BOARD OF PHARMACY

# MEMBER MANUAL

*www.nabp.pharmacy*

National Association of Boards of Pharmacy®

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# CHAPTER 1
# NABP OVERVIEW

**NABP Mission Statement:**

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

**NABP Vision Statement:**

*In**n**ovating **a**nd colla**b**orating today for a safer **p**ublic health tomorrow.*

NABP is a robust organization with a multitude of programs and services designed to support the many facets of pharmacy regulation and compliance as well as reduce administrative burdens for boards of pharmacy. Supporting the shared mission of protecting public health, NABP hosts its Annual Meeting and Interactive Forums to provide board members, executive officers, and other board staff an opportunity to guide Association policy as well as to network with their colleagues from state boards of pharmacy throughout the country.

## NABP STRUCTURE AND GOVERNANCE

NABP is a 501(c)(3) nonprofit association founded in 1904.

NABP membership is composed of both active members and associate members, which are grouped into eight districts. 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 NABP Constitution and Bylaws and require the use of the NABP Clearinghouse for all candidates for the purpose of transferring licensure both into and out of the state or jurisdiction, as provided by the Bylaws of this Association.

Associate members include 10 Canadian provinces 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 (one for each district). 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 their year-long term as president.

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. Nominations may also occur outside the district process. In these cases, individuals must provide written notice to NABP no less 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.

## 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 NABP Constitution and Bylaws are discussed and voted upon. Attendees may also participate in 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 Executive Officer Forum and NABP Interactive Member Forum are held annually. The NABP Interactive Compliance Officer and Legal Counsel Forum takes place every odd-numbered year.

## *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 Association's eight districts to discuss regional issues of mutual concern, as well as national issues affecting the districts.

Important Association business is initiated at the district meetings, where affiliated members are nominated to be candidates for the open Executive Committee member position in their district. Nominees for Executive Committee member positions are voted upon at the NABP Annual Meeting. District members also discuss and draft resolutions to bring to the Annual Meeting for consideration and voting by the full membership. More information about the district meetings is available in Chapter Two.

## *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. Consider sharing your experience and knowledge by volunteering to serve on an NABP committee or task force. Participation in these activities is a rewarding way to assist NABP and the boards of pharmacy in our mission to protect the public health.

Standing committees, which meet every year, include:

- Committee on Constitution and Bylaws
- Committee on Law Enforcement/Legislation
- Committee on Resolutions
- Advisory Committee on Examinations

*Volunteer to serve on an NABP committee or task force at* nabp.pharmacy/volunteer*. Your input is essential to addressing the many issues facing boards of pharmacy and the practice today.*

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

Examination committees dedicated to ensuring the integrity and validity of the examinations meet each year to write and review test questions.

## NABP E-PROFILE AND DATA EXCHANGE

The NABP e-Profile was launched in 2012 to facilitate electronic tracking of continuing pharmacy education (CPE) for pharmacists and technicians. Since that time, the e-Profile system has expanded to become a comprehensive database of licensure, educational, and disciplinary information for pharmacists, pharmacy technicians, and pharmacy-related businesses. Authorized board of pharmacy staff are able to access this important data through NABP e-Profile Connect, a secure online system, in support of daily licensure and compliance activities. In addition, some information is available to authorized users at the schools and colleges of pharmacy.

The following data and services are available through e-Profile Connect:

- Search individual and business e-Profiles
- Report to and search disciplinary Clearinghouse
- View and acknowledge Clearinghouse alerts
- Review licensure transfer applications
- Enter licenses and review verification requests
- Grant exam eligibility
- View score reports
- Access CPE Monitor data
- Find FPGEC candidate status
- Access VPP, Supply Chain, and Blueprint Inspection reports

Boards of pharmacy are encouraged to require the NABP e-Profile ID on licensure applications for pharmacists, technicians, and pharmacy businesses to increase efficiencies and streamline processes as staff use e-Profile Connect to complete examination and licensing tasks. Further amplifying these benefits and reducing administrative burden is the implementation of real-time data exchange and integration with board licensure software and NABP software.

## LICENSURE TRANSFER

Licensure transfer is a cornerstone of the Association's operations, as uniform reciprocity standards and a process for safe, streamlined licensure transfer were the impetus for the formation of NABP. Through the Electronic Licensure Transfer Program® (e-LTP™), pharmacists wishing to obtain licensure in additional states can transfer their license with ease. The

*At present, via e-LTP, pharmacist licenses are one of the most portable and easily transferred of professional licenses.*

program screens applicants' licenses for disciplinary actions, exam history, and eligibility, 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.

