staff can take advantage of the NABP website as a one-stop source of information on NABP’s initiatives, guidance on current issues, meetings, programs, and news. The Publications and Reports section includes links to documents such as the NABP Model Act and NABP committee and task force reports – all available for download at no cost. In addition, the Initiatives section can help boards direct pharmacists, who can in turn direct patients, to free resources on safely purchasing medication over the internet. Information about the NABP Clearinghouse and designating NABP as a state board’s authorized reporting agent for the National Practitioner Data Bank is available in the Member Services section. The Programs section of the site provides a wealth of information on accreditation, license verification, and testing programs. The CPE Monitor section provides easy access for pharmacists and pharmacy technicians to track their CPE activities.

All of the NABP publications described here, as well as timely news articles, program information, and additional NABP documents and news releases, are available on the NABP website at www.nabp.pharmacy.

**AWARX®**

AWARX® is a prescription drug safety program aimed to educate and raise awareness about prescription drug misuse and abuse, secure medication storage and proper disposal, rogue internet drug outlets, counterfeit drug dangers, and safe medication use, among other serious issues.

Among the number of resources available is the online drug disposal locator tool, a searchable database of more than 6,000 permanent medication disposal programs. A downloadable form is available for pharmacies with disposal kiosks to submit their information for inclusion in the database.

In addition, pharmacists can find a wealth of information on diversion, downloadable flyers to provide to consumers, and links to other pertinent resources.

For information, visit the Initiatives section of the NABP website.

**Meetings**

**Annual Meeting**

The NABP Annual Meeting, held each year in May, provides pharmacy board members and staff, as well as other pharmacy stakeholders, with the opportunity to participate in business sessions, during which officers and members of the NABP Executive Committee are elected and resolutions are discussed and voted upon. In addition, when applicable, amendments to the Constitution and Bylaws are discussed and voted upon. Attendees also have the opportunity to participate in timely educational sessions addressing issues affecting the boards and the regulation of pharmacy practice.

**Interactive Forums**

The NABP Interactive Forums provide state board of pharmacy members and staff the opportunity to discuss common issues of concern. Each forum also provides in-depth information about NABP programs that are available to help the boards as they work to protect public health through pharmacy regulation. Further, experts are invited to present on regulatory and practice issues of highest priority to the boards.
The NABP Interactive Compliance Officer and Legal Counsel Forum takes place every odd-numbered year. The NABP Interactive Executive Officer Forum and NABP Interactive Member Forum are held annually.

**District Meetings**

The joint district meetings of NABP and the American Association of Colleges of Pharmacy afford a unique opportunity to address not only professional issues affecting today's pharmacy practice, but also educational matters influencing tomorrow's pharmacists. Held annually, the district meetings bring together members of the boards of pharmacy and faculty of the schools and colleges of pharmacy in each of the Associations' eight districts to discuss regional issues of mutual concern, as well as national issues affecting the districts.

In addition, important Association business is initiated at the district meetings, where affiliated members are nominated to be candidates for the open Executive Committee member position representing their district. Nominees are presented and votes are cast for Executive Committee member positions at the NABP Annual Meeting. District members also discuss and draft resolutions to bring to the Annual Meeting for consideration by the full membership. It is at the Annual Meeting that these proposed resolutions are voted upon.

**Task Forces and Committees**

As board of pharmacy members, your input is essential to addressing the many issues facing the boards of pharmacy and the practice today. Participation in these activities is a rewarding way to assist NABP and the boards of pharmacy in our mission to protect the public health. Consider volunteering to serve on a committee or task force.

Standing committees, which meet every year, include:
- Committee on Constitution and Bylaws
- Committee on Law Enforcement/Legislation
- Resolutions Committee
- Advisory Committee on Examinations

Single-issue task forces are developed each year and often address topics from resolutions approved at the Annual Meeting.

Examination committees write and review test questions to ensure the integrity and validity of the examinations.

**NABP Foundation**

The NABP Foundation is an Illinois not-for-profit corporation established in 1969 and formed to support the Association’s research and developmental projects and educational programs. The Foundation’s 501(c)(3) status allows it to receive tax deductible contributions to carry out its charitable and educational purposes.

The NABP Foundation oversees the research and developmental stages of all projects and programs. For example, when the Pharmacy Program was under development, it was under the NABP Foundation. When new programs are fully operational, they are incorporated into the general operations of NABP.

Educational and research programs such as NABPLAW Online and the State Newsletter Program are also managed under the NABP Foundation.

The properties, affairs, and business of the Foundation are managed and controlled...
by the Foundation Board of Directors, which is composed of the same members as the NABP Executive Committee. The Foundation is governed by similar Constitution and Bylaws as the Association.
Chapter Summary

- NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.
- NABP membership is composed of both active members – members who have formally approved the Constitution and Bylaws of the Association and require the use of the NABP Clearinghouse – and associate members. The 54 active members include the 50 United States state boards of pharmacy and the boards in the four jurisdictions of District of Columbia, Guam, Puerto Rico, and the Virgin Islands. Associate members include 10 Canadian provinces, Australia, and The Bahamas.
- The Association is governed by its Executive Committee, whose officers and members are elected during the Association’s Annual Meeting.
- NABP operates e-LTP for pharmacists wishing to obtain licensure in additional states.
- VPP provides the capability for boards of pharmacy to share critical licensure information for pharmacies and other facilities operating in multiple states.
- The NABP Multistate Pharmacy Inspection Blueprint Program assists the state boards of pharmacy in continuing to develop their own robust inspection capabilities. The Blueprint Program allows states to ensure their own inspection forms and processes cover minimum requirements agreed upon by the majority of member boards.
- NABP maintains a national Clearinghouse of licensure information on pharmacists, pharmacies, technicians, interns, and wholesale distributors that is provided by the Association’s member boards of pharmacy. In return, NABP provides boards of pharmacy with monthly reports of disciplinary actions taken against licensees.
- The NABP PMP InterConnect program is a highly secure communications exchange platform that facilitates the transfer of PMP data across state lines to authorized users while ensuring that each state’s data-access rules are enforced.
- NABP develops and administers the NAPLEX, a psychometrically sound national examination that is used by all member boards as a requisite for licensure. The MPJE is required by 49 member boards and tests the applicant’s knowledge of federal and state pharmacy law. NABP also develops and administers the FPGECE, which is one component of the FPGEC.
- Participating state boards of pharmacy may use the CPE Monitor service to assist in the process of ensuring that pharmacists and pharmacy technicians have completed state-mandated CPE requirements for relicensure, recertification, or reregistration. Also, CPE Monitor provides pharmacists and technicians a means for tracking their ACPE-accredited CPE credits. In 2018, NABP began offering a choice of two plans to help pharmacists manage their licensing requirements. Both plans, Standard and Plus, are available via the new NABP e-Profile mobile app. The Standard plan is free; the Plus plan costs $29.95 per year.
Chapter Summary (continued)

- **NABP operates several accreditation and verification programs to provide uniform standards** in three particular areas: online pharmacies, wholesale distributors, diagnostic OTC medical device distributors, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). These programs include Verified Internet Pharmacy Practice Sites (VIPPS), Verified-Accredited Wholesale Distributors (VAWD), Verified-Accredited Device Integrity Program (VDIP), DMEPOS, and the .Pharmacy Verified Websites Program.

- **NABP offers to its members legal resources, several publications, and several opportunities for networking through the Annual Meeting, Interactive Forums, and district meetings.** Board of pharmacy members are also encouraged to participate by serving on task forces and committees.

- **Consumer protection programs offered by NABP include the AWARxE Prescription Drug Safety Program and the Internet Drug Outlet Identification program.** AWARxE aims to educate and raise public awareness about rogue internet drug outlets, counterfeit medications, prescription drug abuse, and medication safety, among other serious issues. The Internet Drug Outlet Identification program aims to identify and review websites marketing medications to consumers in order to determine whether the sites are in compliance with state and federal laws as well as NABP patient safety and pharmacy practice standards. To help protect consumers, NABP publishes the Not Recommended Sites list at www.safe.pharmacy.

- **NABP and NABP Foundation® are Illinois not-for-profit corporations with 501(c)(3) status.** The Foundation supports the Association's research and development projects and educational programs.
Duties and Responsibilities – Protection of Public Health

The sole responsibility of a board of pharmacy is the protection of the public health and welfare. This fundamental concept is the most important set forth in this Member Manual. It is the duty of a board to license those persons seeking to enter the profession who meet the legal competency standards necessary to practice pharmacy, and to discipline those licensed pharmacists who fail to follow legal and professional standards of practice.

Boards of pharmacy are statutorily created governmental bodies and their powers are authorized by the legislation under which they are established. The specific duties and responsibilities of a board member are generally not detailed in a state pharmacy practice act or other legislation. For example, Section 201 of the NABP Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act), in establishing the duties and responsibilities of the board, reads as follows:

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 the 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.

Individual board members are charged with the responsibility of regulating the profession by carrying out the duties specifically set forth in statutes and regulations. Therefore, the first task of a board member should be to become completely familiar with the statutes and regulations pertaining to the practice of pharmacy in his or her state.

Board members should also be familiar with federal legislation and regulations, particularly the Federal Food, Drug, and Cosmetic Act and the federal Controlled Substances Act. On many occasions, state and federal agencies will cooperate closely in law enforcement activities. Also, it is common for state legislation to be modeled after federal acts and, therefore, to be interpreted by state courts based on federal court decisions.

In addition, board members should develop a familiarity with parliamentary procedures or Robert’s Rules of Order, rules that are commonly used in board meetings to ensure they are run fairly and orderly.

Members of a board of pharmacy, as public officials, must apply the statutes, rules, and regulations of their state in an unbiased manner. All actions taken by a board member and board are subject to scrutiny by the profession, the legislative and judicial branches of government, and the public, and to be valid and enforceable, must be based upon an objective consideration of legal evidence and application of relevant laws and rules or regulations.

**Conflict of Interest – Disqualification**

Board members must be constantly aware of and avoid conflicts of interest. Board members are viewed as the state board. Therefore, their image and reputation must be impeccable if the state boards are to remain a viable force in state government.

A board member must conscientiously avoid any attempt to regulate the economics of the profession through the establishment or enforcement of board rules and regulations, or through any selective applicability of such rules and regulations to any particular pharmacist or group of pharmacists. A board member must consistently apply rules and regulations in an objective, unprejudiced manner for the protection of the public health.

In many instances, board members are active members of one or more pharmacy associations. There is no reason why a board member should not retain these memberships. However, members should avoid serving as officers in these associations. Members should also avoid serving on association committees that develop policies that could influence the board’s adoption of rules and regulations, or the enforcement of rules and regulations in a manner that might be prejudicial to a particular pharmacist or groups of pharmacists.

In the event board members discover that their views may have been prejudiced by activities related to their professional service, they should abstain or disqualify themselves from participating in board proceedings involving the relevant areas. Failure to do so may result in the reversal or setting aside of the board’s decision in disciplinary matters, or rule and regulation adoption.

For example, suppose a board member served on an association committee involved in screening new applicants for membership in the association. Pharmacist Smith is rejected by the committee following proceedings in which the board member participated. Later,
Pharmacist Smith is called before the board of pharmacy on a disciplinary matter. The board member should disqualify himself or herself from participating in the Smith deliberations whether or not the reason for rejection of association membership was related to the reason for the disciplinary proceedings, since the board member’s judgment has, at least, the appearance of being tainted.

Possible conflicts of interest in the regulation of individual pharmacists could include the following:

(a) a board member who is a relative or close friend of an individual being subjected to possible disciplinary action; or

(b) a board member who maintains a pharmacy and is in competition with a nearby location whose pharmacist is subject to possible disciplinary action.

In the second example, the board’s decision may substantially affect the economic position of that board member. It is advised that in such a situation, the board member seriously consider disqualifying himself or herself. Unfortunately, it is not easy, in many instances, to readily ascertain whether a conflict is serious enough to require disqualification. If any doubt exists, a board member should consult board counsel. The important factor is to be aware of these areas of possible conflict.

Confidentiality

Much of the information to which board members become privy constitutes confidential or privileged information. State freedom of information acts and/or right of privacy acts generally determine the confidentiality status of such information. Generally, information in the files of applicants and regulants should be released only upon appropriate court order, or in accordance with appropriate board policies. Board members should be familiar with the provisions of statutes related to information held in agency files, and should avoid discussing any such information except in the context of board functions.

Board Member Liability

Judgments by boards and board members require a good working knowledge of their state practice acts in their entirety, particularly when considering the establishment of rules and regulations to be adopted by a board in order to implement the act. Also, decisions of board members must be carefully considered to avoid any possibility of liability regarding any particular applicant for licensure or any licensed pharmacist who is subjected to possible disciplinary action by the board.

Board members should understand that even while acting in their official capacity, irresponsible activities could lead to possible personal liability on the part of the board member. Under normal circumstances, a board member acting under legislative directive, in good faith, within the scope of his or her authority, who neither knew nor should have known that an act of that board member may have been in violation of the practice act or in deprivation of the constitutional rights and privileges of the affected party, will be protected from personal liability. This protection or immunity from liability is a judicially established concept that was developed to permit administrative officials to carry out their duties and responsibilities without fear of liability. The immunity concept, however, does not protect a board member from lawsuits, nor does it guarantee the board member complete immunity from liability. It is only where the board member acts within the scope of the member’s statutory authority in a reasonable and unbiased manner that the board member will avoid ultimate liability.

The NABP Newsletter article “I.N.S.P.E.C.T. . . . Find Out What It Means To Me” presents a case that centered on whether certain board of pharmacy staff acted within their scope of authority in a reasonable and unbiased manner, and the article concludes
that “Pharmacy board members, staff, and other agency personnel must be aware of their duties and responsibilities and operate under the delineated authority of the board and in good faith at all times. Immunity principles will generally protect regulatory persons who follow this mantra.” The article has been reprinted in the Appendix to this manual.

**Constitutional Rights**

One of the most common actions brought against administrative officials involves allegations that an individual’s constitutional rights have been violated. Such cases typically involve an alleged violation of the individual's right to due process of law and equal protection under the law, namely those rights established in the 14th Amendment of the United States Constitution. Such cases are decided in a proceeding under Section 1983 of the federal Civil Rights Act, which establishes monetary and injunctive remedies to an individual when a government official (such as a board member) subjects the individual or causes the individual to be subjected to the deprivation of any rights, privileges, or immunities secured to that individual by the US Constitution or federal statutes.

Suits of this nature are generally brought against the board as a whole and also against the members as individuals. The damages sought are usually extremely large. Under current court interpretations, the state is generally liable for the acts of individual state governmental officials, but the civil rights statute does not preclude individual liability, and this possibility should not be disregarded.

A case involving a pharmacist working in conjunction with several other licensed professionals to provide care to a patient and due process issues is reviewed in the *Innovations* article “Flotsam and Jetsam” in the Appendix to this manual.

**Antitrust Laws**

It is incumbent upon board members to have an understanding of the existence of the antitrust laws and the relevant implications of these laws, as there appears to be a growing tendency to assert antitrust liability upon administrative officials. Several years ago, there was a prevailing concept that state officials acting in their official capacities were absolutely immune from the antitrust laws. This concept of complete immunity has been eroded by court interpretation over the past several years.

Antitrust laws regulate combinations, conspiracies, and monopolies in restraint of trade, including price fixing and other matters that involve the economics of the profession. Board members may ask why they should be concerned about antitrust laws when their sole responsibility is the protection of the public health, and when they have been instructed to avoid the economics of the profession in carrying out their duties as board members.

It is not always easy to ascertain when a board’s action may have an economic effect that could be construed as involving a combination or conspiracy in restraint of trade. For example, prohibitions against the advertising of prescription drug prices could conceivably be construed as a price fixing mechanism. Other general policies could be construed as attempts to lessen competition, even though the effect on competition may not have been considered by a board member.

Damages sought under the antitrust laws are tripled pursuant to statutory authority. For example, if a judgment is entered for $300,000 because of antitrust violations, the total judgment automatically becomes $900,000. Whenever you are in an area in which you believe you could conceivably fall within the purview of the antitrust laws, you should seek advice from legal counsel.
In 2015, a case involving an antitrust action was addressed by the US Supreme Court in *North Carolina State Board of Dental Examiners v Federal Trade Commission*, 574 (U.S. (2015). In the North Carolina case, the court ruled the North Carolina State Board of Dental Examiners was not immune from the application of antitrust laws. For more information, see the NABP 111th and 112th Annual Meeting Reports of Counsel available in the Publications and Reports section under Officer Reports on the NABP website at www.nabp.pharmacy.

**Tort Liability**

Board members are also troubled by potential tort liability, particularly the tort of defamation of character, which includes both libel (written) and slander (verbal). Can a board member be held liable for accusations made against pharmacists in the normal course of issuance of a complaint or for those which are asserted at a disciplinary hearing? What if a pharmacist is found to have violated the practice act, is disciplined by a board, and is later successful in overturning the board decision by a court appeal? What is the liability of a board member signing a complaint against a pharmacist?

Generally, if board members are acting within the scope of their authority, in good faith, and in an unbiased manner, they will be completely protected against liability under torts such as defamation of character. To hold otherwise would, from a practical standpoint, deter board members from fearlessly fulfilling their duties and responsibilities. In all instances, however, the board members should insist that facts alleged against a pharmacist be substantiated to the greatest extent possible to avoid any allegations that a claim is so frivolous as to constitute gross negligence on the part of a board member and cause that board member possible liability.

**Decision Making With Conviction**

If an individual accepts appointment to a board of pharmacy, it becomes the duty of that individual to carry out responsibilities that include making decisions, which in many instances involve the livelihood of a pharmacist or an applicant seeking admission into the profession. These decisions must be made fairly and fearlessly. This chapter has isolated certain areas where the decision-making processes may require great thought and, perhaps, legal advice to assist board members in making the hard decisions that must be made to ensure proper protection of the public health.

Finally, a board member should be inquisitive and should not succumb to past practices of a particular board without knowing why certain procedures are being followed. New board members provide a fresh, independent view of the board’s practices and procedures. They should not be reluctant to ask questions to better understand the individual functions of board members.
Chapter Summary

- The protection of the public health and welfare is the primary responsibility of a board of pharmacy.
- A board derives its power from statutes and regulations and carries out its duties and responsibilities accordingly.
- Board members are charged with the responsibility of carrying out duties specifically outlined in statutes and regulations of the board. For example, board members make decisions about licensure and disciplinary actions.
- Board members should be completely knowledgeable of statutes and regulations pertaining to the practice of pharmacy in their state. Board members should also be familiar with relevant federal legislation and regulations.
- Board members must conscientiously avoid any conflicts of interest, such as serving as an officer in an association or participating in board of pharmacy meetings in which they may have prejudice related to outside associations or financial matters, or a relationship to a pharmacist who is subject to possible disciplinary action.
- Board members should be familiar with the provisions of statutes related to information held in agency files, and should avoid discussing any such information except in the context of board functions. Generally, information in the files of applicants and regulants should remain inviolate and should be released only upon appropriate court order, or in accordance with appropriate board policies.
- Board members should be familiar with common causes of liability, act in good faith, rely on facts, and seek legal counsel when needed.
  - Common causes of liability include a violation of an individual’s constitutional right to due process and equal protection under the law, antitrust violations, and tort liability.
  - A board member acting in good faith in his or her official capacity and exercising accepted skills in the performance of his or her duty will generally be exempted from personal liability; however, this is not guaranteed unless such actions by the board member are reasonable and unbiased.
- Board members may fearlessly perform their duties if they act in good faith, remain completely unbiased, insist that allegations against a regulant be substantiated to the greatest extent possible, and ensure that the regulants in the profession are accorded “their day in court.”
Statutory Qualifications

A license to practice pharmacy can be defined as a certification by a state agency (the board of pharmacy) that the holder has met the statutory requirements necessary to qualify to practice pharmacy. While these requirements vary from state to state, they generally include the following:

1. Submitting a written application in a form prescribed by the board of pharmacy;
2. Attaining the age of majority;
3. Demonstrating good moral character and temperate habits;
4. Graduating and receiving the appropriate professional degree from a board-approved pharmacy degree program;
5. Completing an internship that has been approved by the board of pharmacy or demonstrated to the board’s satisfaction experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board;
6. Successfully passing any examinations required by the board of pharmacy; and
7. Paying required fees.
Good Moral Character

While most of the requirements can be fulfilled by verifying official documents, such as transcripts, determining good moral character may be somewhat subjective. The requirements for good moral character and temperate habits normally need refinement through rules and regulations. Courts generally uphold and enforce such requirements because, they reason, health regulatory boards are primarily composed of members of the profession being regulated and, therefore, are capable of applying such standards to their respective peers with specificity and exactness. Such character requirements can only be expected to be sustained by the courts when the person whose character is being challenged had notice or reasonably should have known that his or her conduct reflects detrimentally upon his or her character. Overall, the enforcement of character requirements will be upheld by the courts when they are reasonably related to the protection of the public health, safety, and welfare.

The public has the right to expect the highest degree of integrity from practicing pharmacists. When matters of character truly reflect upon integrity, they should be considered in determining whether or not a candidate should be licensed or a pharmacist disciplined. Such enforcement standards, however, must be uniformly and fairly applied to all candidates and practitioners.

The information necessary to determine whether or not a candidate possesses good moral character and temperate habits is obtained through the application for licensure, character affidavits, and other incidental sources of information that may be available to a particular board. Any such information must be carefully examined before a determination can be made as to its effect, if any, on the character of an individual. For example, the fact that an individual has been arrested on one or more occasions may have no bearing on the individual’s character, particularly if no prosecutions followed the arrest, or if the individual is exonerated on subsequent trial. Further, not all convictions, standing alone, would necessarily disqualify an individual from licensure. Many people have been involved in traffic offenses or, perhaps, convictions arising from childhood or college pranks that do not necessarily reflect on that individual’s ability to practice pharmacy nor do they substantiate the theory that licensure of such individual will have a possible detrimental effect on public health.

Decisions become increasingly difficult in areas such as income tax evasion, or the commission of felonies. Under normal circumstances, such convictions would involve moral turpitude, thus permitting the refusal to grant a license or justifying disciplinary action. The difficulty becomes much greater, however, where an individual pleads nolo contendere (no contest, as opposed to pleading guilty) or, after being found guilty, is pardoned or paroled. What do you do with the candidate who has been convicted of a drug offense, but whose conviction is ultimately expunged?

When these situations arise, board members must determine whether or not the offense should be considered in determining moral character and, if it should, whether or not it is of such a nature as to render questionable the reputation of the individual in regard to the practice of the profession. In addition, board members must determine whether the individual’s debt to society has been paid through fines or a prison term and if the individual has been rehabilitated. There must also be an awareness of statutory implications since some states, by a statute, specifically preclude the denial of an issuance of a license based solely on a felony conviction when the individual has been restored to society.

These issues cannot be taken lightly. Board members must make the determination as to whether or not an individual is fit to enter
the practice of pharmacy and, to do so, must on many occasions make some very difficult decisions. There is legal precedent, however, supporting the denial of a license by reason of lack of good moral character and temperate habits; this precedent can be made available to board members by board counsel. The chances of having board decisions upheld when based on lack of good moral character can be greatly enhanced when appropriate rules or regulations have been adopted setting forth the standards and guidelines that the board will be following when making character determinations. Rulemaking and due process are discussed further in Chapter 5 of this manual. In addition, a case involving a licensee who omitted significant information on his application for licensure and whose license was ultimately revoked is reviewed in the *NABP Newsletter* article “Ouster Based on Omnibus Omissions” in the Appendix to this manual.

**Graduation Requirement**

The various jurisdictions require that an individual be a graduate of an approved program from a school or college of pharmacy. This requirement is established in some instances by statute and in others by regulation. Under any circumstances, the responsibility for determining which schools and colleges are to be recognized as approved schools and colleges should be lodged with the state board of pharmacy.

The ACPE was established in 1932, and is the national accrediting agency for schools and colleges of pharmacy and providers of continuing pharmacy education. It is recognized as such by the secretary of education, US Department of Education, and the Council on Postsecondary Accreditation. ACPE is an autonomous agency whose Board of Directors consists of representatives of the American Association of Colleges of Pharmacy, the American Pharmacists Association, NABP, and the American Council on Education.

Since its inception, ACPE has set accreditation standards for degree programs of colleges of pharmacy. The professional program accredited by ACPE is that leading to the doctor of pharmacy degree (PharmD), which is the sole entry-level degree recognized in the practice of pharmacy. ACPE has established policies and procedures for periodic review of the curriculum of schools and colleges to ascertain whether or not the established accreditation standards need revision.

Schools and colleges are periodically reviewed against the accreditation standards. The accreditation process includes periodic ACPE on-site evaluations of schools and colleges to secure information on the physical facilities, the student body, the faculty, and other areas related to the accreditation process. An annual list of accredited degree programs is published by ACPE. Board members will be asked, on occasion, to join the ACPE visitation team and observe the evaluation process. Attendance at a visitation is highly recommended to aid the board member in understanding the accreditation process and to fulfill the statutory responsibility of the board to approve schools and colleges.

Boards of pharmacy have traditionally relied upon ACPE to determine the standards that accredited programs should meet. Boards do not have the expertise, the time, or the funding to fully engage in the accreditation process. For legal purposes, as mentioned above, the responsibility for determining approved schools and colleges should be lodged by statute in the board of pharmacy. The board may then adopt a rule or regulation under which it accepts as accredited institutions those schools and colleges whose programs meet the minimum standards established, from time to time, by ACPE.
Standards are established through a democratic process, which includes all facets of the profession, the educational community, and the public. Boards of pharmacy have input into the establishment of these standards. The board should place in the minutes of its annual meeting those schools and colleges that meet these requirements and are recognized as approved schools and colleges by the board. This provides notice to all prospective students of those schools and colleges whose degrees will be honored for purposes of initial licensure into the profession.

Problems have occurred in some instances in which states have, by statute, specifically provided that approved schools and colleges are those schools and colleges that have been accredited by ACPE. Such statutes and regulations have been challenged from time to time by individuals who claim that the specific designation of ACPE as the arbiter of what constitutes an accredited school or college is the unconstitutional delegation of state power to a private outside body. If a statute or regulation is found to be constitutionally unsound, the situation in regard to eligibility for licensure can become chaotic. This problem can be avoided as set forth above, whereby the state statute vests in the board of pharmacy the responsibility to determine approved schools and colleges and the board, by regulation, adopts, as a minimum, the accrediting standards accepted from time to time by ACPE. While the distinction may seem slight, it is legally sound.

Denial of License

After consideration of a candidate’s qualifications, the board of pharmacy must decide whether or not to grant initial licensure. When it is determined that a license should be denied, due process should be followed. If the individual has failed to pass the licensing examination, the denial is somewhat routine. When a license is withheld by reason of a question concerning the more subjective requirements, such as good moral character, a record should be established to support the denial.

The candidate should also be advised of the reason(s) for the board’s refusal to issue a license. The candidate should be afforded the opportunity to appear before the board to review its decision. In this instance, if a good record has been established, the board will undoubtedly be able to uphold the refusal to issue the license not only at the administrative level, but also at the court levels, should the candidate choose to seek court review. The candidate must be afforded due process. Activities of a board, particularly in areas such as the denial of licensure and the disciplining of regulants, are subject to attack in the courts on a constitutional basis. The board must be prepared to affirmatively meet any such attack.

Scope of Practice

A license grants the recipient pharmacist the privilege to practice pharmacy in the state where the license was issued. The privilege is, of course, subject to the existing statutes and regulations of the state that controls the practice. It is difficult in some states to determine exactly what the practice encompasses because of the broad, general statutory and regulatory references thereto. In other states, however, the scope of practice is defined statutorily as in the NABP Model Act. Section 104 of the Model Act defines the practice of pharmacy as follows:

The “Practice of Pharmacy” means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of
emerging technologies and competency-based training.

A definition of this nature is most helpful in that it sets forth the areas of the practice that are reserved solely to the licensed pharmacist. Any individual not so licensed who engages in the functions set forth in the definition would be improperly engaged in the practice of pharmacy. If the act permits the board of pharmacy to discipline unlicensed personnel who are engaged in the practice, the board can do so. If the individual who is improperly engaging in the practice is doing so under the supervision and at the direction of a licensed pharmacist, the board, under normal circumstances, can proceed against the licensed individual also. For this reason, it is important that the scope of practice be defined, whether by statute or regulation, or both, so that the board can effectively limit the practice to competent licensed personnel in order to protect the public health.

**Scope of License**

The license provides to the holder the right to practice pharmacy, which if suspended or revoked is of grave concern to the holder. This necessitates the utmost care and fairness when board members exercise their responsibilities and duties to regulate the profession and, particularly, individual pharmacists. (This concept is more fully discussed in Chapter 7, Adjudication Proceedings.)

There has been controversy among legal scholars as to whether a license is a property interest, or whether it merely bestows upon the recipient the privilege to practice the profession. As a property interest, it would be entitled to a high degree of constitutional protection. As a privilege, while it is still entitled to certain constitutional protection, the standard is somewhat less.

**Transfer of Pharmacist Licensure**

Transfer of licensure is a process that permits an individual who is licensed in State A to become licensed in State B without the necessity of taking a licensure examination. It is a procedure that has been followed in most professions for many years. Basically, if a candidate at the time of initial licensure in State A meets similar qualifications that were required of candidates who were at that time licensed in State B, State B will license the candidate.

Since its establishment in 1904, NABP has advocated the licensure of candidates by licensure transfer under uniform requirements. NABP membership consists of the boards of pharmacy in each state of the US, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, The Bahamas, and 10 Canadian provinces. Active member boards are those that have agreed to permit licensure transfer pursuant to standards established by the statutory law of the state and that are compatible with the Constitution and Bylaws of NABP. As a result of this cooperative effort, pharmacy enjoys the finest system of licensure transfer among all the health professions in the US.

Licensure transfer is authorized by the statutes of those states that allow licensure through this process. Qualifications of candidates as provided in those statutes must be met in order for a candidate to be eligible for licensure without examination. Because all active member boards use the North American Pharmacist Licensure Examination® (NAPLEX®), the matter of licensure transfer has been made more uniform. Additionally, active member boards are required to submit disciplinary information to the NABP Clearinghouse so that license transfer applicants can be screened for eligibility. The
NABP Clearinghouse serves as a national database of educational, competence, licensure, and disciplinary information on pharmacists licensed by the boards and aids in determining the acceptability and qualifications of candidates requesting the transfer of examination scores and licenses into their jurisdictions. Candidates for licensure transfer may also be subject to interview by the state in which they are seeking a license and may be required to take a jurisprudence examination to demonstrate an understanding of laws of the state into which they are transferring. In 48 jurisdictions, the NABP Multistate Pharmacy Jurisprudence Examination® (MPJE®) is recognized and used to assess candidates’ knowledge of state pharmacy law. Licensure transfer is initiated through NABP, which acts as a clearinghouse for participating states.
Chapter Summary

- General statutory requirements for licensure include submitting an application, attaining the age of majority, demonstrating good moral character, graduating and receiving a professional degree from a board-approved pharmacy program, completing an internship, passing examinations required by the board, and paying fees. The requirements vary from state to state.

- Requirements of good moral character demanded by many state boards will probably be upheld in court when those requirements are reasonably related to the protection of the public health, safety, and welfare; when such board regulations are clear and well-defined; and when the person whose character is being challenged should reasonably have known that his or her conduct was detrimental to his or her character.

- Statutes or regulations require that individuals graduate from an approved program to be eligible for licensure. Boards determine which schools and colleges are approved and generally rely on the ACPE to determine standards.

- Problems can be avoided if state statutes vest in the board of pharmacy the responsibility to determine approved schools and colleges and then, in turn, the board by regulation adopts, as a minimum, the accrediting standards accepted from time to time by the ACPE.

- State statutes enacted to provide that approved schools and programs are those with ACPE accreditation are discouraged to avoid the unconstitutional delegation of state power to a private outside body.

- Since its inception, ACPE has set accreditation standards for degree programs of colleges of pharmacy, and schools and colleges are periodically reviewed against these standards. Board members should be present as observers at ACPE college of pharmacy on-site evaluations to become familiar with the accreditation process and to fulfill the statutory responsibility of the board to approve the pharmacy schools and colleges from which the board will accept applicants to the profession.

- If the board decides to deny licensure to a candidate, due process must be followed. Board activities such as denial of licensure are subject to attack in the courts. The candidate must be notified of the reason(s) for denial and afforded the opportunity to appear before the board.

- The pharmacists’ scope of practice should be defined clearly in statutes as exemplified in the NABP Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, Section 104. Such definitions can empower the board to discipline unlicensed personnel who are engaged in the practice, for example.

- In states that allow licensure transfer, the process is authorized by state statutes. Through the cooperative efforts of NABP and its member boards – for example, through use of the NAPLEX and NABP Clearinghouse – pharmacy enjoys the finest system of licensure transfer among all the health professions.
Chapter 4
Examinations

Chapter Objectives

After completing this chapter, you should be able to answer the following questions:

- Why was the North American Pharmacist Licensure Examination (NAPLEX) developed?
- How is NAPLEX developed?
- How is the Multistate Pharmacy Jurisprudence Examination (MPJE) developed?
- What steps must foreign pharmacy graduate candidates take to secure licensure in the United States?
- What pretests and resources are available for candidates preparing to sit for NAPLEX or the Foreign Pharmacy Graduate Equivalency Examination (FPGEE)?

Purpose of the Examination

Every jurisdiction in the United States requires that a candidate successfully pass an examination in order to be eligible for initial licensure. This is one of the most important, if not the most important, qualifications for entry into the practice. The purpose of the examination is to determine whether the candidate meets the minimum competencies necessary to ensure that the candidate can practice in the profession without endangering the public health.

Valid Examinations – NAPLEX/MPJE

For many years, pharmacy licensing examinations were prepared and administered by individual boards of pharmacy. As a result, the test content and difficulty in a particular state differed from the test in every other state. Questions were not based on commonly determined competencies, nor were they prepared under acceptable test preparation practices because statistics used to substantiate test reliability were nonexistent or ignored. National comparisons were impossible, hindering licensure reciprocity.

Over the past few decades, testing procedures used in many areas, from college admission tests to employment tests to occupational licensing tests, have been scrutinized. Litigation challenging test validity increased dramatically. Constitutional attacks on testing programs resulting by reason of discrimination became commonplace.

In order to improve the caliber of the pharmacist licensing examination and to provide test development procedures that would help ensure that these examinations were valid and would withstand administrative and judicial attack, the National Association of Boards of Pharmacy® (NABP®) developed the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE).
Examination® (NAPLEX®), previously known as the NABPLEX®. NABP initiated studies and surveys to ascertain the competencies necessary for entry into the practice and developed the NAPLEX blueprint. NABP employs a unique system for the preparation of examination questions that utilizes item writers working in all facets of the profession. The NAPLEX Review Committee reviews, revises, and finalizes test questions. The NABP Advisory Committee on Examinations establishes policies pertaining to the program.

NABP utilizes the expertise necessary to ensure the highest professional standards and the appropriate technical procedures for the examination. A uniform method for scoring of the licensing examination is also used. As a result, boards may assure the public and the candidate that successive examinations are basically equivalent and are appropriately geared to measure competencies necessary for a sufficiently knowledgeable candidate entering the practice of pharmacy. Two articles, “Board Shoots: Does not Score” and “He Shoots, He Rescores,” review and illustrate the importance of examination development standards and uniform scoring, and relevant legal issues for the state boards of pharmacy and are included in the Appendix to this manual.

The NAPLEX is a 250-question examination delivered in a computerized, fixed-form. It is offered throughout the year through a national system of test centers. Currently, all 50 states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands use the NAPLEX.

In 1998, NABP introduced the computer-adaptive MPJE, which is currently offered in 49 jurisdictions as a means of assessing a licensure candidate’s knowledge of state and federal pharmacy law. Item development for the Multistate Pharmacy Jurisprudence Examination® (MPJE®) is coordinated by NABP staff with the individual state board of pharmacy. The MPJE is also offered throughout the year through a national system of test centers.

Each state board has an opportunity to submit MPJE test items on an annual basis. These items are reviewed and edited by the MPJE Review Committee and are made available to all participating jurisdictions for inclusion in their respective state pools for pre-testing, if appropriate. All states are required to review their state pools on an annual basis to ensure relevancy among the items.

The examinations are the copyrighted property of NABP. Each state, by virtue of being a member of NABP, has input into the continuing development of the NAPLEX and MPJE programs.

Eligibility Services

NABP confirms eligibility to take the NAPLEX and MPJE for the boards of pharmacy in Colorado, Maine, Michigan, Nebraska, Oregon, and Utah. With the launch of the new online customer application and enhanced e-Profile Connect in April 2018, NABP can now expand this service to additional boards. States interested in this service may contact the Member Relations and Government Affairs department via email at GovernmentAffairs@nabp.pharmacy for more information.

Testing Accommodations

NABP and the boards of pharmacy abide by all applicable federal and state statutes relating to the accommodation of disabled individuals. To ensure the security and integrity of the examinations, the board of pharmacy will evaluate Americans with Disabilities Act (ADA) accommodation requests in consultation with NABP. Testing accommodations for candidates with disabilities will be made only with the authorization of the board of pharmacy. Candidates seeking licensure in Colorado, Florida, Maine, Michigan, Nebraska, Oregon
and/or Utah are evaluated directly by NABP and are subject to the Association’s approval.

**Foreign Pharmacy Graduate Examination Committee Certification**

The Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program serves as a means of documenting the educational equivalency of a candidate’s foreign pharmacy education, as well as the license and/or registration to practice pharmacy. In the process of FPGEC Certification, candidates must document their educational backgrounds, pass the NABP Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and pass the Test of English as a Foreign Language internet-Based Test. Earning the FPGEC Certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 states, District of Columbia, Guam, and Puerto Rico.

**Testing Resources**

NABP provides the NAPLEX/MPJE Candidate Application Bulletin for download on the Association’s website. The Bulletin provides candidates with detailed information about policies and procedures that will guide them through the process of applying for and taking the examinations. In addition, the Bulletin sets forth the competency statements and generally describes the NAPLEX and MPJE programs. Candidates may download the Bulletin and apply for the exams on NABP’s website at www.nabp.pharmacy.

Like the NAPLEX/MPJE Bulletin, the FPGEC Candidate Application Bulletin is also available for downloading from the NABP website at www.nabp.pharmacy.

NABP also offers practice examinations for the NAPLEX and FPGEE. These internet-based practice examinations allow candidates to familiarize themselves with the testing experience.

**Pre-NAPLEX**

The Pre-NAPLEX® provides pharmacy students and graduates with a chance to preview the NAPLEX experience before examination day. It is the only NAPLEX practice examination written and developed by NABP.

The Pre-NAPLEX consists of 100 questions. Not only does the Pre-NAPLEX have the same “look and feel” of the NAPLEX, it uses questions from previous NAPLEX examinations. At the conclusion of each practice examination, candidates will receive an estimated range of scores. The Pre-NAPLEX provides candidates with information on their performance answering a subset of questions similar to those they will encounter on the NAPLEX. The test can be accessed at www.pre-naplex.com or on the NABP website, www.nabp.pharmacy.

**Pre-FPGEE**

The Pre-FPGEE® is a practice examination for those candidates planning to sit for the FPGEE. NABP developed the Pre-FPGEE to provide graduates of foreign pharmacy schools with a preview of the FPGEE testing experience.

The web-based practice examination is accessible through www.nabp.pharmacy and www.prefpgee.com. Candidates will have the opportunity to experience questions that are similar to those that appear on the FPGEE.

The Pre-FPGEE consists of 66 questions. At the conclusion of each practice examination, candidates will receive an estimated range of scores that they could expect to achieve on the FPGEE.
Chapter Summary

- In order to improve the caliber of the pharmacy licensing examination and to provide test development procedures that would help ensure that the examination is valid and will withstand administrative and judicial attack, NABP developed the NAPLEX.

- NABP utilizes the expertise necessary to ensure the highest professional standards and the appropriate technical procedures for the NAPLEX. A uniform method for scoring of the licensing examination is also used.

- Each participating state board has an opportunity to submit MPJE test items on an annual basis. These items are reviewed and edited by the MPJE Review Committee and are made available to all participating jurisdictions for inclusion in their respective state pools for pre-testing, if appropriate. All states are required to review their state pools on an annual basis to ensure relevancy among the items.

- FPGEC Certification Program serves as a means of documenting the educational equivalency of a candidate’s foreign pharmacy education, as well as the license and/or registration to practice pharmacy. In the process of FPGEC Certification, candidates must document their educational backgrounds, pass the NABP FPGEE, and pass the Test of English as a Foreign Language internet-Based Test.

- Resources available to candidates include the NAPLEX/MPJE Candidate Registration Bulletin, the FPGEC Candidate Application Bulletin, and the examination competency statements available at www.nabp.pharmacy. Pharmacy students and graduates may wish to take the Pre-NAPLEX at www.pre-naplex.com for a fee. FPGEC candidates may wish to take the Pre-FPGEE at www.prefpgee.com.
Rulemaking procedures, as with most other administrative procedures, are designed to ensure basic and fundamental fairness throughout agency proceedings by providing both the regulated and otherwise affected public with adequate notice and opportunity to participate in the agency’s rulemaking process. By definition, a rule is generally any statement of general applicability that:

1. implements, interprets, or prescribes law or policy; or
2. defines the organization or the procedure and practice requirements of an executive entity of state government.

In general, agencies of the executive branch of state government do not have inherent rulemaking authority. The authority to adopt rules and regulations must be specifically delegated by the state legislature. In that same vein, the rule or regulation must be reasonably related to the legislative intent and purpose of the statutory enactment.

Any proposed rule should make clear reference to the agency’s rulemaking authority and the particular section of the state statute being implemented, interpreted, or specified. When referring to rules defining an agency’s organization and its procedures and practice requirements, you should generally consider such items as:

1. a brief description of the agency;
2. the officers and employees of the agency and how they are appointed or selected, their terms of office, as well as their duties and responsibilities;
3. a similar breakdown of the staff units or sections and/or bureaus of the agency;
4. address of the home office and any field offices, and specifically, where needed forms and information may be obtained; and
5. citation to all applicable statutes and rules relating to the agency’s operation and how to practice before the agency.

Chapter Objectives

After completing this chapter, you should be able to answer the following questions:

- What is the purpose of a rule, and how do boards get authority to create rules?
- What is the procedure for rulemaking?
- When is an emergency rule appropriate and authorized?
- Under what circumstances may rules be challenged?
- What can board members do to eliminate lengthy and embarrassing reversals of board rules by judicial review?
Procedures for Adopting Rules

As a preface to this section and at the risk of being overly repetitious, we must continue to bear in mind that the rule must be reasonably related to the purposes of the existing statute.

Paramount to adopting any rule is proper and adequate notice of the agency’s intent to adopt a particular rule.

Proper Notice Should Include:

- a short and simple statement of the purpose and effect of the proposed rule;
- a summary of the proposed rule and the need for it; ensure all interested people have an opportunity to obtain a verbatim copy of the rule;
- the statutory authority permitting the promulgation of the rule;
- where and how the complete text of the rule may be obtained; and
- the time and place of the hearing, and the procedure for making written and oral statements.

Most state laws require that this notice be published. This might require publication in newspapers of general circulation throughout the state, or perhaps it might be limited to some official state publication for which individuals or groups can receive a subscription. Such publications may routinely go to the various wire services so that the news media can then disseminate the pertinent information to the public. Of course, specific notice requirements vary somewhat from state to state.

Persons regulated by an agency, or those who have a legitimate substantial interest in an agency rule, will generally have a right to petition or request of an agency that they be provided with at least the minimum public information concerning the need and authority for the proposed rule. Most state administrative procedure acts will give affected persons an opportunity to appear before the agency proposing the rule and present evidence and argument in support of, or in opposition to, the agency’s intended action. In fact, the agency’s action may well be subject to invalidation if substantially interested persons are not afforded this opportunity.

In many instances, a person regulated by an agency, or one having a substantial interest in an agency rule, may petition the agency to adopt, amend, or repeal a rule. In such cases, the agency generally cannot ignore such a petition, and it must take some affirmative action to either implement rulemaking or formally explain why it refuses to do so.

After public input, the agency may give further consideration to the proposed rule, and it may:

- modify the proposed rule to meet any objections (major modifications would most probably result in having to renotice the rule and initiate new rulemaking proceedings);
- withdraw the proposed rule; or
- refuse to modify the proposed rule.

Emergency Rules

An emergency rule is one necessitated by some impending need or immediate and present danger limited to some state action necessary to protect the public health, safety, and welfare of the citizens of the state. The agency implementing the emergency rule must be prepared to document the danger as well as both the need and the fairness of the rule.

An emergency rule, under most state administrative procedure acts, will remain in effect for only a limited period of time, generally not to exceed 90 days. At the end of the 90-day period (or whatever period is defined by statute), the agency generally cannot renew the rule on an emergency basis.
Of course, the agency can, during the initial emergency period, begin procedures for the adoption of a permanent rule to cover what might be thought to be a continuing or recurring situation.

Emergency rulemaking authority must be specifically authorized by statute and is closely scrutinized by both the legislative and judicial branches of government. It should be exercised with great restraint and only when necessitated by an immediate need and present danger.

**Rule Challenges**

In many states, a substantially interested person may challenge the validity of a proposed rule by requesting an administrative determination in a separate proceeding before an independent agency or hearing office. Likewise, a person substantially affected by an existing rule may seek an administrative determination of its validity by initiating similar administrative procedures. In most states, all administrative remedies are exhausted prior to seeking direct court review.

The grounds for challenging either a proposed rule or an existing rule generally fall into one of three categories, which may be stated as follows:

1. the rule is an invalid exercise of validly delegated legislative authority;
2. the rule is an exercise of invalidly delegated legislative authority; or
3. the rule is without any legislative authority whatsoever.