NABP continues to work with its member boards of pharmacy to enhance the e-LTP process to support the future of pharmacy practice.

## NABP CLEARINGHOUSE AND NPDB

The NABP Clearinghouse is a national database of 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. Accessible to boards of pharmacy via e-Profile Connect, the information housed in the Clearinghouse is a vital component used in determining the acceptability of pharmacists who request transfer of licenses into other states or jurisdictions. The Clearinghouse is also used to support all the NABP accreditation programs. Active member boards agree via the NABP Constitution and Bylaws to submit all final adverse actions in a timely manner to NABP.

The National Practitioner Data Bank (NPDB) is a web-based repository operated by the US Department of Health and Human Services containing information on medical malpractice payment and certain adverse actions related to health care professionals. NPDB is a workforce tool that prevents practitioners from moving state to state without disclosure or discovery of previous damaging performance. Federal and state licensing and certification agencies, including boards of pharmacy, must report final adverse actions taken against health care practitioners, providers, or suppliers to NPDB. As NABP collects and provides essentially the same data through the NABP Clearinghouse, the Association can serve as the board's authorized reporting agent. By providing this service, NABP seeks to ease the burden these reporting obligations place on the board's resources – both staff and financials – by allowing the board to enter sanctions just once via e-Profile Connect.

## COMPETENCY ASSESSMENT PROGRAMS

In the late 1960s, NABP member boards recognized the need for a national licensure examination to be developed using uniform standards. At that time, each board developed its own examinations; member boards recognized that a national licensure examination would address

the growing complexities of pharmaceutical sciences and pharmacy practice and help to ensure that all new practitioners entering the field meet competency standards.

## *NAPLEX*

The Association coordinated the development of the North American Pharmacist Licensure Examination® (NAPLEX®), which was first administered in its earliest form in 1972. Now, the NAPLEX is utilized by all 54 member boards to determine if a candidate for licensure in their 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 results transmitted to other state(s), in addition to their primary state, if their request is received according to the program guidelines.

## *MPJE*

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

*The MPJE is utilized by 48 member boards of pharmacy and is customized for each participating state. Learn more about our examinations at* **nabp.pharmacy/members.**

## *FPGEC/FPGEE*

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 who did not earn their primary degree in pharmacy from an Accreditation Council for Pharmacy Education (ACPE)-accredited program 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, and after earning a passing score on Educational Test Service's (ETS') Test of English as a Foreign Language internet-based Test (TOEFL iBT), candidates must pass the FPGEE as the final step 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 schools and colleges of pharmacy.

## *Practice Exams*

NABP offers practice exams for all three examinations. The Pre-NAPLEX®, Pre-MPJE®, and Pre-FPGEE® are affordable study tools that give applicants a realistic experience to help them prepare for test day. The practice exams supplement each examination's competency statements, which NABP encourages all test takers to utilize as they study.

## *Eligibility Services*

NABP confirms eligibility to take the NAPLEX and MPJE for the boards of pharmacy in Colorado, Kentucky, Maine, Michigan, Nebraska, Oregon, Rhode Island, and Utah. Eligibility includes validating transcripts provided directly from the school or college of pharmacy. NABP ensures rules provided by each jurisdiction are followed for the eligibility process.

***NABP's eligibility service alleviates administrative burdens for board staff while ensuring that candidates meet state testing requirements.***

Paperless processing with reduced wait time for candidates.

Candidate backgrounds verified through the NABP Clearinghouse.

Candidates notified of their status by NABP.

### *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 suitable for students in all professional years, and schools may want to administer it throughout all levels to monitor student growth.

## CPE MONITOR

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


### *How It Works*

State boards of pharmacy may access CPE Monitor data through e-Profile Connect to assist them in ensuring that pharmacists and pharmacy technicians have completed state-mandated CPE requirements for relicensure, recertification, or reregistration. The status of individual pharmacists and technicians is available on demand. Boards wishing to obtain a bulk report that provides data on all licensees in their jurisdiction may do so by contacting the NABP Licensure department.

Whether checking individual e-Profiles or reviewing a bulk report, board staff are saved the trouble of manually collecting and documenting paper CPE statements for audits during license renewal.

### *CPE Monitor Plans*

In 2018, NABP began offering a choice of two plans to help pharmacists manage their licensing requirements.