In general, rule challenge proceedings are fairly formal, with procedures clearly outlined in the state’s administrative procedure act. They are not too dissimilar from the adjudicatory proceeding that seeks to discipline a licensee for allegedly violating the provisions of the practice act.

Generally, a hearing officer will conduct a fact-finding hearing allowing all interested parties to make both oral and written statements. Documents, if properly authenticated, will be admitted into evidence. In some states, both examination and cross-examination of the parties are permitted. Likewise, discovery techniques such as interrogatories and depositions may be permitted and even allowed into evidence.

Usually, within a specific statutory time frame, the hearing officer will render an order either declaring the rule valid, or wholly or partly invalid. In most states utilizing this procedure, the hearing officer’s order continues final agency action and is, thus, judicially reviewable without first going back to the agency whose rule or proposed rule is being challenged.

Within the scope of this challenge procedure, one rather interesting question that is apparently still open to debate in many states is whether or not a hearing officer sitting in a quasi-judicial capacity as a part of the executive branch of government can hold a rule wholly or partly invalid on the grounds that it is unconstitutional. Traditionally, only the judicial branch of government can rule upon the constitutionality of a rule or regulation presumably based upon a statutory enactment. In this area, we may well be entering upon a new era of power being vested in a quasi-judicial hearing officer.

As a board member having to ultimately anticipate possible administrative and/or judicial review of your actions, you should make every effort to comply with all of the procedural due process requirements of law attendant to rulemaking. Use this general checklist to ensure that procedural due process is being utilized.

**Procedural Due Process Checklist**

- Clearly and simply state organizational rules;
- Ensure all interested people have...
an opportunity to obtain a verbatim copy of the rule;
- Properly advertise a public hearing to receive any and all testimony and evidence regarding the proposed rule;
- If the pertinence and relevance of the testimony and evidence is questionable, allow it to become a part of the record; and
- Ensure your public hearing is properly recorded so that, if questioned, you can show that basic and fundamental fairness was properly afforded all participants.

If followed, the guidelines may well provide you with an edge if your actions are subjected to scrutiny or judicial review.

**Preemption**

Board members should also be aware of the concept of preemption. This doctrine, adopted by the US Supreme Court, holds that certain matters are of such national, as opposed to local, character that federal laws preempt or take precedence over state laws. As such, a state may not pass a law inconsistent with the federal law. A case involving preemption is reviewed in the NABP Newsletter article “Preemption: The Maine Reason Canadian Importations Put on Ice,” in the Appendix to this manual.

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**Chapter Summary**

- Rules implement, interpret, and more clearly define the intent of the legislative statutes. Rules may also define the organization or the procedure and practice requirements of an executive entity of state government. The authority to adopt rules and regulations must be specifically delegated by the state legislature. Further, a rule or regulation must be reasonably related to the legislative intent and purpose of the statutory enactment.

- Boards must give proper and adequate notice of the agency’s intent to adopt a rule; most state laws require that such notice is published. Persons regulated by the agency or other affected persons have the right to request information concerning the proposed rule and to appear before the agency in order to present information in support of or in opposition to the rule. Existing rules may also be challenged by affected persons.

- Emergency rules may be put into effect when impending need or immediate and present danger limited to some state action is necessary to protect the public health, safety, and welfare of the citizens of the state. Emergency rulemaking authority must be specifically authorized by statute and is closely scrutinized by both the legislative and judicial branches of government.

- A substantially interested person may challenge the validity of a proposed rule, or an existing rule, by requesting an administrative determination in a separate proceeding before an independent agency or hearing office. A rule may be challenged on the basis of its validity in relation to legislative authority. Rule challenge proceedings are fairly formal and follow the state’s administrative procedure act.

- As a board member, you should make every effort to comply with all of the procedural due process requirements of law attendant to rulemaking to eliminate lengthy and embarrassing reversals by judicial review.
Regulatory agencies derive their operational authority from one of two sources – legislative enactments and rulemaking. In exercising such authority, the particular agency or board engages in a continuous process of interpreting the parameters of the relevant practice act or rules promulgated thereunder. Thus, there exists a continuous process of interpretation, which often leaves doubt in the minds of regulants and substantially interested or affected persons as to what their rights and liabilities are in their day-to-day professional activities.

A state’s administrative procedure act may place a duty upon the head of the composite board or agency to clarify any ambiguities or vagueness that may exist in any statutes or rules governing the conduct of the license holder or those persons who are affected by the activities of the license holder. The mechanism developed to accomplish this interpretative process is generally referred to as the declaratory statement.

Generally, the state’s administrative procedure act or the agency’s rules will provide a procedure whereby the regulant or interested persons may petition the agency to issue a declaratory statement. The agency is then required within a specific time frame to issue its statement, which under most states’ authorities would be considered final agency action that would be subject to direct judicial review.

Declaratory statements are most often sought in connection with an agency statute, rule, or order. As a board member, you would most probably be confronted with a request or petition for a declaratory statement in one of the following circumstances:

1. the applicability of a statute, agency rule, or an order;
2. the question of the invalidity of a rule; or
3. the question of the invalidity of a proposed rule.
In each instance, the petition should be carefully reviewed to determine its breadth and scope. Most petitions would concern a particular person or group and a particular set of facts. As such, the declaratory statement might well be narrow in scope and not binding on the agency as to other persons or groups, or other factual patterns. This is especially true when dealing with the applicability of a statute, rule, or order.

If the ambiguity relates to the applicability of a statute, agency rule, or an order, it seems logical that the agency or board should be called upon to interpret the parameters of its particular practice act and the rules and orders promulgated thereunder. For example, a petition or request for a declaratory statement to a board would be appropriate to seek clarification for the following ambiguities:

- whether, under the state’s pharmacy practice act, it would be proper for a pharmacist to dispense medication based on a prescription written by an optometrist;
- whether, under the state’s pharmacy practice act, it would be proper for a pharmacist to dispense medication based on a prescription signed by a certified physician’s assistant;
- whether, under the state’s pharmacy practice act, a retail pharmacy may keep its prescription department open only 20 hours a week, while the sundry department is open 60 hours per week; or
- what is immediate and personal supervision regarding the utilization of supportive personnel.

As stated earlier, the agency’s interpretation as embodied in its declaratory statement is subject to judicial review.

Items dealing with the question of the invalidity of a rule or proposed rule also merit discussion. The person or persons could be challenging the rule or proposed rule on the grounds that it constitutes an invalid exercise of duly delegated legislative authority. Most state statutes delegate to an agency or board the authority to promulgate rules to assist them in implementing the statute. Implicit in this delegation of rulemaking authority is the proviso that the agency or board must act consistent with the statute and not exceed its authority.

Admittedly, boards representing certain professional expertise sometimes feel that the statute in question is inadequate to properly police the profession. Therein lies the temptation to legislate by rule in order to cure the statutory deficiencies. This, however, cannot be legally accomplished through the mechanism of rulemaking as it constitutes an invalid exercise of duly delegated legislative authority. This area is discussed in more detail under the chapter on rulemaking (Chapter 5). As a member of a composite board, you may, under your particular administrative procedure act, be called upon to review the extent of your rulemaking authority. In some states, the administrative procedure act delegates this function to an independent hearing officer housed within a totally autonomous agency of state government. Still other states maintain the more traditional approach and retain this reviewing authority solely within the judicial branch of government.

You, as a board member, must check your own state law to determine what role, if any, you maintain in the area dealing with the issuance of declaratory statements.
Chapter Summary

- **Declaratory statements are requested of the board members by regulants to**
  clarify any ambiguities or vagueness that might appear in the statutes or rules affecting
  the activities of the regulant.

- **Requests for a declaratory statement could be used by substantially affected**
  persons to challenge existing or proposed rule changes on the grounds that statutes
  did not specifically provide for the rule or rule modification.

- **As a board member, check your own state law to determine what role, if any, you**
  maintain in the area dealing with the issuance of declaratory statements.
Agency hearings can encompass a myriad of different matters that could properly include investigations, discipline, declaratory statements, and rulemaking. In this chapter, however, the emphasis is on the disciplinary proceeding with some discussion of the investigative hearing.

**Due Process**

Any discussion of disciplinary proceedings involves a clear understanding of the term “due process of law.” This term encompasses a basic list of certain fundamental requirements amended to an administrative disciplinary proceeding. The due process concept does not require a “perfect” hearing in all respects. Rather, due process requires that the party or parties receive a “fair” hearing. A perfect hearing is a virtually impossible utopian goal to achieve. However, operating in an area that guarantees fundamental fairness to participants is not...
only expected of board members, but is a constitutional right.

The fundamental requisite of due process is the opportunity to be heard. Intrinsic to this opportunity is a timely and adequate notice of the factual allegations that forms the basis of the state’s contention that a regulant has violated certain basic provisions of a particular practice act (for our purposes, the existing state pharmacy practice act).

The notice of a hearing or contemplated disciplinary action is generally incorporated in or accompanied by an administrative complaint or some other document that is issued by the regulatory agency. This complaint or notice of contemplated action is measured against various due process requirements, and the fundamental due process requirements are listed in the checklist below.

**Due Process Checklist – Complaint or Notice of Contemplated Action**

- Adequate notice of the time and place of the proposed hearing must be given.
- The substantially affected party should be apprised of the procedures that shall be employed during the course of the proceeding or at least specific reference to the appropriate statutes and agency rules and regulations that will contain the procedures that are to be followed during the proceeding.
- The document should contain a statement of the legal authority and the jurisdiction of the agency under which the hearing is to be held. This statement should contain specific reference to the particular sections of your applicable state statutes and, if applicable, the rules and regulations of your agency.
- The document should contain a plain, clear, simply stated statement of the matters asserted by the agency and the issue involved. The statement should include at least a brief factual basis that prompted the agency action and the forthcoming administrative disciplinary hearing.
- The complaint document should clearly inform the substantially affected regulant of a right to counsel or representation by some other qualified representative of his or her choice.

If the complaint or other appropriate documents do not contain this fundamental information, your regulatory agency may have created sufficient prejudicial error to permit judicial intervention and action without the necessity of even looking for error at the actual administrative hearing. It is really inexcusable for a regulatory agency to be called to task at this early stage of the administrative proceedings, where such notice requirements can usually be met with little effort on the part of the agency’s prosecuting attorney.

In addition to the above-stated notice requirements with which the regulatory agency must comply, the agency or designated hearing officer, as the case may be, must afford the aggrieved license holder certain minimal procedural protections. As a prospective member of any hearing panel, you must be ever conscious of ensuring that the license holder is afforded the following minimum procedure requirements:

1. Full opportunity of the affected person or persons to respond.
2. The right to bring or compel by subpoena witnesses at the hearing.
3. The right to present evidence and/or argument on all issues involved.
4. The right to conduct cross-examination and submit rebuttal evidence.
5. The right to submit proposed findings of fact, conclusions of law, and orders.
6. The right to file exceptions to any order or recommended order, as the case may be.
7. The right to continuance where justified.
8. The right to refuse to testify.

The Right to Discovery

The aggrieved party or parties have certain basic rights to engage in discovery as preparatory to the administrative disciplinary proceeding. Such discovery may be accomplished either by using motion pleadings or discovery techniques.

Motion pleadings are designed to test the strength and validity of a complaint as well as to afford the parties the ability to engage in discovery. Although there are numerous types of motions available in an administrative proceeding, the two with which board members would be most often confronted are the motion for more definite statement and the motion to dismiss.

Similarly, fact finders will often be confronted with a motion to dismiss. This type of motion is appropriate where, assuming the truth of the factual allegations in the complaint, the state has either (1) failed to state a cause of action or (2) failed to state a proper basis upon which the agency may take action. Simply, either the actual facts or existing laws do not justify agency action against the license or permit holder. If such is the case, then board members sitting in their quasi-judicial capacity should dismiss the administrative complaint.

The most commonly used discovery techniques are (1) written interrogatories; (2) oral depositions; and (3) requests for admissions.

Written interrogatories comprise a series of questions furnished by one of the parties to the adjudication proceeding, the answers to which he or she alleges are necessary to the preparation of a defense and the ability to knowledgeably proceed through the administrative hearing.

Oral depositions, although similar to written interrogatories in some respects, are a more effective, though more expensive, discovery tool. Here, the regulant, or more likely his or her attorney, may depose individuals who presumably have information bearing on the administrative proceedings. The advantage to the oral deposition is that one answer may inspire many additional questions, which can immediately be posed. With respect to written interrogatories, the framer who wishes to ask additional questions would have to again sit down and compose them, provided there is sufficient time prior to the actual hearing.

Request for admission is another effective discovery device and also a practice welcomed by fact finders. The reason is that a request for admission will generally serve to narrow the issues that need to be proved at the administrative hearing. The fewer the issues subject to proof, the shorter and presumably less complex the fact-finding hearing.

Under most state administrative procedure acts, subpoenas, when needed, will be issued to effect discovery upon proper request to the presiding agency or hearing officer. The procedural rules of each agency should set forth the manner in which to request the issuance of subpoenas. A subpoena is nothing more than an order of the appropriate agency or hearing officer compelling compliance with a request for discovery. It should be noted, however, that the issuance of agency subpoenas or orders may be properly challenged upon the following grounds:

1. The subpoena or order directing discovery was unlawfully issued.
2. The subpoena or order is unreasonably broad in scope.
3. The requested material under discovery is irrelevant.
You, as a quasi-judicial officer, may be called upon to review and rule upon such petitions or motions.

What is the effect of a failure to comply with an agency subpoena or order directing discovery? Since most state regulatory agencies do not have authority, the affected party or parties must seek enforcement in a court of competent jurisdiction. You, as a quasi-judicial officer, would be bound by the order issued by the court of competent jurisdiction. On the other hand, your authority includes the power to grant protective orders when there is an attempt to exceed the limits of legitimate discovery.

**Powers of the Presiding Officer**

There are certain general powers that are customarily accorded to board members sitting on a hearing panel or to a duly designated hearing officer charged with the responsibility of making findings of fact and issuing an order. These powers conferred by most state administrative procedure acts include:

1. administering of oaths;
2. issuing of subpoenas in order to (a) effect discovery, (b) ensure the presence of witnesses at the hearing, and (c) to ensure the presence of books, records, or other documents properly related to the administrative proceedings;
3. ruling upon motions and other evidentiary matters; and
4. questioning all parties and witnesses for the clarification of issues for the record (with the possible exception of the regulant, who is accorded certain constitutional protection with respect to giving testimony that might tend to incriminate).

**Evidentiary Matters**

As noted above, the presiding officer or officers may rule upon evidentiary matters. Although this can easily become a complex and technical area, some working knowledge of the law of evidence is essential to anyone who at one time or another must assume the role of a presiding officer in an adjudication proceeding.

First, nothing can be treated as evidence unless it is introduced into evidence. Matters outside of the hearing record must clearly be ignored. Consideration of extraneous matters may jeopardize the board’s decision.

Under most administrative procedure acts, the general rule is that administrative findings must be supported by competent and substantial evidence. Administrative adjudicatory orders not supported by such evidence are often found to be arbitrary and will not receive the blessing of court enforcement. This does not mean that regulatory agencies are bound by the strict or technical rules of evidence governing civil trials. In fact, the acceptance of irrelevant or incompetent evidence will not render an order invalid so long as there is other competent and substantial evidence within the record to support the ruling.

Some general rules of evidence applicable to administrative proceedings may be stated as follows:

1. Irrelevant, immaterial, or unduly repetitious evidence should be excluded.
2. Hearsay evidence (evidence not proceeding from the personal knowledge of the witness but from the mere repetition of what the witness has heard others say) may be used for the purpose of supplementing or explaining other evidence, but it cannot in and of itself be used to support an administrative finding.
3. Verified copies of documentary evidence are generally admissible if the original is not readily available.

Evidentiary standards in administrative actions are the subject of the *NABP Newsletter* article.
“Burden May Be Burdensome,” included in the Appendix to this manual.

**Ex Parte Communications**

An ex parte communication occurs when one of the parties or some other individual communicates with the presiding officer or board about the adjudicatory proceeding without the presence of the other or both of the parties as the case may be. The general rule is that ex parte communications are prohibited by law when relative to the merits of the case. In the event of an ex parte communication, the presiding officer or board should place the ex parte communication in the record. Some states provide fines for failure to make such disclosure.

For example, the most common ex parte communication a board member will be subjected to concerns attempted communications from peers in reference to a pending administrative complaint. It is generally accomplished via a phone call from a pharmacist in that community who wishes to either discuss the forthcoming case or presumably shed some light on the facts surrounding the case. In such cases, the board member should immediately refuse to discuss the matter and inform the particular individual that, as an ultimate fact finder, the dissemination of such information to the board member in this type of manner would be highly improper. The individual should be informed that if information is to be given surrounding a particular case, it should be transmitted directly to the person charged with the responsibility of presenting and prosecuting the case.

**What Constitutes the Record of the Adjudication Proceeding**

Consistent with most administrative procedure acts, the record of the administrative disciplinary proceeding would include:

1. all notices, pleadings, motions, and intermediate rulings;
2. all evidence received;
3. any matters officially recognized;
4. questions and proffers or proof and any objections thereto and rulings thereon;
5. any proposed findings and/or recommendations submitted by any party to the proceeding;
6. any recommended order or final order submitted by a hearing officer or a board panel;
7. any other pertinent staff or legal memoranda submitted during the hearing or prior to disposition of the case;
8. all matters placed on the record after an ex parte communication; and
9. the official transcript.

**The Recommended Order**

In most states where the presiding officer is someone other than the head of the agency or regulatory board, a recommended order would be reviewed by the agency head or regulatory board. In such cases, the recommended order would generally consist of:

1. findings of fact;
2. conclusions of law;
3. interpretation of administrative rules, if applicable;
4. recommended discipline or penalty, if applicable; and
5. any other information required by law or agency rule to be contained in the order.

All parties to an administrative proceeding should have an opportunity prior to the rendition of any recommended decision or opinion to submit proposed findings of fact, conclusions of law, and recommendations.
to the presiding officer. Likewise, after the rendition of a recommended order, the agency or board receiving the order should allow each adversary party an adequate number of days in which to submit written exception to the recommended order.

The Final Order

The current trend in administrative procedure acts places the following requirements on the agency or board in enacting a final order:

1. The agency or board may adopt the recommended order as its final order without a review of the record.
2. The agency or board may reject or modify conclusions of law and interpretation of administrative rules in the recommended order without a review of the record.
3. The agency or board may not reject or modify findings of fact unless the agency or board determines, from a review of the complete record and states with particularity in the final order, that the findings of fact were not based upon competent, substantial evidence or that the proceedings on which the findings were based did not comply with essential requirements of law.
4. The agency or board may generally accept or reduce the recommended discipline or penalty without a review of the record, but may not increase the recommended discipline or penalty without a review of the entire record.

Default

A default situation occurs when a party required by law to respond within a specified period of time fails to do so. Based upon existing case law, it would appear that default is not an automatic procedure that can be based solely upon the license or permit holder’s inaction.

If the regulant fails to respond to an administrative complaint, a default order may be entered, provided:

1. the presiding officer or board notifies the licensee or permittee that a default order will be considered at a certain time and place.
2. that the licensee or permittee is afforded an opportunity to present evidence in opposition to or in mitigation of the proposed default.
3. the presiding officer or board considers the matter in a default proceeding prior to rendering a default order.

In addition, it is strongly recommended that testimony and evidence be presented to support the allegations in the complaint, even if the licensee or permittee fails to respond. Courts in various states have required the presentation of such a *prima facie* case (such as will suffice until contradicted and overcome by other evidence).

Notice by Publication

What happens when a regulant is nowhere to be found, but probable cause exists that he or she has violated the applicable professional practice act? A method of notice by publication exists in most states whereby constructive service of process can be obtained upon a regulant through newspaper advertisements. Most state publication statutes require that notice of intended administrative action be placed in a newspaper of general circulation once a week for three consecutive weeks in the area where the regulant was last known to reside. Thereafter, the agency may proceed as if service was actually made. However, similar to the section above on default, it is still incumbent upon the agency to present sufficient testimony and evidence to build a *prima facie* case and support the factual allegations in the administrative complaint.
The Emergency Suspension Order

The emergency suspension order, which must be authorized by statute, is a growing trend in administrative law. Surprisingly, this trend clearly strains our concept of constitutional protections and due process of law. It may well represent the zenith of the state’s police power to protect the citizens of that state.

In essence, the agency or board may suspend the license of a professional based upon investigative information alone and prior to convening any type of fact-finding proceeding when there is a clear demonstration of an immediate and serious harm to the public posed by the continued practice by that particular license holder. The most common example would be the professional who has become impaired due to the excessive use of drugs and/or alcohol (the pharmacist who is unable to properly dispense the correct medication upon presentation of a prescription). Because this is such an awesome power, it should be used sparingly and only where the evidence is clear and unequivocal that an immediate and serious danger to the public exists. A haphazard and flippant use of this power could very possibly subject the user to federal and/or state litigation and the possibility of personal liability for damages. A case involving a licensee who was ordered to complete an evaluation after claims were received that questioned the licensee’s ability to practice safely is reviewed in the NABP Newsletter article “Evidence of Ebriety” in the Appendix to this manual.

The Investigative Hearing

Although all states do not utilize the so-called investigative hearing and although it is technically a part of the investigative process, the investigative hearing is a procedure that merits discussion, as it permits members of a regulatory board to engage in a form of administrative or quasi-judicial adjudication within the agency’s investigative process.

If such a hearing is scheduled, a transcript of the proceedings is generally required. The introduction of both written data and oral statements is permitted. Further, any persons appearing at such a hearing have a right to counsel or some other qualified representative at their own expense.

The investigative hearing might well be considered in the nature of a “probable cause” proceeding that could be viewed as somewhat analogous to a grand jury proceeding. The important point to remember during this type of investigative hearing is that the investigating officer (or officers) is participating in the investigation and is performing a type of executive function rather than a purely quasi-judicial function. As such, those participating in the investigative hearing are inevitably being tainted to some extent by the information that is received. The investigating officers will most probably be conducting this proceeding with a view toward making some form of report and recommendation to the regulatory agency.

Clearly, under this type of procedure, basic due process requirements would seem to dictate that the investigating officer (or officers) be recused and not participate in any adjudication proceeding that may be initiated based in part or in whole upon the findings and recommendations of that investigating officer. In fact, it is not inconceivable or even unusual that the investigating officer (or officers) will be called to appear as a witness in the adjudication proceeding.

The investigative hearing can have one of three results:

1. a conclusion of the investigation with an agency finding of no probable cause;
2. a determination by the agency that further information is necessary and that the investigation must be continued; or
3. a conclusion of the investigation with a finding that probable cause does exist. If such is the case, the agency at this point would commence the adjudication phase of its responsibilities by most probably preparing the administrative complaint that would be the basis for the adjudicatory proceeding.

Various states require that information acquired in the course of an investigation be kept confidential unless and until probable cause is found to file an administrative complaint against the regulant. As such, the information compiled in the course of an investigative hearing would, in many states, not be subject to public inspection scrutiny unless an agency determination is made that probable cause exists to issue the complaint or accusation that commences the adjudicatory proceedings. This requirement, however, would not generally restrict any person giving an oral statement from obtaining a copy of the transcript of his or her statement given at the investigative hearing.

**Pending Criminal Proceedings**

The situation often arises when a board is faced with an alleged violation of its practice act while, at the same time, similar or identical proceedings are pending before a criminal court of competent jurisdiction. In such instances, the regulatory board will generally be confronted with a request that the administrative proceedings be held in abeyance pending the final outcome of the criminal proceedings.

In rare instances, there may be compelling reasons why the board might wish to continue an administrative matter when a criminal investigation is still pending and where a state or US attorney or law enforcement agency needs more time to complete its case. However, absent such compelling reasons it is contended that a regulatory board has a paramount responsibility to proceed under the state police power and prosecute the deviant license holder. Courts have recognized these compelling interests and have recognized that the state police power overrides other constitutional-like arguments of the regulant, such as his or her testimony before an administrative board being used against him or her in the criminal proceeding. Not acting promptly could result in criticism of the board for failing to correct a danger to public health and welfare.

**Judicial Review**

The subject of judicial review is both extensive and technical and does not pertain specifically to the day-to-day responsibilities of a board member. As such, a detailed discussion does not appear in this manual. However, two matters do specifically relate to the responsibilities of board members and merit discussion.

The first matter has already been discussed, but its importance cannot be overemphasized. The matter pertains to the record of the administrative proceedings established by the pleadings, evidence, and any hearings before a hearing officer and/or the board as a result of an administrative complaint being issued.

The issue is simple. Except where a trial de novo (new trial) is specifically authorized by statute, when an administrative matter is appealed to the courts, that judicial tribunal is limited solely to the record created by the regulatory agency below. Its decision will either stand or fall based upon the record presented to the court. At this point, it is far too late to place additional facts and evidence before the court. As such, board members must constantly be aware of the importance of establishing a complete and thorough record at the administrative hearing.

The second matter concerns the issuance of a stay when a licensee has been subject to
either a suspension or revocation and the licensee now seeks judicial review. The initial question is, who may consider and, if appropriate, grant a stay of administrative discipline? The answer is twofold under most state statutes. Generally, both the regulatory board and the courts have concurrent jurisdiction in this area. The licensee will often request a stay of the suspension or revocation before the board first, and, if unsuccessful, will then make that same request of the court when the notice of appeal is filed. When such a request is made directly to the courts, the board, by and through its legal counsel, will be given an opportunity to oppose the request for a stay.

A case illustrating many of the topics covered in this chapter is presented in the NABP Newsletter article “The Vinci Code,” which has been reprinted in the Appendix to this manual. The NABP Newsletter article “Retest Reasonable Reality for Recommended Reinstatement of Revoked Registration” reviews important distinctions between revocation and suspension, as well as reinstatement considerations, and is also included in the Appendix.
In order to comply with due process requirements, it is incumbent upon the board to provide timely and adequate notice of the factual allegations pertaining to the case, and to conduct a fair hearing that will allow participants the right to be heard. A complaint or notice of contemplated action should be issued and should follow the guidelines for due process presented in this chapter (see page 43).

Members of hearing panels must ensure that the license holder is afforded the minimum procedure requirements provided in this chapter (see page 44).

The “right to discovery” is a tool used by the regulant to assist in the preparation of his or her defense to the board’s allegations or to seek dismissal of charges. Such discovery may be accomplished either by using motion pleadings (either the motion for more definite statement or the motion to dismiss) or discovery techniques (by written interrogatory, oral deposition, or request for admission).

Powers accorded the board hearing officer generally include such items as administration of the oaths, ensurance of the presence of all witnesses, rulings on motions, and clarification of issues for the hearing record.

Administrative findings must be supported by competent and substantial evidence. Nothing can be treated as evidence unless it is introduced into evidence. Hearsay evidence in an administrative hearing is admissible, but cannot be used by itself to support an administrative finding of fact.

When an ex parte communication occurs, such as communications from peers in reference to a pending administrative complaint, the presiding officer or board should place the ex parte communication in the record.

Board members must constantly be aware of the importance of establishing a complete and thorough record at the administrative hearing. The record of the adjudication proceeding must include all items outlined on pages 47 of this chapter.

A recommended order is reviewed by the agency head or board if the presiding officer is someone other than the agency head or board. The board may take one of several actions in determining the final order and these are outlined on pages 47 and 48. A default situation occurs when a party required by law to respond within a specified period of time fails to do so.

If authorized by statute, an emergency suspension of a license may be issued when there is a clear demonstration of immediate and serious harm to the public posed by the holder’s continued practice.

In an investigative hearing, the officer(s) is performing a type of executive function rather than a purely quasi-judicial function. This officer should not participate in any adjudication proceeding initiated by an investigative hearing, as he or she may be not be unbiased.

When a board is faced with an alleged violation of its practice act while similar proceedings are pending before a criminal court, the regulatory board will generally be confronted with a request that the administrative proceedings be held in abeyance pending the final outcome of the criminal proceedings. In most cases, when board action is subjected to judicial review, only that record established by the board hearing will be considered by the courts.
Chapter 8
Agency Investigations

Chapter Objectives

After completing this chapter, you should be able to answer the following questions:

- What are the roles of an inspector?
- What kind of training and knowledge will an inspector need to complete inspections that will hold up in potential disciplinary hearings?
- When is a warrant needed?
- Is a potential criminal defendant undergoing an inspection or audit required to be advised of his or her Miranda rights?
- Why must the investigative, prosecutorial, and adjudicative functions of the board be segregated?

The Investigative Process

Most boards of pharmacy employ or are assigned inspectors whose jobs involve inspections and audits of pharmacies and investigatory duties pertaining to formal and informal complaints. While the purpose of this manual is not to detail such matters as audit procedures or investigation procedures, there are certain aspects of the investigatory function that should be familiar to board members.

The investigatory process is one of the most vital functions of the board, and it is extremely important that inspectors receive appropriate initial training and continuing education, since their duties encompass the legal technicalities upon which a disciplinary proceeding may turn. In order to ensure that evidence introduced at a disciplinary hearing is not jeopardized, the training must include such legal concepts as chain of evidence, search and seizure, confidentiality, and entrapment.

An inspector must also be trained in appropriate techniques with regard to inspecting and auditing pharmacies and investigating complaints, as well as methods of preparing clear and concise reports for use by the boards. When conducting investigative duties, the inspector must also be constantly aware of the scope of his or her authority, since activities outside this scope may jeopardize subsequent disciplinary proceedings.

Inspectors should understand that they represent the pharmacy board and that their activities directly reflect upon the board. They should not be overzealous or arrogant in exercising their responsibilities. Their initial
approach may well determine whether or not a pharmacist or other individual will be cooperative.

One of an inspector’s major roles should be to educate the pharmacist, who, through ignorance or oversight, may have violated a statute or board rule or regulation. The inspector should use good judgment in determining what matters can best be settled by the inspector in the field, as opposed to those that should be referred to the board for further action. In this way, the inspector not only renders services to the board, but also to the profession.

Search and Seizure

Inspectors must be cognizant of the constitutional limitations in gathering evidence, particularly when auditing pharmacies. State and federal constitutions permit the suppression of evidence obtained in illegal searches and seizures. The law is complex and not always clear as to when an administrative warrant is needed in the audit process.

In most audits, pharmacists are very cooperative because they generally are in compliance with the law. The problem arises, however, when a recalcitrant pharmacist questions the authority of an inspector to audit books, records, and drug supplies without an appropriate warrant. The inspector is then on the horns of a dilemma. If the inspector obtains an administrative warrant, the pharmacist has the opportunity to remove or alter possible incriminating evidence. If the inspector is insistent upon proceeding, and is successful, the inspector may well jeopardize any possible disciplinary action against the pharmacist by obtaining evidence through an illegal search and seizure.

When is a warrant needed? Under normal circumstances where a statute provides for routine inspections of commercial enterprises during normal business hours, a warrant is not necessary. Legal scholars have argued that even absent the statutory authority, when professionals accept their licenses and enter the practice, they imply consent to those practices necessary to regulate the profession, including routine audits. Under any circumstance, however, if the pharmacist knowingly and voluntarily consents to the audit, the pharmacist is precluded from alleging that any evidence obtained was through an illegal search and seizure. If the inspector threatens the pharmacist with disciplinary action or in some other manner in order to gain access to the store without securing a warrant, it is likely that the “consent” extracted through undue pressure will not be recognized as a knowing or meaningful consent.

In the event a pharmacist refuses to permit inspection of his or her store, it would generally be wise for an inspector to obtain an administrative warrant, particularly when inspecting areas not generally open to the public. Obtaining such a warrant is not difficult since in most jurisdictions the inspector need only execute an affidavit and submit it to his or her appropriate state officer. A warrant will generally be issued on a routine basis in a relatively short time period.

On many occasions, state inspectors actually have knowledge of possible irregularities at a particular pharmacy, or persons are carrying out an audit at the request of state or federal law enforcement officials seeking evidence for possible criminal prosecutions. Under such circumstances, an audit cannot be classified as routine. If any trouble is anticipated and the inspection is not routine in nature, a warrant should be obtained prior to the time when the inspector enters the premises.

Law enforcement officials using board inspection to secure possible criminal information run the risk of having evidence that was intended for use in the criminal proceedings suppressed, even though such evidence would be admissible in a disciplinary
proceeding. If the board inspector is classified as an agent of the law enforcement agency, it is highly probable that a criminal search warrant may be deemed to have been necessary in those situations where the pharmacist will not consent to the inspection. Problems become increasingly difficult when an inspector acts in a dual capacity for his or her state board and agencies engaged in criminal prosecution.

Is it necessary for an inspector to comply with the Miranda rule, which requires that a potential criminal defendant be advised of the criminal's rights? Since the inspector is checking compliance under the pharmacy practice act and any evidence secured would be utilized in an administrative disciplinary hearing, and since no arrest is being made, the Miranda warning is not necessary. However, where the evidence may also be used in criminal proceedings, counsel should be consulted to determine the possible applicability of the Miranda rule. The area of illegal search and seizure is very complex. If an inspector is in doubt, the inspector should contact board counsel for advice.

The Relationship Between Inspectors and Board Members

It is essential that the investigative, prosecutorial, and adjudicative functions of the board be carefully segregated in order to ensure all regulants fair and unbiased consideration by the board. When these functions overlap, due process may be violated. For example, if a board member is privy to an inspector's report containing information secured during an investigation of a pharmacist, it is inferred that the board member might well be prejudiced in subsequent board proceedings. Access to such information prior to a hearing would likely constitute a denial of due process to the pharmacist in question and render any proceedings in which that board member participated subject to constitutional attack. The likelihood is that any disciplinary action meted out by the board under these circumstances would be set aside by appeal to the appropriate court.

For that reason, acceptable communications between board members and inspectors must be clearly defined, especially where investigative reports are concerned. A procedure should be established whereby the information secured by an inspector can be analyzed and a final decision made as to whether or not the facts merit further proceedings by the board. In many instances, the reports of inspectors are submitted to the executive secretary of the board, who then makes the determination as to what action, if any, is warranted. The secretary will often confer with legal counsel about the advisability of instituting formal proceedings. The board members receive no information prior to hearings other than the complaint itself and, perhaps, documents that may have been filed by the parties in the formal disciplinary proceedings.

Some boards have traditionally assigned the duty of screening possible disciplinary actions to one or more members. In a situation where board members become privy to inspectors’ reports and other information, it is usually necessary for those board members to disqualify themselves from subsequent hearings on the cases they have screened.

In many states, administrative disciplinary hearings are held before a hearing officer, who determines the facts and makes a recommendation to the board on what he or she considers to be an appropriate resolution of the case. The board acts essentially as a jury and accepts, rejects, or modifies the hearing officer's recommendation. Even when a hearing officer is utilized, it is important that board members have no “inside” information prior to the hearing and, in particular, access to an inspector’s files. These same precautions...
must be taken where a board member serves as a hearing officer.

In order to avoid such problems, boards should consider establishing formal procedures for processing complaints in a manner that prevents inappropriate information from being placed in the hands of the board members. It is important that board members also avoid discussing cases with inspectors, since the information they may receive prior to a hearing, whether in writing or merely by word of mouth, could endanger subsequent board actions. Appropriate use of the board’s administrative officer can be most helpful in avoiding the due process problems discussed in this chapter.

Chapter Summary

- Board members are not expected to perform the investigative work of the inspectors, but they should have basic knowledge of how the investigative process for their board functions. An inspector providing the best service to his or her board will spend adequate time educating members of the profession as well as ensuring compliance.
- Inspectors must receive appropriate initial training and continuing education, including training on relevant legal concepts, inspection and auditing techniques, preparation of clear and concise reports, and scope of authority. Inspectors must be cognizant of the constitutional limitations in gathering evidence, particularly when auditing pharmacies.
- In the event a pharmacist refuses to permit inspection of his or her store, it would generally be wise for an inspector to obtain an administrative warrant, particularly when inspecting areas not generally open to the public. If any trouble is anticipated and the inspection is not routine in nature, a warrant should be obtained prior to the time when the inspector enters the premises.
- Where the evidence may also be used in criminal proceedings, counsel should be consulted to determine the possible applicability of the Miranda rule, which requires that a potential criminal defendant be advised of the criminal’s rights.
- It is essential that the investigative, prosecutorial, and adjudicative functions of the board be carefully segregated in order to assure all regulants fair and unbiased consideration by the board.
  - For example, acceptable communications between board members and inspectors must be clearly defined, especially where investigative reports are concerned. Even when a hearing officer is utilized, it is important that board members have no “inside” information prior to a hearing and, in particular, access to an inspector’s files.
  - Further, where a board member has the duty of screening possible disciplinary actions, that board member should disqualify himself or herself from further participation in the adjudication process.
In general, a sunshine law is a legislative enactment that requires open public meetings by various state and local bodies. In most instances, the law is directed to the executive branch of government with an exemption for the state’s chief executive officer (the governor). Both the legislative and judicial branches of government have remained immune.

More specifically, the law most often states that any board or commission of any state agency or authority or any authority of any county, municipal corporation, or any political subdivision except as otherwise provided in the Constitution, shall open its meetings to the public at all times.

By judicial construction, this statute has been given a very broad application. The feeling clearly seems to be that the public interest is best served by a liberal open public meeting law.

Activities Covered

The sunshine law appears to cover every aspect of an agency’s decision-making process. The theory is that the public interest demands access to public deliberations and policymaking decisions. It is designed to pierce the veil of such bureaucratic terms as “informal conferences,” “caucus,” “executive sessions,” and “fact discussions.”

In short, any activity on the part of officials forming a composite group that is vested with a public trust and able to formulate policy that can affect the citizens of the state is subject to the sunshine law. As such, each of you as board members in your particular state may find that certain activities previously presumed to be private are now, in fact, covered by the sunshine law. Examples might be briefing sessions, workshop meetings, informal discussions, or any other...
meeting of a public body, even where no formal vote is taken.

**Examples**

An example of broad interpretation of the sunshine law was reached by one of our state supreme courts involving an ad hoc committee of private citizens who were appointed as an advisory group to consult with a professional land-planning firm hired by the city to update and revise its comprehensive zoning plan. In that case, the court stated that a subordinate group or committee selected by a governmental authority is not free to meet in private. If the committee is engaged in the conception of a proposed zoning ordinance, the public interest is sufficient to justify its inclusion within the provisions of the sunshine law. The court went so far as to state, “When in doubt, the members of any board, agency, authority, or commission should follow the open meeting policy of the State.”

Many sunshine laws contain such language as “except as otherwise provided by the Constitution.” This is a legislative means of recognizing that the state’s constitution takes precedence over any legislative enactment and, as such, constitutional exceptions may well exist to any government in the sunshine law.

For example, one state constitution guaranteed collective bargaining for public employees. Because the record before the court contained clear, uncontroverted testimony by a reputable national authority to the effect that meaningful collective bargaining would be destroyed if full publicity were accorded at each step of the negotiation, preliminary or tentative negotiations between a negotiator employed by a school board and teacher representatives were held to be exempt from the statute. The court stressed that the recommendations of the board’s negotiator were required to be presented, aired, and voted upon by the board in a public meeting. It was the court’s conclusion that this procedure satisfied the sunshine law requirements in light of its constitutional exception. The court additionally ruled that the board was not prohibited by the statute from meeting privately with its negotiator before and during negotiations for purposes of consultations and giving instructions to the negotiator.

**Disciplinary Proceedings**

One of the areas of prime concern to regulatory board members is the effect of the sunshine law on quasi-judicial proceedings, the so-called disciplinary proceeding where the revocation or suspension or other discipline of a license may result. Clearly, the evidentiary hearing itself is public. In some states, the deliberations of the board are also public in nature. In one such case, a court rejected the argument of the board that administrative tribunals acting in a quasi-judicial capacity fall more properly within the judiciary than the executive branch of government. That court held that once the legislature transforms a branch of a board’s responsibilities and duties into that of a judicial character so that the board may exercise quasi-judicial functions, the prerogatives of the legislature in the matter do not cease. The court reasoned that if the legislature may delegate quasi-judicial powers to the board and regulate the procedures to be followed in hearings before the board, it follows as a matter of common logic that the legislature may further require all meetings of the board at which official actions are to be taken to be meetings open to the public. Thus, the court found that a board exercising quasi-judicial functions is not a part of the judicial branch of government and, as such, is subject to the sunshine law.

On the other hand, there are court decisions that reason that the legislature is not empowered by statute or otherwise to prescribe the conduct of the internal government of the judicial branch, as such constitutional authority is vested
solely and exclusively in the judicial branch of government. Therefore, although the legislature is possessed of the authority to vest quasi-judicial functions in a regulatory board, once it has transformed a certain portion of that board’s responsibilities and duties into that of a judicial character, its prerogatives in the matter cease. Thus, neither the public nor the press would have any more right to enter into the judicial deliberations of the members of a regulatory board than they have to enter into the conference room of the supreme court of the state when the members of that court are deliberating a judicial question, or into a jury room when those citizens are deliberating upon their verdict.

The area of this discussion that appears to have remained longest outside the purview of the sunshine law is that of the attorney-client privilege, which can be convincingly argued as a basic ethical requirement under a state board’s canon of ethics. In summary, an attorney, even if representing a state body, is bound by certain ethical requirements and duties in the conduct of certain pending or impending litigation. In this respect, one court held that the legislature was without any authority to directly or indirectly interfere with or impair an attorney in the exercise of his or her ethical responsibilities as an attorney and officer of the court. The court stated that an attorney may not be placed in the untenable position of having to choose between a violation of a statute or a violation of a specific canon of ethics insofar as they clearly conflict. In practical terms, the court was permitting certain confidential communication between the attorney and client even if said client was, in fact, a public body preparing for and participating in matters in litigation.

However, another argument has more recently emerged, which notes an alleged basic misunderstanding of the scope and purpose of the so-called attorney-client privilege. In essence, that privilege does not belong to the attorney, but, rather, belongs to the state agency that the attorney represents and serves. Carrying this rationale forward, one can argue that under the sunshine law, the regulatory agency is without statutory authority to raise the privilege. In effect, the legislature, by passage of the sunshine law, has waived or prohibited use of the attorney-client privilege for all such public bodies.

Clearly, this question is still open to debate. Agency investigations and investigative reports resulting therefrom are discussed in Chapter 8.

Notice Requirements

Assuming that some aspects of the sunshine law apply to your state, the question that now arises is whether or not notice of such meetings should be given to the public and the news media regarding the time, place, and subject matter. The answer is yes. Notice may be considered a mandatory aspect of a sunshine law.

The specific type of notice will vary from state to state, depending on state statutes or, in their absence, judicial decisions. When in doubt, always think in terms of reasonable notice as to (1) what is timely; (2) what means to disseminate the information; and (3) how to describe the subject matter to be considered.

Violation of the Sunshine Law

First and foremost, one must consider that a state sunshine law may well provide for criminal penalties. Even if only a misdemeanor, the offense can carry the possibility of imprisonment and/or a fine. Such penalty provisions are not unusual and should be seriously considered. Because such provision is clearly criminal in nature, intent to commit the violation will probably have to be proven even though the statute may not speak to that issue. In addition, the logical effect of a violation of the sunshine law is to invalidate and render void ab initio (from the beginning) the subsequent governmental action that was initially considered in the nonpublic meeting. This conclusion is supported by judicial decision.
Chapter Summary

- A sunshine law is a legislative enactment that requires open public meetings by various state and local bodies. More specifically, the law most often states that any board, except as otherwise provided in the Constitution, shall open its meetings to the public at all times.

- Board members may find that certain activities previously presumed to be private are now, in fact, covered by the sunshine law. Examples might be briefing sessions, workshop meetings, informal discussions, or any other meeting of a public body, even where no formal vote is taken.

- One of the areas of prime concern to regulatory board members is the effect of the sunshine law on disciplinary proceeding where the revocation or suspension or other discipline of a license may result. The evidentiary hearing itself is public, and, in some states, the deliberations of the board are also public in nature.

- If some aspects of the sunshine law apply to your state, notice of relevant meetings should be given to the public and the news media regarding the time, place, and subject matter. The specific type of notice will vary from state to state, depending on state statutes or, in their absence, judicial decisions.

- The logical effect of a violation of the sunshine law is to invalidate and render void from the beginning the subsequent governmental action that was initially considered in the nonpublic meeting.
Chapter 10
Sunset Laws

Chapter Objectives

After completing this chapter, you should be able to answer the following questions:

- What is a sunset law?
- How could a sunset law affect a board of pharmacy?
- What can boards do in anticipation of sunset laws?
- How can boards use sunset laws in a positive manner to create stronger laws in their state?

Of considerable interest for governmental agencies that exist to regulate a particular profession, such as boards of pharmacy, is the concept of sunset. Simply put, sunset provides a specific termination date for each regulatory program. In effect, the program goes out of existence on the established sunset date unless the state legislature specifically renews it. The automatic termination date is the key to sunset.

Under sunset, regulatory programs are to exist only to the extent necessary to protect the public health, safety, and welfare. It is based on the premise of minimum government regulation and intervention in the private sector. Although agencies are effectively placed on the defensive, it is contended that the purpose of sunset is not to see how many programs can be abolished. Nevertheless, the regulatory agency and its programs will die if the legislature fails to reenact the enabling statute. The practical effect is to provide veto power to the state legislature, which can kill legislation merely by refusing to consider it. This was clearly felt by one state’s psychologists when, by inaction of the legislature, the psychological practice act was automatically repealed.