**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 for basic tracking of their CPE activities. Pharmacists and technicians have access to the standard plan.

*Boards of pharmacy may access CPE Monitor data for individual pharmacists and technicians at any time through e-Profile Connect. Learn more about this and other NABP member services at* **www.nabp.pharmacy/members.**

**Plus Plan:** The plus plan is an annual subscription for pharmacists that provides features for advanced monitoring of CPE compliance by state. It eliminates the need to manually cross-check required types of CPE credits, while automatically tracking their progress in every state where they have a license. Additional features include:

- 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

## INSPECTION SERVICES

As member boards of pharmacy worked to enhance their pharmacy inspection processes, they identified NABP as the most efficient facilitator of a solution that would both balance the needs of the boards and make the protection of public health a primary concern. The Association has worked closely with the board members, inspectors and compliance staff, and board executive officers to create tools and services that will enable state boards to build robust inspection programs within their state.

## *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 Inspection Blueprint and focus on general areas of pharmacy and national compounding standards, including US 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 Certification in Sterile Compounding for Inspectors 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>.

## *Verified Pharmacy Program*

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

The Verified Pharmacy Program® (VPP®) provides boards of pharmacy with inspection and license verification services and ensures that they have complete and accurate information to make pharmacy licensure decisions. Pharmacies can apply to VPP or when states lack the resources to conduct timely and robust inspections they can contract with VPP to bridge the gap. Through this program, NABP inspectors perform on-site pharmacy inspections at no cost to the boards of pharmacy. On-site inspections that observe for compliance with USP Chapters <795>, <797>, <825>, and <800> are also performed if needed.

VPP information may be accessed by board staff through the information sharing network in e-Profile Connect. Additional information available in e-Profile Connect 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; and
- information related to individual e-Profiles, including those of the pharmacist-in-charge (PIC) in the state of domicile, as well as any nonresident PICs. Board staff receive alerts when a new document is available in business e-Profiles for pharmacies that are licensed in, seeking licensure in, or shipping medications into their state.

### *Supply Chain Inspection*

The Supply Chain Inspection program is for businesses engaged in prescription drug, prescription medical device, and certain over-the-counter medical device distribution. Participants of the program receive an inspection report that may satisfy an inspection requirement from an entity or agency. Similar to VPP, state regulators, including the boards of pharmacy, can use the Supply Chain Inspection program to obtain inspection and license verification information helping to ensure that they have complete and accurate information to make licensure decisions. The supply chain inspection is not an accreditation. The state determines a facility's compliance based on the findings of the inspection, and completion of the inspection does not imply NABP endorsement or approval. The business models that are eligible to pursue an inspection are listed on the NABP website. A supply chain inspection is a prerequisite for successfully obtaining NABP's Drug Distributor Accreditation and OTC Medical Device Distributor Accreditation.

## 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 programs to provide uniform standards for wholesale distributors and pharmacies.

Applicants for NABP accreditations undergo reviews to determine compliance with accreditation standards, licensure verification, on-site surveys, and screening through the NABP Clearinghouse. 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.

### *Drug Distributor*

Established in 2004, Drug Distributor Accreditation, formerly known as the Verified-Accredited Wholesale Distributors® (VAWD®) program, helps to protect the public from the threat of counterfeit drugs affecting the US drug supply. Drug Distributor Accreditation provides added protection by seeking to ensure 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.

### *OTC Medical Device Distributor*

Launched in 2016, OTC Medical Device Distributor Accreditation, formerly known as the Verified-Accredited Device Integrity Program® (VDIP®), helps prevent diverted or suspect diagnostic over-the-counter (OTC) medical devices from entering the US medical supply chain. It accredits distributors of diagnostic OTC medical devices that may be delivered by a pharmacy pursuant to a prescription.

### *Community Pharmacy*

NABP's Community Pharmacy Accreditation accredits pharmacies for advanced-level patient care programs and services. Community Pharmacy Accreditation standards focus on three performance areas: practice management, patient care services, and quality improvement.

### *Compounding Pharmacy*

NABP's Compounding Pharmacy Accreditation evaluates and accredits compounding pharmacies to ensure the highest level of patient care and reduction of risks associated with compounding practices and medication safety. Compounding Pharmacy Accreditation includes a thorough review of compounding-specific requirements, including evaluating compliance with USP standards <795>, <797>, and nonsterile and sterile compounding. VPP is a prerequisite for this accreditation.