Possible Legislative Changes

During the implementation of sunset, state legislative assemblies, or at least some members of those bodies, will undoubtedly begin the process from a rather radical position, knowing that the end result will likely involve considerable compromise. The following composite is clearly a gross exaggeration of what might happen in your state as a result of sunset. However, you may well be confronted with any one or more combinations of these possible changes.
Possible changes in the adjudication process:

1. The creation of a master regulatory agency with full power over the budget of each board and the transfer of the employees of each regulatory board to the master agency.
2. All complaints from consumers and law enforcement agencies will be directed to the master agency.
3. Employees of the master agency will investigate all of the complaints.
4. As a basis for preparing an administrative complaint, the master agency will make determination as to whether probable cause exists. If so, the administrative complaint will be prepared by prosecuting attorneys employed by the master agency, and they will proceed with the prosecution of the case.
5. The administrative hearing will be held before a hearing officer or hearing examiner, who would be an attorney and an employee of another autonomous state agency, which might be referred to as the “Division of Administrative Hearings.”
6. The hearing officer, or hearing examiner, would render a final administrative order. This order would be directly appealable to the courts of the state by either the secretary of the master agency or the aggrieved regulant or licensee.

Possible Changes in Rulemaking

1. Regulatory boards may propose rules and regulations, but such proposals would be subject to the veto power of the master agency. In other words, boards could suggest appropriate rules, but their comments would be considered to be merely advisory.
2. On the other hand, the master agency could promulgate rules and regulations affecting the various professions. Those rules would not be subject to challenge by the various regulatory boards.
3. All existing rules and regulations would be automatically repealed on the effective date of the new sunset legislation. Any proposed rules or reenactment of old rules would be subject to the notice and public hearing procedures under the administrative procedure act of the state.

Possible Changes in Continuing Education

Mandatory continuing education would be abolished, and in its place there would be a provision for periodic re-examination of each professional every seven years.

Possible Changes to Examinations

1. All examinations for licensure would be prepared, administered, and scored by the master agency.
2. Licenses would be directly issued by that agency.

These “worst-case” scenarios are based on the assumption that the legislature most likely would take a far-reaching position knowing that the end result would be subject to compromise throughout the legislative process. Thus, the pictures painted are likely the worst that might be expected. The bottom line, obviously, would effectively strip the various regulatory boards of their traditional peer review and other authorities.

Things to Do in Anticipation of Sunset

Based upon the assumption that it is better to take a positive approach to problem solving than to passively sit back and wait for the impending gloom to envelop you, there are certain definite things you can do to prepare for the sunset process in your state.
Work closely with your state professional association to achieve acceptable legislative goals.

When board members meet with members of state associations, such as legislative committees, sunshine laws will probably apply and, as such, public notices may have to be given and procedures, such as executive sessions, may not be permitted. However, these sunshine provisions may not apply when only the board attorney or board secretary is meeting with members of the state association.

The public may not be aware of the accomplishments of an effective regulatory board. Furthermore, the state legislature may not be fully aware of the overall effectiveness of regulatory boards. Frequently, it may be too late to disseminate information about the activities of boards after the sunset review has started.

**Strategies for Promoting the Value of the Board**

A published newsletter is an excellent vehicle in which to report to the legislature, members of the profession, and the consumer important activities of the board and information affecting both the public and license holders. More than 30 state boards of pharmacy publish newsletters through the NABP State Newsletter Program. The premise of such a newsletter is that an informed professional is the best avenue to protect the public health.

Publication of disciplinary proceedings inform the practitioner, the public, and members of the legislature whether the board is effectively functioning under the police power of the state. Reports of this nature should be sent to the NABP Clearinghouse, so they can be transmitted to all boards.

Comments and announcements can be designed to benefit the consumer and, under the Federal Communications Commission requirements for public broadcasting, be used on radio and television stations.

Contact should be made and maintained with sunset committee staff and with key legislators as early as possible. Early and ongoing communications can assist them and influence their thinking about the duties, responsibilities, and problems of regulatory boards. However, do not infer that your regulated profession is “unique.” They have heard that the other 25 (or more) professions in the state are “unique,” too.

**Navigating the Politics**

Sunset is a political, not a judicial, process. Organize a constituency to communicate with legislators and to testify before committees of the legislature.

Some regulatory boards have been able to accomplish a limited “end run” of sunset by proceeding into an in-depth revision of their laws a year or two in advance of the sunset date. This has been accomplished by going before a legislative committee other than the one with overall reform jurisdiction. The committee with this jurisdiction is likely to give deference to the work product of another committee with subject matter jurisdiction, if the work product is not obviously at variance with sunset principles.

Sunset may afford an opportunity to improve the position of the regulatory board. It may be possible to develop a stronger or better law. For example, the landscape architects in Florida converted a “title” act to a “practice” act. Now all landscape architects in Florida must be licensed.

If the House side of the legislature appears to be too large and unwieldy, boards are better off concentrating their efforts on the smaller but equally powerful Senate side. The smaller body may prevent a disastrous sunset.

It is important not to overlook the governor. Even if the legislature reenacts the practice act, the governor has veto power.
In a sunset year, that power can be more devastating than any other power because the result of its exercise can mean the complete absence of any regulation of the profession. In one state, both the foresters and electronic repair workers learned about the power of the veto. After the legislature reenacted their statutes, the governor vetoed them. They are no longer licensed in that state.

It is preferred that if a positive approach, as outlined previously, is followed by the various professions of your respective states, the sunset process may result in maximizing your benefits, while minimizing the pain.

**Chapter Summary**

- **Sunset provides a specific termination date for each regulatory program. In effect, the program goes out of existence on the established sunset date unless the state legislature specifically renews it by reenacting the enabling statute.**

- **Under sunset, regulatory programs are to exist only to the extent necessary to protect the public health, safety, and welfare. It results in termination of the use of the police power of the state and is based on the premise of minimum government regulation and intervention in the private sector. This chapter includes examples of what might happen in your state as a result of sunset.**

- **In anticipation of sunset laws, work closely with your state professional association to achieve acceptable legislative goals.**

- **Use a published newsletter as a vehicle in which to report to the legislature, members of the profession, and the consumer important activities of the board and information affecting both the public and license holders.**

- **Contact should be made and maintained with sunset committee staff and with key legislators as early as possible. Early and ongoing communications can assist them and influence their thinking about the duties, responsibilities, and problems of regulatory boards. Organize a constituency to communicate with legislators and to testify before committees of the legislature. Communication with the governor is also important, since he or she, of course, has the power to veto statutes.**

- **Sunset may afford an opportunity to improve the position of the regulatory board. It may be possible to develop a stronger or better law.**
Chapter 11

Typical Board of Pharmacy Meeting Agenda

I. Call to Order; Establish a Quorum

Avoid roll call. Whoever is taking the minutes of the meeting can see who is there and insert the names in the minutes, including, but not limited to, board members, staff, and guests. Also, the person taking the minutes shall then determine whether a quorum is present to conduct necessary business.

II. Adopt the Agenda

Board shall make a motion to adopt the agenda before business is conducted.

III. Approval of the Minutes of the Last Meeting

Approve or approve-as-corrected with corrections made on the official copy rather than reflecting them in the current minutes. If audio recordings are used, the approval should say something about reusing, deleting, or even destroying the recordings.

IV. Additions to the Agenda

From an administrator’s viewpoint and, to a lesser degree, from the board members’ viewpoint, this option should be utilized only in extreme cases or if the next meeting is scheduled for a future date considered too distant to facilitate action.

V. Reports

Each inspector gives a brief written summary of unusual activities that are not legal in nature at this time. Board members may also give a brief report related to their involvement with board activities.

VI. New Business

Any new item that needs board attention and is not covered in other sections of the agenda should be placed here. New items usually require more background
information. Topics and items that may fall under new business include, but are not limited to:

A. Rules discussions  
B. Presentations to the board  
C. Committee and meeting updates

**VII. Disciplinary Considerations**

(Here, a break with *Robert’s Rules of Order* [Parliamentary Procedure] can be made. Even though the disciplinary activities could be placed under “New Business” once, if they are continued to another meeting, or discussed later in the same meeting, an orderly trail of the specific issue can be difficult to maintain. This section of the agenda can be modified to fit any board procedure or legal requirement.) Under Disciplinary Considerations place:

A. Completed investigations to be acted upon by the board.  
B. Unsigned telephone contacts that might warrant a board-instituted complaint (investigation).  
C. Audits:  
   1. authorized;  
   2. completed pending board action;  
   3. pre-hearing conferences;  
   4. hearings;  
   5. court actions; and  
   6. follow-ups.

**VIII. Old Business**

**IX. Unfinished Business**

**X. Adjournment**

Note: Certain portions of board meetings, such as time designated for reviewing disciplinary cases, may be closed to the public, if authorized by state law.
For Board Members

I. Familiarize yourself with the rules of order and policies and procedures.
II. Be willing to contribute your thoughts and ideas in a constructive manner. It is much more beneficial to the workings of the board to offer an alternative course of action than to solely disagree.
III. You may only speak after receiving permission from the chair; be courteous to the chair or anyone else.
IV. Determine the proper method of introducing a motion and restrict your remarks to issues rather than personalities.
V. Exercise your right to vote and refrain only when there is a clear conflict of interest. To not vote is a vote counted with the prevailing side.
VI. Any conflict of interest should be declared at the onset of the discussion, and the board member involved must then refrain from any further participation with relation to the specified issue. This may vary from state to state. (Board members may wish to clarify any issue with respect to conflict of interest with the attorney general of the state.)

For Board Chairperson or President

Prior to the Meeting:

I. Familiarize yourself with current standing rules and policies of the board.
II. Review for yourself basic parliamentary procedures and terminology, particularly dealing with motions.
III. Arrange a meeting at least 30 minutes before the board meeting with the administrative staff, secretary, or executive director to review the planned agenda (see Chapter 11, Typical Board of Pharmacy Meeting Agenda).
   A. Determine necessity for formal action on agenda items as opposed to indicating what the “board noted,” or other designations.
   B. Identify potential trouble spots in agenda and develop alternate plans for handling these matters.
   C. Identify members of the board qualified to lead discussion and make appropriate motions when needed.
   D. Anticipate agenda items that might require further study and identify members likely to fulfill this assignment. Contact these members ahead of the planned meeting, if possible, or at least before the specific item on the agenda is due to be discussed.
E. Determine what items not already on the agenda might be addressed in an informal manner, if time permits, and how much time could be allowed.

F. Determine what items can be handled by consent rather than a vote (i.e., “If no objection is heard, agenda items [specific mentions] are adopted.” Usually utilized to save time on such routine matters as minutes, intern licenses, etc).

During the Meeting:

I. The chair must maintain decorum and move the meeting in a purposeful manner that projects confidence in the board members and their ability to act.

II. The chair should refrain from strong, argumentative, partisan views.

III. Keep discussion focused on the agenda item, allowing only one person to speak at a time, but refrain from becoming dictatorial.

IV. Repeat and explain the motion prior to a vote so all members fully realize the facts and what action a positive as well as a negative vote will produce.

V. Make sure everyone on the board is aware of voting procedures, and regardless of what the chair feels is the outcome, always call for the positive and negative vote, and announce the results.

VI. Attempt to handle as many matters as possible by consent.

VII. When in doubt on a point, take time to research the item in question and determine the proper procedure. Do not be led by an “angry crowd.”

VIII. Remember that all of your rulings are designated as from the “chair,” not “I” or “we.”

IX. Remain helpful to board members in the proper method of framing and presenting their motions.

X. The chair may vote or not vote on any issues. It is vital when the chair’s vote breaks a tie or creates a tie and prevents a motion from carrying.
Providing members of the boards of pharmacy, along with administrative staff, inspectors, and attorneys with certain immunity protections is essential to the efficient and undeterred operations of any such administrative agency. In short, regulatory board personnel acting within the scope of authority and in good faith will likely be provided with protections from liability based upon challenges from disgruntled licensees.

Of course, in addressing complex legal issues as applied to equally complex fact patterns, mistakes may be made in the administrative process providing a basis for challenging the decision of the regulatory board. Substantiating on appeal a legal basis for reversing and/or remanding an administrative ruling does not consequently provide a basis for subjecting the administrative board and/or its members to liability in the form of damages. Importantly, the agency personnel must act within the scope of authority and in good faith. Consider the following.

The Washington State Board of Pharmacy conducts periodic inspections of pharmacy permit holders to determine compliance with applicable laws regulating the practice of pharmacy. Board inspectors assign numeric grades to each facility resulting in recognition as “class A” (score of 90 to 100), “conditional” (score of 80 to 90), or unsatisfactory (score below 80). A pharmacy receiving an unsatisfactory grade is subject to disciplinary action if its score does not increase to 90 or better within 14 days of the unsatisfactory finding. Thus, such pharmacies are subject to re-inspections on short notice. Further, the Board is authorized to summarily suspend a pharmacy’s permit for an unsatisfactory classification if the pharmacy’s conditions “represent a clear and present danger to the public health, safety, and welfare.” A summary suspension results in immediate loss of the permit (or pharmacist’s license) without a hearing. Shortly after such a summary suspension, the licensee and/or permit holder will be afforded a hearing on the merits.

An individual (licensee) was licensed as a pharmacist in 1980. In 1995, the licensee purchased a pharmacy (facility) and acted as its sole pharmacist. In December 1998 while undertaking routine inspections, the facility was the subject of an unsatisfactory score of 79. In February 1999, the facility had improved its conditions and received a class A score of 94. Despite these improved conditions, the Board’s two inspectors (collectively referred to as inspectors) re-inspected the facility in July 1999 and provided an unsatisfactory score of 48. In August 1999, the inspectors graded the facility unsatisfactory with a score of 56.

The licensee alleged that the inspectors subjected him to non-stop harassment, including yelling and pounding on the counters while the licensee was attempting to select, count, and prepare medications. Based upon the record established in the ensuing litigation, the licensee and Board had had numerous interactions related to citations for dispensing in non-child-resistant containers and without a written request, failing to obtain chronic conditions of patients from pharmacy, incorrect National Drug Code numbers, improper recordkeeping, and others.
Many of the encounters involved the inspectors and some of the interactions resulted in lost points during the facility inspections.

Based upon the unsatisfactory inspection reports, the executive director of the Board filed an *ex parte* motion for summary suspension of the facility permit and license, effectively closing the pharmacy. A summary suspension occurs without a hearing and is granted under circumstances whereby the public are placed at serious risk of significant harm. Under circumstances where a summary suspension is granted, the license holder will be provided with a hearing within a time period specified in law.

The potential or imminent risk to the public provides a basis for the immediate suspension of the license. On August 17, 1999, and without a hearing, the facility permit and pharmacist license were summarily suspended by the Board. The licensee was notified of the suspensions and the docketing of a September 10, 1999 hearing date.

Specifically, the notice provided to the licensee stated that if a written motion to challenge the summary suspension were filed, he would waive his right to the September 10, 1999 hearing.

On August 30, 1999, the licensee waived his right to the expedited hearing by filing a motion to modify and stay the ruling of the Board. This motion was denied and a hearing was eventually set for December 7, 1999. The summary suspension caused the licensee and his business to incur substantial financial losses. Based upon his inability to fund a defense, the licensee entered into a consent agreement whereby the license and facility permit were suspended for a five-year period. In addition, the consent agreement “acknowledge[d] that the evidence is sufficient to justify the . . . findings” and he waived his right to a full hearing and was accepted and entered by the Board in February 2000. The consent agreement did not address a right to sue.

In 2002, the licensee filed suit against the state of Washington, the Washington State Department of Health, the Board, the two inspectors, and the executive director. The lower court granted summary judgment in favor of the defendants on multiple issues, but allowed certain counts against the inspectors in their individual capacities to stand. In addition, counts related to negligent supervision and interference with a business were also allowed to proceed. The Board appealed the lower court ruling and the appellate court dismissed under summary judgment all counts against the defendants based upon immunity, the fact that no due process violations occurred, and failure to exhaust administrative remedies. Note, summary judgment basically means that the litigation can be decided under matter of law in that there are no material issues of fact under dispute. Thus one issue on appeal would be whether there exists a genuine issue of material fact. The licensee appealed the matter to the Washington Supreme Court.

Initially, the Supreme Court noted that the licensee did not appeal the finding of absolute immunity related to the actions of the executive director and affirmed the dismissal of him from the litigation. Next, the court turned to the issue of whether the inspectors were entitled to qualified immunity. The court identified two questions to consider. First, whether the licensee’s allegations establish a connection between the actions of the inspectors on multiple issues, but allowed certain counts against the inspectors in their individual capacities to stand. In addition, counts related to negligent supervision and interference with a business were also allowed to proceed. The Board appealed the lower court ruling and the appellate court dismissed under summary judgment all counts against the defendants based upon immunity, the fact that no due process violations occurred, and failure to exhaust administrative remedies. Note, summary judgment basically means that the litigation can be decided under matter of law in that there are no material issues of fact under dispute. Thus one issue on appeal would be whether there exists a genuine issue of material fact. The licensee appealed the matter to the Washington Supreme Court.

Before addressing the specific two questions above, the court analyzed (continued on page 74)
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the due process rights to which the licensee may be entitled. In its review, the court held that, in spite of the fact that the inspectors were not the ultimate decision-makers regarding the fate of licensees, such inspectors can cause the violation of due process rights through their actions. That is, the actions of those involved in the investigative process can, under certain circumstances, form the basis for liability. Indeed, the federal statute under which the litigation was pursued states that persons who, under color of any statute subjects or causes to be subjected, any citizen to be deprived of certain rights may be subject to liability. Thus, if the inspectors wrongfully fabricated evidence of an emergency causing the summary suspension of the licenses, such may subject the defendants to liability.

Turning its attention to the issue of whether there exists a genuine issue of material fact, the court held in favor of the licensee/permit holder. The court noted that a reasonable juror could infer that the inspectors arbitrarily lowered the inspection scores of the licensee under the facts known to the court. The opinion reviewed the numerous facts regarding the 1998 and 1999 inspections of the pharmacy and, “in a very close case,” found that a genuine issue of material fact existed as to whether the inspectors wrongfully fabricated an emergency and knew or should have known such fabrication would cause the immediate suspension of the license or permit without a hearing.

Likewise, the court found the existence of issues of material fact when assessing the constitutional claims of the licensee. It noted that the Board did not present irrefutable evidence that the violations discovered by the inspectors during the 1998 and 1999 inspections would have typically resulted in inspections scores of 48 and 56. Based upon the allegations of the complaint, the court held that a reasonable juror may credit the licensee's version of the events, rather than that of the inspectors.

Next, the court addressed the issue of qualified immunity and whether the defendants should be afforded protections thereunder. It stated that government officials performing discretionary functions are immune “if their conduct is objectively reasonable when measured against clearly established law.” The court held that the inspectors should have known under these circumstances that their actions (perhaps fabricating circumstances which would result in an emergency suspension without a hearing) could reasonably result in a violation of constitutional rights. Accordingly, the court held that the inspectors were not entitled to qualified immunity.

Finally, the court held that the licensee did indeed exhaust his administrative remedies, a prerequisite to pursuing the litigation. It stated that the Board arrived at a final determination defined as a definitive act of the agency, which is binding until and unless set aside by a court. The court noted that the waiver by the licensee of a right to a prompt hearing did not change the fact that the Board reached a final determination as it agreed to the entry of the consent agreement.

Accordingly, the Washington Supreme Court reversed the appellate court and found that there exist genuine issues of material fact, which preclude summary judgment.

Pharmacy board members, staff, and other agency personnel must be aware of their duties and responsibilities and operate under the delineated authority of the board and in good faith at all times. Immunity principles will generally protect regulatory persons who follow this mantra.

There are many additional facts surrounding the above case, which cannot be described in this Newsletter article. However, to the extent discretionary acts are undertaken, agency personnel, such as inspectors, need to be fully trained and aware of the application of these acts.

Ouster Based on Omnibus Omissions

By Dale J. Atkinson, JD

It is essential that regulatory boards gather and consider all relevant information from applicants seeking licensure in their respective jurisdictions. Of course, boards must ensure that information requested from applicants is indeed relevant and that application questions are phrased to conform with legal requirements and restrictions. Boards of pharmacy are encouraged to review and, if necessary, modify their applications for licensure and renewal. Based upon the language of the practice act, rules/regulations, and other applicable laws, decisions can be made as to what information is relevant and necessary to make informed licensure eligibility determinations. If the licensure applications do not request relevant information, the boards of pharmacy will be unable to make informed eligibility decisions. Conversely, if the law does not allow for certain information to be gathered, licensure applications must be modified to eliminate any such inquiries.

Assuming the law allows for such inquiries, boards of pharmacy must assess what information is necessary to determine if an applicant possesses the requisite moral character to qualify for licensure. Also, such moral character questions must take into consideration laws related to use of criminal convictions, disclosure of disabilities, confidentiality, and others. Boards are encouraged to seek legal guidance when reviewing applications for licensure and renewal, as both misrepresentations and omissions of information are relevant in licensure decisions. One major component to licensure eligibility determinations in any profession is the educational prerequisites, some of which may include pre-and/or postgraduation residencies or practical experience. Consider the following.

An individual (Respondent) who graduated in 2000 from Ross University School of Medicine (located on the island nation of Dominica) returned to the United States to participate in his residency program. He originally undertook a residency program at Grand Rapids Medical Education and Research Center in Michigan. He was not awarded credit for this residency due to deficient performance in several areas, including failure of an in-service examination and conduct related to self-prescribing medications. In 2001, he participated in a residency at Thomas Jefferson University in Pennsylvania, but was asked to leave after the university learned of his failed first-year residency, a prerequisite to admission. In 2002, the Respondent participated in a residency at the University of Wisconsin – Marathon County in Wausau. On his application for this residency, he omitted his prior two residencies and withdrew prior to commencement.

In 2003, the Respondent secured a residency at Deaconess Hospital in Indiana and failed to identify his previous three residencies on his application. Here again, the Respondent failed his in-service examination, was suspended for writing prescriptions for his wife, and was excluded
from Medicare for failure to pay his student loans. As a result, he was terminated from the Deaconess residency before completion. In 2004, the Respondent participated in and completed a residency at Jackson Park Hospital in Illinois. As part of this residency, he filed an application for a temporary license with the Illinois Department of Financial and Professional Regulation (Department). On his licensure application, the Respondent failed to identify his prior failed residencies, yet certified under penalty of perjury that his application was true and correct. In addition, the Respondent fabricated an employment history to account for his time during the failed residencies.

In August 2007, the Respondent applied for a permanent medical license in Illinois, wherein he again omitted all but his Jackson Park residencies and also fabricated his employment history to address time frames during his failed residencies. The Respondent was granted a permanent medical license in Illinois. Sometime during this time frame, the Respondent applied for licensure as a physician in Ohio. In October 2008, the State Medical Board of Ohio notified the Respondent that it proposed to deny his application for licensure, noting that he made 22 false statements between 2001 and 2008 to conceal his poor track record in residencies. While the Respondent did not affirmatively notify his current Illinois employer of the pending Ohio licensure denial, such information was discovered and he was terminated from his employment. In September 2009, the Ohio Board permanently denied his application for licensure.

In February 2010, the Illinois Department filed an administrative complaint against the Respondent alleging multiple violations of the Illinois Medical Practice Act. After a hearing, the administrative law judge recommended that the Respondent’s license be revoked. After a rehearing where relief was denied, the Department revoked the Respondent’s license. The Respondent appealed the matter to the circuit court, which determined the penalty was too severe and remanded the case back to the Department. On remand, the Department suspended his license indefinitely for a minimum of three years and reserved the right to revocation pending the outcome of any appeal. Again, the circuit court reversed the matter and remanded it back to the Department, finding the penalty too severe.

On remand, the Department indefinitely suspended his license for a minimum of 19 months, again reserving the right to appeal the revocation reversal. Once more, the circuit court reversed the sanction as overly severe and remanded it back to the Department. Finally, the Department indefinitely suspended his license for a minimum of nine months and the circuit court upheld this decision. The Department appealed all three circuit court decisions.

The appellate court outlined the standard of review and noted that its analysis was of the administrative tribunal, not the decision of the circuit court. It also noted that the courts defer to the factual findings and interpretations of the Board. Even if the administrative findings are determined to be correct, the sanctions imposed by the agency can still be reversed if they are found to constitute an abuse of discretion.

The court noted that the facts were not in dispute and that the Respondent did, in fact, misrepresent his residencies and employment history, and omitted additional relevant facts in procuring his Illinois license. It also emphasized that the Ohio Board permanently denied the Respondent’s application for his medical license in Ohio. The Respondent argued that the sanction was too severe, as his actions did not endanger patient safety or welfare and, thus, the sanctions were arbitrary.

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In support of his argument, the Respondent cited a previous case involving an applicant for a license as a foreign-trained barber with an unblemished record who misrepresented his credentials. The court distinguished the public protection perspectives of barbers from physicians. Further, in the current case, theRespondent exhibited a “sustained pattern of fraudulent conduct . . . designed to conceal subpar performance and question-
able conduct in connection with three residencies he was unable to successfully complete.”

The court referenced a more relevant case involving an attorney who omitted significant information on his application for admission to the bar. These omissions justified the subsequent revocation of his license. Similarly, the Respondent also omitted significant relevant information in securing his license. While his checkered record may not have resulted in a bar to licensure, his actions prevented a “meaningful assessment” of his qualifications and fitness to practice medicine. Although the Respondent may be competent to practice, his actions exhibited a longstanding pattern of deceit that calls into question his fitness to hold a license. Any sanction short of revocation would allow the Respondent “to benefit from his deliberate deception by retaining a license that he was never entitled to in the first place.” Accordingly, the court reversed the circuit court and reinstated the original revocation of licensure by the Department.

This case illustrates the importance of access to and exchange of information at not only the board level, but also at the education and postgraduate level to ensure accurate information is available when assessing one’s eligibility for access to educational programs and ultimately licensure.


He Shoots, He Rescores
By Dale J. Atkinson, JD

The process for developing, administering, scoring, and maintaining a valid, defensible, uniform examination program designed to assess an applicant’s knowledge as one criterion of eligibility for licensure is complex and fraught with the potential for litigation. Examination owners, like NABP, go to great lengths to ensure that the licensure examinations are legally defensible through validity and reliability processes in the developmental stages of the program. In addition, exam administration and scoring processes (which sometimes involve third-party exam vendors) must support the defensibility of the program. Further adding to the layer of legal complexities, is the reliance by regulatory boards on the expertise of associations of regulatory boards and/or examination entities for such examination services and essential minimum competence determinations.

Disgruntled individuals may elect to contest the application, licensure, and/or examination processes at numerous steps along the continuum. Of course boards of pharmacy enjoy various levels of immunity to ensure boards and board members are not deterred from the important public protection mission encompassing the enforcement of the practice acts and regulations. Consider the following where an examinee challenged the exam entities, but not the regulatory board.

The United States Medical Licensing Examination (USMLE) is a three-part exam that all state medical boards require allopathic physicians to pass as a prerequisite to licensure by the respective state board. The USMLE consists of Step 1, Step 2, and Step 3. The National Board of Medical Examiners (NBME) administers Steps 1 and 2, scores all three steps, and is responsible for reporting exam scores and performing score rechecks. The Federation of State Medical Boards (FSMB) administers Step 3 and receives requests for score rechecks of Step 3 scores. Upon receipt of requests for score rechecks, the FSMB forwards such requests to the NBME for regrading.

Beginning in 1994, a medical student/applicant for licensure (examinee) took the Step 1 examination on six occasions, passing on his sixth attempt. Just prior to his sixth attempt, the examinee filed a lawsuit alleging the NBME failed to provide him with reasonable testing accommodations under the Americans with Disabilities Act (ADA). While the litigation was pending, the examinee passed Step 1 and failed Step 2 on two occasions.

In June 1998, the examinee and NBME entered into a settlement agreement whereby certain testing accommodations were agreed to be granted and the examinee released the NBME from all claims of discrimination. As part of the settlement, the NBME agreed to not retaliate against the examinee in any manner with the testing and scoring of future exams taken by the examinee. The agreement also advised the examinee that the NBME did not determine requests for accommodations for Step 3 of the USMLE. The FSMB was not a party to the June 1998 settlement agreement.
Between July 2003 and November 2006, the examinee took Step 3 of the USMLE on five occasions. Step 3 is delivered in two parts: a multiple choice section and a computer-based case simulation (CCS). Scoring of the Step 3 exam is achieved through a computerized scoring program by NBME whereby the multiple choice and CCS portions are bundled. The USMLE Bulletin of Information sets forth the contractual parameters for applying for, taking, and scoring the examinations.

In August 2004, the examinee timely requested a rescore for his July 2004 examination. NBME undertook the rescore and informed the examinee that his results were confirmed. The examinee’s requests for rescores of his previous Step 3 attempts were rejected by NBME as not timely filed. The examinee commenced litigation in United States District Court against the NBME and the FSMB alleging that the defendants breached the terms of the settlement agreement by not objectively regarding the exams. The examinee also alleged that the NBME “lied” about scoring the exams in the same manner as all other examinees (as required by the settlement agreement), and that the scoring procedures were not objective and fair. Finally, the examinee alleged violations of the ADA and the Minnesota Human Rights Act (MHRA). After numerous procedural gyrations, the examinee sought to amend his complaint and the NBME and FSMB objected and cross motioned for summary judgment. Summary judgment is a procedure whereby the court determines the litigation as a matter of law and without the need for a trial on the merits because there are no issues of material fact in dispute.

The district court first discussed the standard of review before turning its attention to the merits of the legal arguments. Regarding the legal arguments, the court first disposed of any claims related to NBME that occurred prior to the June 1998 settlement agreement. Based upon the settlement and release, all such claims were dismissed.

The court next addressed the settlement agreement and found that the agreement did not entitle the examinee to any extraordinary scoring re-checks, but merely required the NBME to rescore using the same procedures used for any other examinee’s rescores. Thus, the court found that any alleged failure to recheck the scores by hand (as examinee requested) did not constitute a breach of the settlement agreement. The court also found that the FSMB was not a party to the settlement agreement and therefore any allegation of a breach of the settlement agreement by FSMB must also be dismissed.

Next, the court turned its attention to the allegations of a breach of contract. It found that in New York a contract is formed between the testing organization and the test taker when the test taker agrees to be bound by the terms of the testing organization’s registration bulletin. As noted by the court, the testing organization must perform “a good faith compliance with the [bulletin’s] stated procedures.” The court rejected the arguments of the examinee that the NBME and FSMB breached their contractual obligations by grading his examination in an unfair and discriminatory manner and by failing to rescore his exam in accordance with internal policies. In short, the court held that the examinee provided nothing more than unsubstantiated, conclusory allegations that could not withstand NBME’s motion for summary judgment.

Regarding FSMB, the court held that not only was FSMB not responsible for the score recheck (as that was the responsibility of the NBME), but many of the rechecks in dispute were not requested in a timely manner and as required under the bulletin. Because the examinee did not fulfill...
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his condition precedent of requesting a score recheck in a timely manner, the breach of contract claim against FSMB must be dismissed.

Finally, the court addressed the ADA and MHRA allegations. Due to the time periods and the fact that a three-year statute of limitations exists for claims under the ADA and a one-year statute of limitations exists under the MHRA, the court dismissed claims under the ADA that accrued prior to August 2000 and under the MHRA that accrued prior to August 2002.

To the extent claims may have survived the statute of limitations, the court addressed the ADA and the factors that must exist to state a claim. They include that the examinee must demonstrate that:

- he is a qualified individual with a disability;
- the defendants are subject to the act; and
- he was denied the opportunity to participate in or receive the benefits from the defendant’s services/programs or was otherwise discriminated against by the defendants by reason of his disability.

The court held that the examinee failed to present evidence that he was disabled, relying instead on alleged stipulations in the settlement agreement. In fact, the settlement agreement stipulated that the NBME would not challenge the attention deficit disorder diagnosis with respect to future examinations and requests for accommodations. The court noted that such a stipulation is not a concession that the examinee is disabled. Because the ADA and MHRA rely upon similar criteria, and because the examinee failed to proffer evidence establishing his disability, the court dismissed the ADA and MHRA claims, resulting in a complete dismissal of the litigation.

Boards of pharmacy are encouraged to understand the examination process, including the development, administration, scoring, and reexamination procedures used by NABP. In the event of litigation, there exists a possibility that the relevant board may also be a party to the dispute. This is especially important in a process whereby the examination and licensure process and decision are made in a more contemporary basis than in human medicine where the exams are taken over a longer period of time during the education of the candidate.

Grant v National Board of Medical Examiners, 2009 WL 1457698 (US District Ct. NY 2009).

The issue of delegation of authority and the extent to which statutes and rules or regulations should designate by name a private sector examination (like the NABP North American Pharmacist Licensure Examination®) or a passing standard as a mandatory prerequisite to licensure always presents interesting legal issues. Equally important is the necessity of the regulatory board to follow the mandates of the enabling legislation to ensure legal sustainability for actions taken. Consider the following.

The California Medical Practice Act created and empowered the Medical Board of California (board) to protect the public through enforcement of standards relevant to the licensure of physicians. The practice act calls for the board to, among other criteria, administer licensing exams as a prerequisite to licensure. Specifically, the statute requires applicants to “obtain a passing score established by the [board]…” Further, the law calls for the board to “establish a passing standard by resolution.” Such legislation had been in place for multiple decades.

One of the exams relied upon in the licensure process is the United States Medical Licensing Examination (USMLE) developed by the National Board of Medical Examiners and the Federation of State Medical Boards (FSMB). The USMLE is a three-part examination used by medical boards to assess minimum competence of applicants. Part III of the USMLE has been used by the board since 1994. In short, the board approved an oral resolution in November 1994 that it would accept the USMLE Part III for licensure purposes in the state of California. However, the board did not name or establish a passing score for any of the USMLE parts in that oral resolution or any resolution since that date. Instead, the board has accepted the recommended passing score established by the FSMB as the standard to be applied to California applicants.

Historically, the board undertook various actions to accept and recognize the USMLE as part of its licensure process, including entering into a contract for use of the exam. The 1999 contract for use of Part III delegated from the board to the FSMB all aspects of the exam. The board retained only the right to refer applicants to the FSMB, inform the FSMB of any eligibility requirements that may exist in addition to the FSMB requirements, and to make final decisions concerning requests for test accommodations. This legal relationship was reconfirmed in a letter of understanding signed in 2003.

In addition to the California statute that empowered the board to recognize an examination or examinations for purposes of the licensure process, the statute provides that applicants must pass Part III of the USMLE on no more than four attempts in order to be eligible for licensure. Thus, applicants who fail to successfully complete Part III on four attempts are ineligible for licensure in California.

A graduate of Stanford University and the University of Rochester School of Medicine and Dentistry (referred to as applicant) was undertaking her residency in neurosurgery at the Los Angeles County Hospital and University of Southern California Medical Center. As a residency participant, she was not licensed to practice medicine. In March 2008, the applicant registered to take
Part III of the USMLE. At that time, the passing score recommended by the FSMB and utilized by the board was 184. USMLE materials note that the passing level is reviewed periodically and may be adjusted at any time and that such changes will be posted on the USMLE Web site.

In April 2008, a notice appeared on the Web site stating that the minimum passing score for Part III had been raised from 184 to 187 and that the new passing score would apply to examinations administered after May 1, 2008. On May 13, 2008, the applicant took Part III of the USMLE and received a score of 184, below the passing standard set by the FSMB. Because this was the fourth attempt, the board notified her that she was not eligible for licensure. Subsequent requests for a waiver of the exam limits were denied by the board.

The applicant filed a petition for a writ of mandate seeking an order that she had passed the exam and for the board to issue her a license. The trial court denied her requests finding that the board implicitly adopted the USMLE passing scores when it recognized the use of the USMLE and that such action satisfied the statutory requirements related to the necessity of a resolution establishing the passing score. The court also recognized the historical recognition of the passing scores dating back to the early 1990s as evidence of compliance with the statutory mandate. The applicant appealed the matter to the appellate court.

On appeal, the applicant argued that the board did not comply with the statute by formally adopting a resolution establishing the passing score. She also argued that the lower court erred by finding that the board implicitly adopted the passing score, by not finding that the board improperly delegated its authority to the FSMB to establish the passing score, and that her due process rights had been violated.

The appellate court reviewed the history of the interactions between the board and the FSMB, including an analysis of the contractual relationship. It further noted that, according to the board’s executive director, it “has nothing to do with the administration of the USMLE.” According to her testimony, “…the board receives the scores for its applicants and accepts the scores as determinative of whether an applicant has passed the USMLE. To [her] knowledge, the board has never questioned nor had reason to question the passing score for the USMLE.” Finally, the court noted that the board “believes it no longer has the authority to set the passing score,” despite the statutory mandate.

Simply stated, the appellate court phrased the issue as, can the statutory mandate that the board establish the passing score by resolution be satisfied impliedly by the board’s consistent acquiescence in the USMLE recommended score and its transferring of administrative control over the examination to the FSMB? The appellate court held that it cannot.

The court focused on the unambiguous language of the statute that requires the board to establish the passing score by resolution. A resolution is a “formal expression of opinion, will, or intent voted by an official body or assembled group.” While it does not require the same formality of the enactment of a statute or promulgation of a rule, a resolution is adopted by a recorded vote of the governing body in accordance with statutory open meetings and agendas laws.

The appellate court held that the lower court erred by recognizing that the board could implicitly fulfill its requirement to adopt a resolution through acquiescence of past actions and that such recognition abrogated the statute. Further, although recognizing the USMLE through contracts and letters of understanding, the
board never addressed the passing score through any of its formal actions. The board simply approved the USMLE without adopting the examination’s passing score via resolution. The appellate court held that there is nothing in the statutory scheme that authorizes the board to adopt the passing score by means other than through formal resolution. Because such formal action was not taken, the board failed to meet its statutory obligations.

Turning its attention to the relief sought, the court held that the applicant is entitled to an order mandating that the board comply with the statute and adopt a passing standard by means of a formal resolution. However, the court also held that it cannot order the board to declare her 184 score received on the fourth attempt to have met a passing standard as there existed no valid resolution by which the score could be declared a passing score. The court held that without an established passing score, the fourth administration was a “futile act” and that it would be unjust to treat the exam administration in question as a legitimate and, in the applicant’s case, last attempt to become licensed to practice medicine in California. Thus, the court concluded that the applicant should be offered another opportunity to take Part III after the board has adopted a passing score through a formal resolution. The court did not address any issues related to previous applicants and/or licensees.

This case presents an important example of reading, understanding, and following the statutory mandates imposed upon boards of pharmacy related to undertaking the essential public protection responsibilities of enforcing the practice act in the interest of public protection. While it may be easy to defer to NABP as the expert in minimum competence exams, board involvement in understanding the development, administration, scoring, passing standard, and maintenance of a legally defensible examination program (even where the statute may not require it) is good practice.

Marquez v. Medical Board of California, 182 Cal. App. 4th 548 (App. Ct. CA 2010)
Burden May Be Burdensome
By Dale J. Atkinson, JD

When undertaking an administrative disciplinary action, the burden of proof necessary to substantiate a finding of guilt is essential to sustaining such board action. Boards of pharmacy are encouraged to understand what burden of proof is necessary to support administrative disciplinary action. In many jurisdictions, a preponderance of the evidence standard is the burden of proof necessary to sustain an administrative prosecution. A preponderance of the evidence is defined as “more likely than not” and is the same burden of proof used to assess civil cases.

Some jurisdictions require a clear and convincing evidentiary standard in administrative actions. Clear and convincing evidence calls for a “more highly probable to be true than not” standard to be met to sustain a decision. A clear and convincing standard requires a greater degree of believability than the preponderance standard.

Finally, a beyond a reasonable doubt standard is used in criminal matters. Beyond a reasonable doubt is described as that no other logical explanation can be derived from the facts except that the defendant committed the crime, thereby overcoming the presumption that a person is innocent until proven guilty. Beyond a reasonable doubt is the most difficult standard to meet from the prosecution perspective, based upon the fact that a person’s liberties are at stake. That is, criminally convicted defendants can be incarcerated and lose certain civil rights.

Further complicating legal issues involving burden of proof questions is the impact of using a civil or criminal conviction as a basis for subsequent administrative action. For instance, if a licensee is convicted in a civil matter by a preponderance standard, can such civil conviction form the basis for subsequent administrative action by the regulatory board? To enhance judicial efficiencies, the legal doctrines of res judicata and/or collateral estoppel may apply. Res judicata and collateral estoppel prevent the re-litigation of matters between the same parties based upon the same material facts under circumstances where all applicable due process and other rights were afforded to the parties. In short, the previous judicial determinations are conclusive of the issues (collateral estoppel) or entire litigation (res judicata) and eliminate the need to re-litigate the facts. When differing burdens of proof apply, the application of these principles becomes complicated. Consider the following.

An employee (licensee) of a real estate brokerage firm represented both buyers and sellers in a residential transaction. The deal fell through and the sellers refused to return the buyers’ deposit. The buyers sued the licensee, the brokerage firm, and the sellers in a civil action. The jury by a preponderance of the evidence found in favor of the buyers against the licensee holding that they breached their fiduciary responsibilities and made misrepresentations. However, the jury also held that the buyers did not prove by a clear and convincing standard that the additional defendant (the sellers) did indeed commit fraud and deceit.

The misrepresentation and breach of fiduciary counts in the civil action formed the basis for an administrative complaint against the licensee before the California Real Estate Commissioner (Commissioner). The applicable California law authorizes discipline based upon a civil
judgment against a real estate licensee for misrepresentation, fraud, or deceit in connection with a transaction for which a license is required. After a hearing, the administrative law judge recommended that no discipline be imposed. The Commissioner rejected this recommendation and imposed administrative discipline. The licensee appealed and the trial court denied his request. He thereafter appealed to the appellate court.

On appeal, the licensee argued that the Commissioner cannot discipline a licensee premised upon a civil judgment that used a preponderance of the evidence standard rather than a clear and convincing standard. Under the California Constitution, administrative discipline against a professional license must be based upon a clear and convincing standard. The Commissioner acknowledged the clear and convincing standard in administrative actions, but argued that the only fact that must be proven by a clear and convincing standard is the existence of a civil judgment based upon fraud, misrepresentation, or deceit with reference to a transaction for which a license is required. No reference to the facts related to the entry of the judgment is necessary.

Thus, the court narrowed the issue to whether the use of a civil conviction determined under a preponderance of evidence standard in a subsequent administrative action violates the principle, under the California Constitution, that the suspension or revocation of a professional license must be based upon misconduct proven by clear and convincing evidence. The court noted the unusual circumstances in the present case in that the licensee in the civil matter was found by a preponderance of the evidence to have acted negligently and to have made false representations. In that same civil matter, the jury held that clear and convincing evidence did not establish that the licensee acted with malice, oppression, or fraud for purposes of imposing punitive damages.

In agreeing with the licensee, the court noted that the doctrine of collateral estoppel was inapplicable to the current case. This conclusion was based upon the fact that the proceedings operate under different burdens of proof (preponderance in the civil case and clear and convincing in the administrative case). In ruling in favor of the licensee, the court rejected the argument of the board that the civil judgment is the operative fact upon which the licensee is subject to discipline, not the acts or omissions of the licensee that led to that judgment.

The court also noted that rather than applying collateral estoppel principles to the case, the actual argument is “whether the legislature can constitutionally authorize the imposition of professional discipline based only on clear and convincing evidence that a judgment has been entered against the professional for license-related misconduct, without requiring that the judgment itself have been based on clear and convincing evidence.” Citing cases dealing with attorneys, the court held that the law is settled and that the doctrine of collateral estoppel principles to the case, the actual argument is “whether the legislature can constitutionally authorize the imposition of professional discipline based only on clear and convincing evidence that a judgment has been entered against the professional for license-related misconduct, without requiring that the judgment itself have been based on clear and convincing evidence.” Citing cases dealing with attorneys, the court held that the law is settled and findings made by a preponderance of the evidence standard in civil cases cannot be given binding effect in a subsequent administrative proceeding because clear and convincing evidence is required.

Accordingly, the court reversed the imposition of administrative sanction against the licensee and directed that the Commissioner’s order be set aside. The court also awarded costs in favor of the licensee.
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While an efficient means of administrative prosecutions, the use of previous civil judgments against licensees is dependant upon consistent burdens of proof. In many jurisdictions, the preponderance standard applies to both civil and administrative matters and will provide a basis for the application of the doctrine of *collateral estoppel* and eliminate the need to re-litigate matters. In jurisdictions where a clear and convincing standard applies in administrative prosecutions, reliance upon a previous civil judgment alone will not suffice and the facts may have to be established using this heightened scrutiny.


The Vinci Code
By Dale J. Atkinson, JD

The procedural and evidentiary rules followed by the judiciary in civil and criminal proceedings provide formality to a process that involves trained and experienced judges and lawyers advocating on behalf of their respective clients. Of course, criminal proceedings, where the right to freedom may be at stake, necessitate the application of all substantive and procedural rights of the accused, including constitutional principles of due process as the “state” executes persons for the protection of society as a whole.

Administrative proceedings, whereby the board of pharmacy prosecutes persons accused of violating the practice act and/or rules or regulations, involve, by design, certain “lay” persons who provide expertise in their particular field of practice. Under these administrative proceedings, which still involve lawyers for each respective party, the strict rules of evidence and procedures are relaxed to provide flexibility to the process and allow volunteer appointees to assist in the adjudication of licensure matters. Consider the following.

An owner/pharmacist and employee/pharmacist (collectively referred to as licensees) were eventually issued a Notice of Opportunity for Hearing by the Ohio State Board of Pharmacy. In a voluminous complaint, the notice alleged the licensees did knowingly sell, conspire to sell, and/or aid and abet the sale of controlled substances when the conduct was not in accordance with applicable Ohio law; specifically, such licensees sold controlled substances to patients “when not for a legitimate medical purpose issued by a prescriber acting in the usual course of professional practice and in compliance with the administrative code rules addressing pain management…”

The charges against the licensees were subsequent to an Ohio State Board of Pharmacy investigation which originally targeted a particular pain management clinic. The clinic closed its doors in December 2003 after the execution of a search warrant and was not the subject of the administrative action against the licensees. However, during the scrutiny of the clinic, investigators discovered that customers of the clinic were having their scripts filled by the licensees’ pharmacy, which was located approximately three to five miles from the clinic. Initial visits to the pharmacy and interviews of the licensees were undertaken by investigators examining the activities of the clinic. During such times, the pharmacy and licensees were not the focus of the investigation.