### *DMEPOS Pharmacy*

Launched in 2006, DMEPOS Pharmacy Accreditation is approved by the Centers for Medicare and Medicaid Services (CMS) and provides a cost-effective and reliable choice for pharmacies seeking durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation. Pharmacies accredited through the DMEPOS Pharmacy Accreditation are doing their part to help ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS products.

## *Home Infusion Therapy Pharmacy*

Launched in 2020, Home Infusion Therapy Pharmacy Accreditation is approved by CMS and provides a cost-effective and reliable choice for pharmacies that provide home infusion therapy services for Medicare patients. CMS requires accreditation for home infusion therapy services billed to Medicare. NABP's Home Infusion Therapy Pharmacy Accreditation ensures that pharmacies meet these new CMS requirements for suppliers billing home infusion services and evaluates a pharmacy's compliance to a comprehensive set of practice standards, including practice management, patient care services, product safety, procurement and inventory management, quality improvements, sterile compounding practices (where applicable), and professional services.

## *Specialty Pharmacy*

NABP's Specialty Pharmacy Accreditation is intended for pharmacies providing an advanced level of pharmacy services and disease management for patients taking medications that require special handling, storage, and distribution requirements. NABP's Specialty Pharmacy Accreditation meets the highest standards, and our tools are infused with NABP's strengths and expertise, including supply chain integrity, clinical care, pharmacy licensure, and compliance. NABP's Specialty Pharmacy Accreditation is designed to meet payer criteria and requirements for provider network participation.

## *Digital Pharmacy*

Digital Pharmacy Accreditation, formerly known as the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, was the first accreditation developed by the Association for the purpose of providing patients with a resource for safe online pharmacy sites. Launched in 1999, NABP's Digital Pharmacy Accreditation is even more relevant today, with customers increasingly looking to the internet for their health care needs, and tens of thousands of illegal online drug sellers distributing products that endanger patient health.

To be accredited, a pharmacy must undergo a thorough review process to establish its compliance with state and federal regulations. Applicant pharmacies must also demonstrate compliance with Digital Pharmacy Accreditation standards, including those addressing patient privacy, authentication and security of prescription orders, and patient management. Applicants must likewise demonstrate adherence to a recognized quality management program.

Though the core tenets of the Digital Pharmacy Accreditation 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 Verified Websites Program (see below) before they can apply for Digital Pharmacy Accreditation. While accredited, they must maintain their active .pharmacy domain name.

### *.Pharmacy Verified Websites Program*

NABP launched the .Pharmacy Verified Websites Program in 2014 to expand on its efforts to help patients easily identify a safe site when buying medication or obtaining medication-related information or services online. The .pharmacy suffix at the end of a web address, in place of ".com" or ".biz," serves as a virtual "seal of approval," signaling to patients that the website is legitimate and safe.

Pharmacies with an online presence and medication-related websites applying for verification are evaluated to ensure that they are compliant with applicable laws and business best practices, such as pharmacy licensure and valid prescription requirements, in the jurisdictions where they are based, as well as where they serve patients. Once companies have demonstrated their compliance with all program criteria, they can register and use a .pharmacy domain name. Successful verification through this program is a prerequisite for Digital Pharmacy Accreditation.

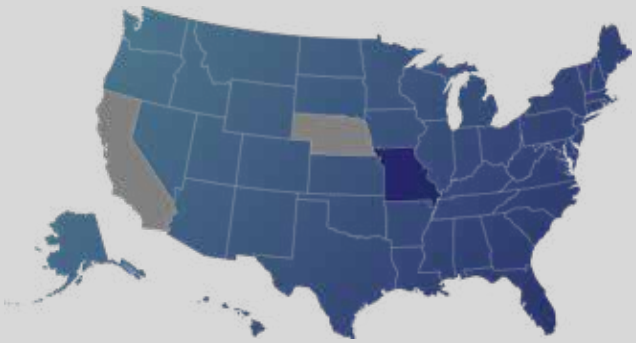
In addition to helping patients identify safe websites, verification through the .Pharmacy Program is recognized by major search engines like Google and Bing, social media platforms like Snapchat, and credit card companies like Visa and Mastercard as meeting their requirements for advertisers and health care merchants. The .Pharmacy Program accepts applications from pharmacies and related entities worldwide. NABP works with health care regulators in countries, including Canada, United Kingdom, Spain, and more, to verify appropriate licensure and compliance with national laws for applicants in those countries.