Investigators reviewed the records of the pharmacy and discovered that in less than four months, the pharmacy had dispensed in excess of 500,000 doses of hydrocodone 10 and carisoprodol 350 milligrams and that 78% of licensees’ pharmacy scripts came from the clinic under investigation. Evidence also revealed that multiple other pharmacies during this time period contacted the Board of Pharmacy questioning the prescribing activities of the clinic based upon red flags noted by the pharmacists. These red flags included customers who came from long distances, paid cash, asked for certain pills by color, and arrived in groups, sometimes in the same car.

In spite of these red flags, including Drug Enforcement Administration evidence that such pharmacy was the second largest...
retail purchaser of hydrocodone 10 tablets in the state of Ohio, the licensees filled these prescriptions in significant volumes. The licensees also received and filled scripts that were faxed to the pharmacy and included multiple scripts on the same fax sheet. Indeed, the licensees actually cut the sheets of faxed prescriptions to separate the multiple orders. Based upon these discoveries, the investigators turned their attention to the licensees resulting in the referenced charges issued in July 2005.

An administrative hearing was held in January 2007 before the Board of Pharmacy with the president of the Board presiding. Significant evidence and testimony was presented during the hearing resulting in an order by the Board suspending the licensees of each respondent for five and three years respectively. The suspensions were based in part on the fact that under the Ohio Administrative Code and the Code of Federal Regulations, pharmacists “have a responsibility with the prescriber to ensure that a prescription is issued for a legitimate medical purpose by a licensed prescriber in the usual course of medical practice.” In short, pharmacists must review every prescription for legitimacy and must make a professional judgment on whether or not to fill the prescription. This accountability to the Board and the public served is based upon professional training, experience, licensure, and continuing pharmacy education in applicable laws. The Board found that the licensees shirked such responsibilities under these circumstances.

The licensees appealed the matter to the trial court, which reversed the ruling of the Board. The trial court held that the Board findings were not supported by reliable, probative, and substantial evidence, that the licensees’ due process rights were infringed during the investigative stages, and that evidentiary rulings of the Board president during the hearing, specifically the admission of hearsay evidence, were prejudicial to the licensees, merit- ing reversal. The Board of Pharmacy appealed the trial court reversal to the appellate court.

The Board first argued that the trial court erred in holding that the Board findings were not supported by reliable, probative, and substantial evidence. The appellate court defined each respective term and reviewed that the appellate court review of a trial court determination is limited determining whether the trial court abused its discretion. Abuse of discretion is more than an error of law or judgment, but rather implies that the trial court’s ruling was arbitrary or unconscionable. An abuse of discretion shows “perversity of will, passion, prejudice, or partiality or moral delinquency.”

The Board argued that none of the prescriptions in question were validly issued, but the licensees argued that there was no direct evidence of such invalidity. The court referred to the lack of specific Ohio cases addressing the scope of a pharmacist’s responsibilities to properly dispense medications. However, it cited other recent federal cases and federal regulations that require pharmacists to “use common sense judgment,” which includes “paying attention to the number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment, the number of doctors writing the prescriptions and whether the drugs prescribed have a high rate of abuse.” The court also noted that hydrocodone and carisoprodol have high abuse potential and a high illegal street market value.

The court noted that at issue was whether the licensees knew or should have known that the prescriptions were not issued for a legitimate medical purpose or in the usual course of medical practice. Based upon the facts and in spite of the lack of direct admissible evidence,
the court held that there was sufficient circumstantial evidence supporting the allegations of the sale of controlled substances when not for a legitimate medical purpose. It therefore found that the decision of the trial court on this issue was arbitrary, unconscionable, and unreasonable in view of the evidence.

Addressing the due process argument, the trial court held that the licensees were denied due process when they were not advised of a right to counsel during the investigative stage of the case as required under Ohio law. Noting that a certain level of formality must exist to apply the statutory right to counsel, the appellate court noted that an informal interview does not trigger such a right. In the current matter, the Board investigator visited and collected information as part of his investigation of the clinic and the licensees were not compelled to answer questions, nor were they not free to leave the interviews that were conducted at the pharmacy. In addition, the court held that the due process rights to notice and an opportunity to be heard were met. Thus, the court sustained the Board’s second assignment of error.

Next the court addressed the argument of the Board that the trial court failed to recognize the scope and duties of the Board president. In its ruling, the trial court emphasized that the Board president was not a lawyer and had “no formal legal or judicial training” and that in the course of the proceedings “allowed non-admissible hearsay evidence to be presented and failed to ensure that [the licensees’] due process rights were protected.” The appellate court reviewed the make-up of the Board and the fact that the statutory scheme does not require the Board president to be a lawyer or have some type of legal training. The appellate court rejected these findings of the trial court and sustained the arguments of the Board.

Finally, the court addressed the Board argument that the trial court failed to use the applicable standards of administrative proceedings regarding the use of hearsay evidence. It held that many of the alleged hearsay admissions were not objected to by the licensees during the proceedings and that these arguments may be waived absent plain error. Further, the court held that administrative proceedings follow a relaxed evidentiary standard and that hearsay statements are permitted where they are not inherently unreliable and may constitute reliable, probative, and substantial evidence. The court noted that there was no evidence that the admitted hearsay statements were inherently unreliable. In addition, the court held that even if the Board erred in admitting certain hearsay evidence, there was overwhelming evidence supporting that the licensees engaged in unprofessional conduct.

Based upon its findings, the appellate court reversed the trial court and upheld the findings and sanctions of the Board of Pharmacy.

This opinion presents an excellent example of how administrative proceedings operate under relaxed standards. Board members who preside over such hearings may not necessarily be versed in or required to abide by stringent legal procedural principles. Of course, all parties are entitled to legal representation and possess the right to appeal matters to the judiciary for review.

_Vinci v Ohio State Board of Pharmacy_, 2010 WL 529468 (App. Ct. OH 2010)
Retest Reasonable Reality for Recommended Reinstatement of Revoked Registration

By Dale J. Atkinson, JD

Under certain circumstances, boards of pharmacy may be placed in the position of reinstating the practice privileges of a fallen licentiate. Boards of pharmacy discipline licensees for a variety of reasons and are advised to draft the final order to include the conditions of reinstatement, if any. If allowed, the board must ultimately determine whether such sanctioned person will be subject to reinstatement of such license and under what conditions. Only a limited number of jurisdictions have the authority to permanently revoke a license; that is, deny such person from ever again practicing pharmacy in that state.

Boards of pharmacy (or a governmental entity empowered to determine the appropriate sanction) must be very careful in fashioning a sanction and should discuss and consider the differences between a licensure revocation and suspension. Differentiation may prove to be a critical factor. A logical starting point is to define and understand the consequences of a licensure revocation and suspension. Keep in mind that the consuming public will most certainly not understand these nuances and likely believes that revocation means that such sanctioned practitioner is removed from the practice permanently.

According to *Black’s Law Dictionary*, Eighth Edition, revocation means “an annulment, cancellation or reversal of an act or power.” Suspension means “the act of temporarily delaying, interrupting, or terminating something.” Administrative jurisprudence also distinguishes between revocation and suspension, holding that when a license is revoked it is extinguished and the former possessor is returned to the same position occupied had the license never been issued. Regarding suspension, previous case law finds suspension as an act by which a party is deprived of the exercise of a right for a period of time, a temporary stop of a right, or a partial extinguishment for a time.

With these distinguishing factors in mind, consider the following. This article will not only include an analysis of the majority opinion, but also an overview of the dissenting opinion.

In 1984, the Commonwealth of Pennsylvania through its Bureau of Professional and Occupational Affairs, State Board of Pharmacy (Board) issued a license to a pharmacist (Licensee). In 1990, the Licensee purchased a pharmacy and thereafter acted as the pharmacy manager. In 1999, the Licensee pled guilty to a felony violation of the Controlled Substance, Drug, Device and Cosmetic Act (Act) for delivering a controlled substance in his capacity as a pharmacist without a legitimate prescription or order of a licensed physician or practitioner. As a result of his conviction and as provided for under Pennsylvania law, the Board automatically suspended the Licensee’s license to practice pharmacy. The Licensee thereafter sold his pharmacy to his sister and continued to work for the store as the general manager for non-pharmacy matters.

During his suspension, the Licensee met all of his continuing education requirements as well as monitored changes in pharmacy practice. After the expiration of a 10-year
period (as provided in law), the Licensee petitioned for reinstatement in August 2009. In response to requests from the Board, the Licensee provided a verification of compliance and a criminal record check indicating no criminal records after the 1999 conviction. After a hearing whereby the Licensee presented unrefuted documentary evidence of his fitness to return to practice, the Board issued an adjudication and order reinstating his license on the basis that he had proven his rehabilitation and fitness to practice, but under the condition that he retake and pass the licensure examinations, namely the NABP North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The Board also held that his license would remain on probation for a three-year period after reinstatement. The Licensee appealed the imposition of the conditions on his reinstatement.

On appeal, the Licensee argued that because the Board acknowledged that he had proven his fitness to resume active practice, the Board exceeded its statutory authority by requiring the successful completion of the NAPLEX and MPJE. In its response, the court noted that in addition to requiring the Board to automatically suspend the license based upon the felony conviction, the Pharmacy Practice Act also empowered the Board to impose additional sanctions upon the Licensee, including revocation of his license. Based upon the statutory language, the authority vested in the Board through the practice act, and the public protection nature of the regulatory activity, the court held that the reinstatement conditions were not clearly erroneous nor did they constitute a manifest or flagrant abuse of its discretion.

Further, the court cited the practice act and the Board authority to exercise discretion to determine whether and when to reinstate a previously sanctioned license. Indeed, the practice act calls for the expiration of at least a 10-year period after the date of the felony conviction before a reinstatement petition will be considered. Under the statute, the Board “may” reinstate a license if certain conditions are met, including the personal rehabilitation since the conviction, taking into consideration the health and safety of the patients and public. Finally, the court noted the authority of the Board to restore or reissue a suspended license and impose “any disciplinary or corrective measure which it might have originally imposed.”

Addressing the imposition of the exam requirements, the court noted the practice act and that reinstatement can be conditioned upon not only rehabilitation, but meeting the act’s licensing requirements. Because the practice act calls for successful completion of the required examinations as a prerequisite to licensure, the court determined that conditioning a reinstatement petition on passing such exam(s) is within the discretion of the Board.

The Licensee also argued that his constitutional rights were violated by the placement of his reinstated license on probation for a three-year period with a right to immediate suspension without a hearing in the event of a violation of his probation. He argued that this authority was not clearly articulated and his right to understand what is expected of him was violated due to vagueness in the law. In rejecting this argument, the court held that the authority and discretion of the Board to impose a wide variety of sanctions was contained in the statute and had already been articulated by the court. Thus, there was no need to repeat such legal justification. In short, the due process rights (continued on page 92)
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of notice and opportunity to be heard were met, thus satisfying the constitutional criteria. Accordingly, the majority court held in favor of the Board and affirmed the conditions of reinstatement, including the successful completion of the NAPLEX and MPJE.

Interestingly, a written dissent was filed in this case that disagreed with the majority. The dissenting judge argued that pursuant to the statutory language, the Board only had the authority to impose re-examination conditions on the reinstatement of a revoked license and did not have the authority to require such conditions on the reinstatement of a suspended license. In short, the judge distinguished between a suspension and revocation of a license, citing the language of the practice act. In relevant part, the Pennsylvania Pharmacy Practice Act states:

“A]ny person whose license, certificate or registration has been revoked may apply for reinstatement, after a period of at least five years, but must meet all of the licensing qualifications of this act for the license applied for, to include the examination requirement, if he or she desires to practice at any time after such revocation.” (Emphasis added.)

Conversely, and as an example of the legislative intent to empower a regulatory board to impose re-examination conditions, both the Pennsylvania Medical Practice Act and Certified Public Accountants Act specifically reference that persons with a revoked or suspended license may, as a condition of reinstatement, be required to successfully complete the licensing examinations. According to the dissenting judge, in order for a regulatory board to act, it must have the legislative authority to do so and such authority is lacking in the Pharmacy Practice Act. While not binding, dissenting opinions can be instructive.

Boards of pharmacy are encouraged to understand the distinguishing factors between licensure suspension and revocation and to clearly articulate in final orders not only the sanctions, but the rights to reinstatement, if any. Complicating the current case was the automatic suspension of the pharmacist’s license based upon the criminal conviction. Perhaps such automatic suspensions should also clearly articulate the discretionary nature and parameters of a reinstatement petition and provide notice to the licensee of the board authority to impose conditions upon any future petition for reinstatement. Marchese v. Commonwealth of Pennsylvania, Department of State, State Board of Pharmacy, 2011 PA Comm. Unpub. LEXIS 801 (Comm. Ct. PA 2011) 0

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Evidence of Ebriety
By Dale J. Atkinson, JD

The issue of determining whether a licensee (or applicant) maintains the physical and mental capabilities to safely and effectively practice the profession can be a challenging undertaking by a regulatory board. Arguably, only an evaluation conducted by a professional versed in the relevant field can provide credible insight into one’s physical or mental well-being. More specifically, determining whether licensees suffer from impairments related to alcohol and drug abuse is equally daunting.

Boards of pharmacy must first ascertain whether they have the statutory authority to require a licensee or applicant to undergo a physical and/or mental evaluation. Further complicating matters is the ownership of the records related to the evaluation and issues regarding privacy and confidentiality. In Iowa, the relevant administrative rules define impairment as “the inability of a pharmacy professional to practice pharmacy with... reasonable safety and skill as a result of alcohol or drug abuse, dependency, or addiction, or any neuropsychological or physical disorder or disability.” Consider the following.

A pharmacist (Licensee) had been licensed since 2010. Based upon records obtained by the Iowa Board of Pharmacy (Board), the Licensee worked for a chain drug store and lived in a hotel within walking distance of the pharmacy. His weekly paychecks were sent to his mother who apparently managed his money and provided him with an allowance. In October 2011, the Licensee was charged with operating a vehicle while intoxicated. In January 2012, the Licensee pled guilty to the charges and was sentenced to either 48 hours in jail or completion of a treatment program for addiction. Later that month, an employment supervisor contacted the Board to inquire if the Licensee had self-reported the operating while intoxicated conviction. The Licensee had not self-reported the operating while intoxicated conviction. The Licensee had not self-reported and, when eventually questioned by the Board, stated that he thought he was not required to report until he applied for renewal of his license.

In February 2012, the Board initiated an investigation of the Licensee. The supervisor reported to investigators that the Licensee “had exhibited problems with short-term memory loss, personal hygiene, and wearing of unclean clothes to work.” The supervisor also provided a written report whereby he “noticed [ketone] smell on [Licensee’s] breath on many occasions, indicating heavy drinking the night before,” and that there had been “second hand reports of public intoxication on [two] occasions.” In June 2012, the Board issued a confidential order for evaluation and required the Licensee to schedule this examination within 10 days. The evaluation was to address the Licensee’s physical and mental condition and his ability to safely practice pharmacy. Under Iowa code, licensees are under a duty to submit to a physical, mental, or clinical competency examination upon probable cause and as directed by the Board.

In July 2012, the Licensee objected to the confidential order arguing that the Board did not have probable cause to mandate the evaluation. A hearing was held in March 2013, during which the Licensee submitted an evaluation completed by an assessment counselor. The evaluation, based upon an interview with the Licensee, indicated that there...
was a low probability of a substance abuse disorder. The Board issued an order in April 2013 rejecting the objections and finding that probable cause existed to require the physical and mental evaluation. It found that credible evidence related to showing up to work with signs of heavy drinking the night before, memory loss, personal hygiene, and soiled clothing at work substantiated the directive to obtain an evaluation. The Board did not accept the counselor evaluation, noting the counselor had not been approved by the Board, the Board had no prior notice of the evaluation, and such evaluation was limited in scope to substance abuse.

In May 2013, the Licensee filed a petition for judicial review. After a December 2013 hearing, the District Court affirmed the Board order and rejected the objections of the Licensee. Thereafter, this appeal followed.

The Court of Appeals addressed the standard of review noting that the Licensee argued that the Board order is not supported by substantial evidence. Substantial evidence is defined by statute as:

The quantity and quality of evidence that would be deemed sufficient by a neutral, detached, and reasonable person, to establish the fact at issue when the consequences resulting from the establishment of that fact are understood to be serious and of great importance.

As with any profession, however, the interests of the public in ensuring the competence of licensees is paramount and the board authority must be recognized.

The Licensee maintains that substantial evidence does not support the decision in large part based upon the Board rejection of the “expert evaluation.” He argued that the Board relied upon hearsay or secondhand evidence continued in the reports (signs of heavy drinking, reports of public intoxication) rather than the evaluator analysis. As noted by the court, the credibility of witnesses falls within the purview of the Board. The court does not reassess the evidence or make its own determinations as to the weight given to differing evidence. Related to the counselor’s report, the court noted the limited scope of the evaluation based upon the limited facts provided. The rejection of the report was not based upon the qualifications (or lack thereof) of the counselor. The Board is not required to accept expert testimony “when the factual basis for those opinions is incomplete or inaccurate.”

The court noted that probable cause in an administrative proceeding is the same as that of a criminal proceeding. In short, the Board must have a “reasonable ground for belief” that the Licensee had an impairment. Based upon the record, the court could sustain the reasonableness of the determinations of the Board. Based upon the foregoing, the court affirmed the lower court and upheld the Board’s determination of probable cause and order requiring the Licensee to undergo a comprehensive mental and physical evaluation.

There is a fine line between the rights of the board to enforce the state’s practice act and relevant laws and the rights of licensees seeking to protect the property interest in the board-issued credential. Mental health and physical evaluations implicate significant confidentiality issues. As with any profession, however, the interests of the public in ensuring the competence of licensees is paramount and the board authority must be recognized.

Doe v. Iowa Board of Pharmacy, 2014 Iowa App. LEXIS 1145 (App. Ct. IA 2014)
Preemption: The Maine Reason Canadian Importations Put on Ice

The legal issues surrounding the introduction of foreign prescription drugs into the United States market are complex and subject to the application of at least the federal and state laws. Further, these issues challenge the concept of federalism whereby state and federal governments share in the regulation of the industry and, under certain circumstances, federal law preempts state law. While states generally have the right to regulate the professions and, potentially, the flow of commerce, such states’ rights are not unfettered and are subject to federal control in the interest of the collective rights of the states. Consider the following.

In 2013, the Maine Legislature passed legislation entitled “An Act to Facilitate the Personal Importation of Prescription Drugs From International Mail Order Prescription Pharmacies,” also known as the Maine Pharmacy Act Amendments (MPA Amendments). The legislation was neither signed nor vetoed by the governor, thus it became effective 10 days after submission by the legislature. The MPA Amendments modified the Maine Pharmacy Practice Act and created an exception to the general requirement that those who engage in the practice of pharmacy be licensed by the Maine Board of Pharmacy (Board). In short, the MPA Amendments exempt from the Maine licensure requirements licensed retail pharmacies located in Canada, Great Britain, Northern Ireland, the Commonwealth of Australia, and New Zealand. Such exempted pharmacies must be duly licensed in their country and, as a result of the MPA Amendments, may “export prescription drugs by mail or carrier to a resident of [Maine] for that resident’s personal use.” Further, the MPA Amendments exempt from licensure an entity that “contracts to provide or facilitate the exportation of prescription drugs from a licensed retail pharmacy” from the countries listed above.

The MPA Amendments also include a “Consumer Choice Preserved” provision that allows residents of Maine to order from licensed retail pharmacies located outside the US (described above) and receive by mail or carrier prescription drugs for personal use. Finally, the MPA Amendments also affirmatively allow licensed retail pharmacies described above to dispense, provide, or facilitate prescription drugs for personal use from outside the US by mail or carrier to a resident of Maine. The justification for the MPA Amendments was based in part on Canadian drugs being “less expensive than those from the United States.” In fact, the purpose of the MPA Amendments was to “expand the definition of a ‘mail order prescription pharmacy’ under the Maine Pharmacy Act to include an entity located outside of the United States that dispenses prescription medications by mail or carrier from a facility not located in [Maine] to a pharmacy or to a patient who resides in [Maine].”

Two Maine licensed pharmacists and three trade associations (Plaintiffs) filed suit under the Supremacy Clause of the US Constitution against the Maine Attorney General and the Commissioner of the Maine Department of Administrative and Financial Services in their official capacities (Defendants). The Plaintiffs argued that the Federal Food, Drug, and Cosmetic Act (FD&C Act) preempts certain amendments to the Maine Pharmacy Practice Act.
After some procedural wrangling, the parties filed competing cross motions for summary judgment, whereby the court is asked to rule on the legal issues without the need for a trial as there are no material issues of fact in dispute. Because the Plaintiffs argued that the MPA Amendments are invalid on their face, the court addressed the constitutionality of the law without any information about the effects of the amendments and/or how such were being enforced. A facial challenge is the most difficult to sustain as the Plaintiff must establish that no set of circumstances exists under which the Act would be valid.

The Plaintiffs argued that the FD&C Act creates a "closed" regulatory scheme that strictly limits the introduction of prescription drugs into interstate commerce. The FD&C Act prohibits the importation or introduction into interstate commerce of any new drug that has not received Food and Drug Administration (FDA) approval and also restricts the reimportation of drugs manufactured in the US but sent abroad to the original manufacturer. Further, in 2003, Congress enacted the Medicaid Prescription Drug, Improvement, and Modernization Act (MMA) which contemplates permitting pharmacists and wholesalers through the promulgation of regulations to import prescription drugs from Canada into the US. Upon certification by the Secretary of Health and Human Services that importation will be safe and cost effective, such regulations will be promulgated; however, no such certification nor regulations have occurred. The Plaintiffs argue that this Congressional contemplation through the MMA further supports the fact that state law regarding the importation of prescription drugs is preempted by federal law through the Supremacy Clause.

The Defendants argued that the MPA Amendments are within the sovereign authority of the state as they merely reduce the reach of the practice act and allow the state to choose not to regulate certain conduct. The Defendants assert the states' rights under the 10th Amendment of the US Constitution and argue that Maine cannot be compelled to administer federal regulatory programs.

In addressing preemption, the court noted that there are multiple ways federal law may preempt state law. First, Congress can expressly state that it is preempting state law. If not expressly stated, the judiciary may infer preemption through either "field" or "conflict" preemption. Field preemption occurs when the intent to displace state law can be inferred "from a framework that is so pervasive . . . that Congress left no room for the States to supplement it or where there is a federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."