NABP encourages pharmacy regulatory authorities, including the state boards of pharmacy, to register a .pharmacy domain name to help raise awareness about the importance of patient safety online. The application process and fees are waived for the boards of pharmacy; boards may contact NABP to request a domain name.

## NABP PMP INTERCONNECT

NABP PMP InterConnect® facilitates the transfer of prescription monitoring program (PMP) data among PMPs 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. Physicians and pharmacists in states where it is used have the means to more easily identify patients with prescription drug abuse and misuse problems, especially if those patients cross state lines to obtain those drugs.

In operation since 2011, this highly secure communications exchange platform ensures that each PMP's data-access rules are enforced as it facilitates the transmission of PMP data to authorized requestors. PMP InterConnect does not house any data, and the system will not inhibit the legitimate prescribing or dispensing of prescription drugs.



There are 52 PMPs (47 states, select counties in Missouri, District of Columbia, Puerto Rico, Guam, and the military health system) participating as of December 2020.

To increase opportunities for interoperability, NABP has partnered with Bamboo Health on other technology that works with PMP InterConnect. One example of such technology is PMP Gateway – a third-party service that works with PMP InterConnect to facilitate the integration of PMP data into the workflow of health care providers' electronic health information systems, including hospitals, hospital systems, and pharmacies.

## 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.

The Association also educates federal agencies about the critical public health protection role that 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. NABP also interfaces with federal agencies, including 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 its membership.

## NABP FEDERAL AFFAIRS

NABP is also dedicated to monitoring specific federal issues and legislation for the boards of pharmacy via the Federal Affairs department. Such issues have included:

- the coronavirus disease 2019 pandemic;
- drug importation;
- implementation of the Drug Supply Chain Security Act; and
- ongoing legislation, including that related to occupational licensing and opioid use disorder.

The NABP Federal Affairs team also provides education to lawmakers on the Association's positions and its mission of protecting the public health. In addition, the department partners with national organizations and stakeholders on behalf of the boards.

## 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 webinars and educational forums for board legal counsel. The forums address legal trends in pharmacy practice and administrative law, as well as relevant court cases for board attorneys. 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 several boards of pharmacy and filed a legal brief in federal court in support of state board regulatory powers over federally registered compounding facilities.

NABP commonly responds to board inquiries about other states' laws on a specific subject, such as pharmacy-related licensure requirements or positions NABP has taken on laws or regulatory guidance.

## PUBLICATIONS AND RESOURCES

### *Publications*

NABP offers many printed and electronic publications to help its member boards of pharmacy stay current on the practice of pharmacy and regulatory issues, as well as on the Association's programs and services. The publications can be accessed on the NABP website and are free unless stated otherwise.

- *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* – provides model language that may be used when developing state laws or board rules.

*Download the Model Act at* **www.nabp.pharmacy/model-act.**

- **NABP***LAW*® Online – State Pharmacy Law and Rules Database – a comprehensive, national database providing 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. Single-user and multi-user subscriptions are available on the NABP website; a special member rate is available for state board of pharmacy offices.
- *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. Executive officers of the boards of pharmacy receive a complimentary copy for their board's use for research purposes. In addition, final-year pharmacy students from ACPE-accredited schools and colleges of pharmacy receive a complimentary copy.


- *Innovations*® – NABP's member magazine provides Association news and articles about issues that affect the regulation and practice of pharmacy. The magazine also features interviews with executive officers, inspectors, and members. Any board member interested in

participating in these interviews should contact commdept@nabp.pharmacy. All board of pharmacy members receive a complimentary subscription for this printed publication.

- State Newsletter Program – partnering with the state boards of pharmacy, NABP produces newsletters that are distributed to licensees in about 30 states on a quarterly basis. Participating states provide information about pharmacy laws and regulations for publication in their customized newsletter.
    - Each newsletter includes a link to the *National Pharmacy Compliance News*, which provides important news and alerts from FDA, DEA, and other federal agencies, as well as information about current national developments affecting pharmacy practice.
    - *State News Roundup* is a monthly compilation of legislative and regulatory updates from the newsletters of boards participating in the State Newsletter Program. All board of pharmacy members automatically receive this complimentary email.
- *NABP Bulletin* – a monthly electronic newsletter for board of pharmacy members and staff that highlights key NABP programs and services, resources, tools, news, and upcoming events.
- *NABP e-News* – weekly email newsletter that provides timely educational, regulatory, and Association news. Members are automatically subscribed to receive the complimentary newsletter.
- *AWARxE® Prescription Drug Safety News* – biweekly electronic newsletter that provides news about prescription drug abuse trends, online pharmacy safety, and medication safety.
- *.Pharmacy News* – monthly electronic newsletter that 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 Program, and more.