Although not rigidly applied, conflict preemption can be categorized as impossibility or obstacle preemption. Impossibility preemption occurs where compliance with both state and federal law is a physical impossibility. Obstacle preemption occurs where the challenged state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Turning its attention to the arguments of the parties, the court first noted that there are competing issues around the various presumptions that can be made. First, there is a presumption that a statute is valid. On the other hand, and as argued by the Plaintiffs, there is a presumption of preemption as the MPA Amendments infringe on an area traditionally reserved to the states. In this case, the Defendants countered that the relevant field is limited to the regulation and licensure of pharmacists and pharmacies, a subject matter traditionally left to the states.

While recognizing the local sphere of public health and safety and the states rights to regulate the licensure of pharmacies and pharmacists, the court noted that the (continued on page 97)
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MPA Amendments extend beyond the regulation and licensure of such pharmacies or pharmacists. “The MPA Amendments do not, as the State asserts, simply repeal state licensure regulations; the MPA amendments select five countries whose licensed retail pharmacies ‘may export’ prescription drugs to Maine residents.” In fact, the MPA Amendments attempt to enable the importation of cheaper foreign pharmaceuticals. Further referencing the FD&C Act, the court noted the federal regulatory scheme and the prohibition of importation or introduction into interstate commerce of any new drug not approved by FDA. Additionally, Congress specifically legislated the issue of Canadian importation through the enactment of the MMA, buttressing the intent of the federal regulation of products in interstate commerce.

Regarding the 10th Amendment, the court cited the fact that although the states cannot be compelled to enact or administer a federal regulatory program, the Amendment does not save a law that “obstructs” federal law. “Federal law may preempt state law even where the federal government may not compel a state government to enact or administer a federal legislative or regulatory scheme.”

The Defendants cited cases regarding marijuana legislation; however, the court held that such cases are not on point as the federal government included a savings clause in the Controlled Substances Act that expressly provided that Congress did not intend to occupy the field. Thus, the previous jurisprudence involving marijuana laws that allow for the enactment of state statutes was not subject to a field preemption analysis.

This case addresses the very important issue of preemption as related to states’ rights and the importation of prescription drugs on a state-by-state basis. Pursuant to this judicial ruling, states are preempted from legislating in this arena. It is likely that additional state statutes will be enacted and challenged. Stay tuned.


Flotsam and Jetsam

Boards of pharmacy regulate pharmacists and technicians who work in conjunction with other licensed professionals in providing care to patients. The interactions among these licensees form the basis for each professional to contribute expertise into the health care decision-making process. In most cases, such licensees are “related” in that the patient relies on the medical team to determine the appropriate care. In addition, these professionals may have overlapping scopes of practice that enhance the care provided and add a measure of legal and regulatory checks and balances. At times, the ultimate decision maker and responsible party may be difficult to decipher. Consider the following.

The Delaware Department of Corrections (DOC) has multiple facilities that house persons convicted of crimes and sentenced to incarceration. The DOC has two vendors relevant to this matter. Connections Community Support Programs, Inc (Connections), provides medical care for inmates. Correct Rx Pharmacy Services, Inc (Correct Rx) provides pharmacy operations for the DOC. According to the judicial opinion, the Correct Rx location relevant to this case is not a pharmacy, but is a “medicine room” where medications are administered to patients.

Connections employs nurses and nursing supervisors at the James T. Vaughn Correctional Center (JTVCC). Connections also employs a chief medical officer (referred to as Respondent Physician). Correct Rx maintains a pharmacy warehouse in Maryland and delivers medications to the various DOC locations.

Relevant to this matter are a Correct Rx pharmacist (referred to as Correct Rx Pharmacist) located at the JTVCC, and her supervisor, a pharmacist located at the corporate office in Maryland (referred to as Pharmacist Supervisor).

One inmate (referred to as Patient) was housed at the JTVCC. He was diagnosed with hepatitis C and prescribed Sovaldi®, an expensive pill. Each Sovaldi pill costs $1,000, and is sold only in lots of 28. The infectious disease physician prescribed the administration of one tablet per day for 84 days. While not a narcotic, the pills’ count and distribution are tightly controlled based upon their expense.

On March 17, 2015, a Connections nurse spilled 12 Sovaldi tablets onto the floor. As trained, the nurse “wasted” the pills by placing them in the “sharps” container, a box intended for biohazard materials. In an attempt to maintain the course of treatment, the nurse contacted the Correct Rx Pharmacist to request a refill. The Correct Rx Pharmacist contacted the Pharmacist Supervisor regarding the request and what transpired thereafter was the subject of debate. According to the court, the Pharmacist Supervisor asked the Respondent Physician to retrieve the pills from the sharps container. Next, the Respondent Physician directed the nurse supervisor to retrieve the pills. The nurse supervisor and the director of nursing located the sharps container and emptied its contents. Among the “flotsam and jetsam” emptied from the container were diabetic syringes with safety caps engaged, and an equal number of diabetic test strips and lancets. Additional unidentifiable materials were also mixed into the contents.

The nurse and her supervisor inspected the pills with the Correct Rx
The pharmacist was aware that addition to the Respondent Physician, by the hearing officer were that in the practice of medicine. She was charged with unprofessional conduct, including incompetence in deceiving, defrauding, or harming the public. This rule was not part of the charges or unethical, or other conduct likely to bring discredit upon the profession. According to the court, this decision making and authority (or responsibility) to overrule one another. Respondents are entitled to fair notice and an opportunity to be heard, “not a post hoc, post hearing, duty to overrule a pharmacist that was never presented or argued, or an ‘oh by the way’ regulatory violation apparently conceived by the Board after the hearing, after the briefing, after the arguments, while the Board deliberated privately.”

Based upon these conclusions, the court reversed and remanded the matter for consideration by the Board as deemed appropriate. The court also stated that “[w]e have no opinion whether the reusing of pills from a sharps container brings discredit on the profession or should be lauded as a wise use of taxpayer money. Arguments can be made on both sides, none of them were fleshed out below precisely because [Respondent Physician] was not notified that the conclusion was possible.”

While this case addresses fundamental notice and opportunity to be heard and due process issues, the facts and emphasis on the roles of the nurses, pharmacists, and physicians create fascinating questions concerning decision making and authority (or responsibility) to overrule one another.

Spraga v. Delaware Board of Medical Licensure and Discipline, 2017 Del Super LEXIS 384 (Superior Ct DE 2017).

increased scrutiny over their licensing boards and called into question the need to license various professions. In April of this year, the United States Department of Labor indicated its desire for further action on this front by announcing $7.5 million in grant funds to encourage states to engage in occupational licensing reform and reduce excessive licensing. (For a more complete discussion of the trends affecting occupational licensing, see “Patient Safety Concerns Crucial in Licensing Reform Discussions,” in the March 2018 issue of Innovations.) Meanwhile, both in response to and as part of the “portability” trend, states and health care professions alike are looking to make licensing more flexible in relation to state boundaries, in part through the use of multistate compacts that allow health care professionals to practice across state boundaries without obtaining separate licenses for each state. These professions are hoping that carefully designed compacts will facilitate newer methods of providing health care, business models, and workforce mobility, while still protecting the public health and ensuring accountability.

**Enhanced Nurse Licensure Compact**

Originally begun in 2000, the Nurse Licensure Compact (NLC), which was developed by the state boards of nursing, took an early lead among health care professions in creating a multistate license and eventually included 25 participating states. In 2014, the boards of nursing began working to update and enhance the program, ultimately establishing a list of 11 uniform license requirements that applicants for the multistate license must meet, including submitting to state and federal criminal background checks. The new Enhanced Nurse Licensure Compact (eNLC) became effective in mid-2017 and was implemented in early 2018; by mid-2018, roughly 30 states had enacted or were enacting legislation to join the compact.

**Other Health Care Professions Explore Interstate Compact Solutions**

Two partially competing – yet also overlapping – national trends are in the process of altering the landscape of professional licensing. One trend seeks to rein in or eliminate a large amount of licensing and limit the role of licensees in regulating their respective professions; the other focuses more on accommodating the free movement of licensed professionals (including health care providers) and facilitating increasingly common wide-reaching, interstate business models. As part of the “reform” trend, a number of states, including Arizona, Nebraska, and Oklahoma, have greatly increased scrutiny over their licensing boards and called into question the need to license various professions. In April of this year, the United States Department of Labor indicated its desire for further action on this front by announcing $7.5 million in grant funds to encourage states to engage in occupational licensing reform and reduce excessive licensing. (For a more complete discussion of the trends affecting occupational licensing, see “Patient Safety Concerns Crucial in Licensing Reform Discussions,” in the March 2018 issue of Innovations.) Meanwhile, both in response to and as part of the “portability” trend, states and health care professions alike are looking to make licensing more flexible in relation to state boundaries, in part through the use of multistate compacts that allow health care professionals to practice across state boundaries without obtaining separate licenses for each state. These professions are hoping that carefully designed compacts will facilitate newer methods of providing health care, business models, and workforce mobility, while still protecting the public health and ensuring accountability.

“**These professions are hoping that carefully designed compacts will facilitate newer methods of providing health care, business models, and workforce mobility, while protecting the public health and ensuring accountability.**”
The eNLC allows qualifying registered nurses and licensed practical nurses or vocational nurses to have a multistate license that allows them to practice in person or via telehealth in their home state as well as in other eNLC states. The National Council of State Boards of Nursing (NCSBN) has compared the NLC to a driver’s license compact. Like a driver’s license, the NLC license is issued in the primary state of residence. If the nurse moves to a different state, he or she must apply for that state’s nursing license. The nurse must obey the laws of the state in which he or she is practicing. If a law is violated, the state in which the law is violated may remove the nurse’s practice privileges. And if a nurse violates one state’s law and the state takes action against the nurse, the home state is notified (and can usually take action against the licensee). License fees vary by state, and a qualifying nurse in a compact state may automatically be issued an eNLC license that functions as his or her primary license in his or her home state.

**Interstate Medical Licensure Compact**

Physicians began practicing medicine in multiple states in 2017, when the threshold number of states (in this case, seven or more) had adopted the Interstate Medical Licensure Compact (IMLC). The IMLC was written in 2013 and 2014 by a group of state medical board executives, administrators, and attorneys and was facilitated by the Federation of State Medical Boards. Described by its governing commission as a “voluntary expedited pathway to licensure for qualified physicians who wish to practice in multiple states,” the IMLC aims to increase health care access for patients residing in rural or underserved areas, and allow these underserved patients to access medical experts through telemedicine. The IMLC does not differentiate between physicians by specialty. By mid-2018, 24 states and one territory (and the 31 medical and osteopathic boards in those jurisdictions) were participating in the IMLC.

Physicians apply for the IMLC license through the IMLC Commission, which verifies the physician’s qualifications with the applicant’s State of Principal License (SPL); the applicant must also submit to a criminal background check and pay a $700 fee to the Commission. Unlike the eNLC, the IMLC requires physicians to individually select the compact states in which they wish to practice, and individual fees are also paid to each state from which they receive a license. Disciplinary action may be taken against a licensee in any state in which the physician is practicing, and the other compact states may impose the same or lesser sanctions. If the SPL revokes a physician’s license or requires the licensee to surrender or relinquish the license, all IMLC licenses held by the physician are automatically placed in the same status; if a compact state takes a similar action, the license is automatically placed on the same status for 90 days, so other licensing

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**NABP, Member Boards Enhancing e-LTP to Support Evolving Practice**

NABP and its member licensing boards of pharmacy are enhancing their long-established Electronic Licensure Transfer Program® (e-LTP™), which provides license mobility and portability for pharmacists in all United States jurisdictions. The e-LTP process, which currently allows for same-day processing of licensure transfer requests, will be supplemented with new components to support evolving pharmacy practices while maintaining a high level of public protection and patient access to quality pharmacy care.

“We are truly excited to work with our member boards as we continue to find innovative ways to enhance our existing reciprocity system and support the future of pharmacy practice,” says NABP President Susan Ksiazek, RPh, DPh.

Included in the e-LTP process is licensure verification through the NABP Clearinghouse, an essential component of ensuring that pharmacists seeking the authority to practice in multiple states hold a license in good standing.

“The Clearinghouse contains vital disciplinary information that, when combined with NABP’s national database of education, competence, and licensure information, provides the boards of pharmacy with a robust tool as they make licensure transfer decisions,” states Ksiazek. “When protecting patients is foremost in your mind, all of this information is key to determining if a licensure candidate meets the qualifications to practice in your state.”

While the current licensure transfer system offers 100% mobility for pharmacists across all 54 US jurisdictions, accounting for the transfer of more than 164,500 pharmacists’ licenses over the last 10 years, the proposed enhancements to the e-LTP will focus on the rapidly changing practice and regulatory challenges posed by remote practice models and telepharmacy. The member boards of pharmacy and NABP recognize the importance of seeking additional methods of licensure mobility in the e-LTP process to enhance patient access to pharmacists whose licenses have been verified and validated.
compact states and the SPL may conduct their own investigations.

**Psychology Interjurisdictional Compact**

Licensed psychologists may soon be able to practice across state lines on a temporary face-to-face and/or remote (telehealth) basis, via the Psychology Interjurisdictional Compact (PSYPACT). Originally approved in early 2015 by the Association of State and Provincial Psychology Boards (ASPPB) board of directors, PSYPACT legislation had been enacted in six states by mid-2018; the compact becomes operational after seven states have enacted it.

Under PSYPACT, qualified psychologists will be able to apply for ASPPB certificates that would allow them to practice in other compact states under specific circumstances. The E.Passport certificate allows a psychologist to practice telepsychology across jurisdictional lines, in participating jurisdictions, while the Interjurisdictional Practice Certificate permits a psychologist to provide short-term, face-to-face psychological services across jurisdictional lines. Both certificates require psychologists to already possess a “home state” license based on a doctoral degree, and, as with most other compacts, the licensee is subject to complying with the state’s scope of practice when practicing within that state. The home state maintains authority over the license; in essence, action taken by a receiving state against a psychologist affects the licensee’s eligibility to hold ASPPB mobility certificates, while action taken by the home state affects the psychologist’s license. Information about disciplinary actions taken against the psychologist is shared among the home state, receiving state, and commission.

**Other Compacts**

Other health care professions are looking into multistate licensing compacts as well. In 2014, the Federation of State Boards of Physical Therapy launched the creation of a physical therapy compact, for example; in 2017, the legislatures in 10 states had approved compact language and the Physical Therapy Compact became official, although it was not expected to be operational for licensees until mid-2018. In another example, the NCSBN has, along with establishing the NLC/eNLC, worked on a compact for advanced practice registered nurses (APRNs), the APRN Compact. The APRN Compact was approved in 2015, model legislation and rules were issued, and by 2018, three states had enacted APRN Compact legislation (10 states must enact the legislation to reach the implementation threshold). In contrast to other compacts, the APRN Compact has faced opposition from more than 80 professional medical organizations and state medical associations, which have argued that the compact grants prescriptive authority to APRNs and allows them to practice independently of a collaborative relationship with a physician, regardless of state law, and have called on NCSBN to remove or revise the relevant language.

**And Pharmacy?**

At present, pharmacist licenses are one of the more portable and easily transferred of professional licenses. Pharmacists currently manage multiple state licenses through NABP’s Electronic Licensure Transfer Program® (e-LTP®), which is available for all 50 states. Once an applicant submits his or her information for licensure transfer, NABP verifies the information within about two business days – sometimes as fast as the same day – and forwards this to the relevant board(s) of pharmacy for their use in evaluating and processing the application. Most states require applicants to demonstrate their knowledge of local laws and regulations by passing the Multistate Pharmacy Jurisprudence Examination®. Assuming applicants schedule and take their law exam around the same time they submit their application information, transferring a license to a new state can happen within a couple of weeks. (For a recent discussion of the e-LTP program and its changes over time, see “NABP Licensure Transfer Program Stands Test of Time to Support Member Boards’ Reciprocity, Uniformity Needs,” in the April 2018 issue of Innovations.)

Nonetheless, pressures to increase portability of licenses are not going away. And while e-LTP offers one of the health care industry’s more user-friendly and fast systems of transferring licenses between jurisdictions, there remains the possibility that pharmacy regulators may consider other modes of licensure transfer to provide additional flexibility to the system in order to better enable such areas as disaster relief services, or to accommodate certain telehealth practices, while still protecting patient health and safety. Further, NABP members passed a related resolution titled “Cooperative Interstate Registration System” at the Association’s 114th Annual Meeting, held in May 2018. The resolution tasks NABP with exploring the development of enhancements to the current interstate transfer of licensure model operated through NABP by the states, e-LTP, that allows for the processing of transfer requests within 24 hours. In response to this resolution, the Task Force on Mutual-Recognition Licensure will convene on September 11-12, 2018.

In keeping with the resolution, NABP will be working with the boards of pharmacy to examine the issue and help them keep regulation current and responsive to a changing landscape. Updates on this issue will be provided in future issues of Innovations.

**Glossary**

Following are commonly used acronyms in pharmacy:

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<tr>
<th>Acronym</th>
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<tr>
<td>AMCP</td>
<td>Academy of Managed Care Pharmacy</td>
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<td>Accreditation Council for Pharmacy Education</td>
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<td>American Association of Colleges of Pharmacy</td>
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<td>ASHP</td>
<td>American Society of Health-System Pharmacists</td>
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<tr>
<td>ASPL</td>
<td>American Society for Pharmacy Law</td>
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<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<tr>
<td>CHPA</td>
<td>Consumer Healthcare Products Association</td>
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<td>CPSC</td>
<td>Consumer Product Safety Commission</td>
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<td>DEA</td>
<td>Drug Enforcement Administration</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>HDA</td>
<td>Healthcare Distribution Alliance</td>
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<tr>
<td>JCPP</td>
<td>Joint Commission of Pharmacy Practitioners</td>
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<td>NACDS</td>
<td>National Association of Chain Drug Stores</td>
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<tr>
<td>NAPRA</td>
<td>National Association of Pharmacy Regulatory Authorities (Canada)</td>
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<tr>
<td>NCPA</td>
<td>National Community Pharmacists Association</td>
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<td>NCPDP</td>
<td>National Council for Prescription Drug Programs</td>
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<td>NPC</td>
<td>National Pharmaceutical Council</td>
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<tr>
<td>PCMA</td>
<td>Pharmaceutical Care Management Association</td>
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<tr>
<td>PhRMA</td>
<td>Pharmaceutical Research and Manufacturers of America</td>
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<tr>
<td>HHS</td>
<td>United States Department of Health and Human Services</td>
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<tr>
<td>USP</td>
<td>United States Pharmacopeia/United States Pharmacopeial Convention</td>
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The following abbreviations are, for the most part, used internally by NABP:

- **ACE** Advisory Committee on Examinations
- **DMEPOS** durable medical equipment, prosthetics, orthotics, and supplies
- **e-LTP™** Electronic Licensure Transfer Program®
- **FPGEE®** Foreign Pharmacy Graduate Equivalency Examination®
- **FPGEC®** Foreign Pharmacy Graduate Examination Committee™
- **MPJE®** Multistate Pharmacy Jurisprudence Examination®
- **NABPF®** National Association of Boards of Pharmacy Foundation®
- **NAPLEX®** North American Pharmacist Licensure Examination®
- **PCOA®** Pharmacy Curriculum Outcomes Assessment®
- **Pre-FPGEE®** Pre-Foreign Pharmacy Graduate Equivalency Examination™
- **Pre-NAPLEX®** Pre-North American Pharmacist Licensure Examination™
- **VDIP®** Verified-Accredited Device Integrity Program®
- **VAWD®** Verified-Accredited Wholesale Distributors®
- **VIPPS®** Verified Internet Pharmacy Practice Sites®
- **VPP®** Verified Pharmacy Program®

Brief descriptions of some of the organizations referenced on the previous page and definitions for terms used throughout this manual follow.

**Antitrust laws**
Laws to protect trade and commerce from unlawful restraints and monopolies or unfair business practices.

**Combinations**
An alliance of individuals, corporations, or states united to achieve a social, political, or economic end.

**Conflicts of Interest**
Term used in connection with public officials and fiduciaries and their relationship to matters of private interest or gain to them. Ethical problems connected therewith are covered by statutes in most jurisdictions and by federal statutes on the federal level.
The Controlled Substances Act of 1970 repealed the Harrison Narcotics Tax Act of 1914. The CSA exerts its control over a wide variety of abusable drugs by way of federal registration. Registrants include all persons in the legitimate chain or manufacture, distribution, or dispensing of controlled drugs except the ultimate user. The CSA, the Federal Food, Drug, and Cosmetic Act, and the Hazardous Substances Labeling Act are currently the most important federal laws regarding controlled substances. Every state has enacted its own local version of the CSA.

**Declaratory statement**
A statement for the purpose of clarifying the law, removing doubts, or putting an end to conflicting decisions in regard to what the law is in relation to a particular matter.

**Defamation of character**
A representation that conveys an unjustly unfavorable impression; includes libel (written statements) and slander (verbal statements).

**FD&C Act**
Federal Food, Drug, and Cosmetic Act of 1938 regulates the interstate commerce of foods, drugs, cosmetics, and devices.

**GMP**
Good Manufacturing Practices are regulations of FDA, which establish minimal standards for the manufacturing of pharmaceutical products.

**Gross negligence**
The failure to use such care as a reasonably prudent and careful person would use under similar circumstances.

**Moral turpitude**
Act or behavior that gravely violates moral sentiment or accepted moral standards of a community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.

**Nolo contendere**
Type of plea by which the defendant does not admit or deny the charges. The principal difference between a plea of guilty and a plea of nolo contendere is that the latter may not be used against the defendant in a civil action based upon the same acts. A defendant may plead nolo contendere only with the consent of the court.

**Prima facie case**
A case that has proceeded upon sufficient proof to the stage where it will support finding if evidence to the contrary is disregarded. *Prima facie* may refer to a fact presumed to be true unless disproved by some evidence to the contrary.
**Regulation**
An authoritative rule dealing with details or procedures, issued by a regulatory agency of a government, and having the force of law.

**Rule**
An established regulation that:
1. implements, interprets, or prescribes law or policy; or
2. defines the organization or the procedure and practice requirements of an executive entity of state government.

An emergency rule is one necessitated by some impending need or immediate and present danger limited to some state action necessary to protect the public health, safety, and welfare of the citizens of the state. The agency implementing the emergency rule must be prepared to document the danger as well as both the need and the fairness of the rule.

**Statute**
A law enacted by the legislative branch of a government.

**Sunset law**
A statute that requires administrative bodies to justify periodically their existence to the legislature.

**Sunshine law**
A law that requires open meetings of governmental agencies and departments.

**Tort liability**
A private or civil wrong or injury, other than a breach of contract, for which relief may be obtained in the form of damages or an injunction. Three elements of every tort action are: existence of legal duty from defendant to plaintiff, breach of duty, and damage as proximate result.
## Mission Statement of the National Association of Boards of Pharmacy

**NABP Mission Statement**

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

**Vision Statement**

Innovating and collaborating today for a safer public health tomorrow.

### NABP Member Boards of Pharmacy

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<th>Board of Pharmacy</th>
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* Associate Member