## 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. Access past mailbag memos at *nabp.pharmacy/mailbag*.

## NABP WEBSITE

Board members and staff can take advantage of the NABP website – *www.nabp.pharmacy* – as a one-stop source of information on NABP's initiatives, guidance on current issues, meetings, programs, and news.

- Members section – learn more about valuable member resources including inspection services, the NABP Clearinghouse, e-Profile Connect, and important documents such as the *Model Act*. The most current version of this manual, which is updated annually, is also available.
- Resources section – access links to past issues of *Innovations*, NABP committee and task force reports, educational webinars, and more.
- Meetings section – find dates and details for upcoming NABP and District meetings.

NABP hosts a consumer-focused website – *www.safe.pharmacy* – 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 medications use. Visitors to the site can use search tools to find safe websites for purchasing websites online and locate permanent drug disposal locations.

- Safe Site Search – consumers can type in a domain name and see whether it has been verified by NABP or appears on NABP's Not Recommended List. NABP has reviewed over 25,000 websites and found that 95% are not in compliance with state and federal laws as well as NABP patient safety and pharmacy practice standards.
- Drug Disposal Locator – visitors enter their location to find a nearby disposal location from a database of more than 9,600 permanent medication disposal programs. Pharmacies, municipalities, and other organizations request inclusion in the database by submitting our downloadable form.

## NABP FOUNDATION

The NABP Foundation® (NABPF®) 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 in 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 **NABP***LAW* 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 NABP Constitution and Bylaws as the Association.

## CHAPTER SUMMARY

- NABP is the independent, international, and impartial Association that assists its member boards 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 US 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 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.
- 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.
- VPP provides the capability for boards of pharmacy to share critical licensure and inspection information for pharmacies and other facilities operating in multiple states.
- The Supply Chain Inspection program is for businesses engaged in prescription drug and prescription medical device distribution and provides participants with an inspection report detailing a facility's observed practices that may satisfy an entity or agency's inspection requirement. Beginning in 2022, applicants seeking Drug Distributor Accreditation and OTC Medical Device Distributor Accreditation will be required to get an NABP Supply Chain Inspection to determine accreditation eligibility.
- NABP operates several accrediation and verification programs to provide uniform standards in nine areas: Community Pharmacy, Compounding Pharmacy, Digital

Pharmacy, DMEPOS Pharmacy, Home Infusion Therapy Pharmacy, Specialty Pharmacy, .Pharmacy Verified Websites, Drug Distributor, and OTC Medical Device Distributor.

- 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. This data is made available to boards for use in licensing decisions.
- 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 48 member boards and tests the applicant's knowledge of federal and state pharmacy law. NABP also develops and administers the FPGEE, which is one component of FPGEC certification.
- State boards of pharmacy may use CPE Monitor data 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.
- 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 by performing regular outreach and ensuring proper resources are available. The NABP Federal Affairs department monitors specific federal issues and legislation for the boards of pharmacy, as well as provides education to lawmakers on the Association's positions and its mission of protecting the public health.
- NABP offers to its members legal resources and various publications, such as the *Model Act State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy,* **NABP***LAW* Online, the *Survey of Pharmacy Law, Innovations,* the State Newsletter Program, and four e-newsletters.
- NABP offers its members 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.
- NABP and NABPF are not-for-profit corporations with 501(c)(3) status. The Foundation supports the Association's research and development projects and educational programs.

# CHAPTER 2
# THE BOARD MEMBER

## 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 their 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 in an orderly manner.

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.

## NABP/AACP DISTRICT MEETINGS

### *District Meetings*

The joint district meetings of NABP and the American Association of Colleges of Pharmacy (AACP) 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 in their district. District members also discuss and draft resolutions to bring to the Annual Meeting for consideration by the full membership.

### *Executive Committee Member Nominations*

During the district meetings, board delegates vote to nominate candidates who will run for NABP Executive Committee open member positions in their district. When there is an open NABP Executive Committee member position for a district, the district may nominate up to two candidates at its district meeting.

After the district meeting, there is also an opportunity for individuals to be nominated outside the district process. Nominees for Executive Committee officer positions of president-elect and treasurer submit their interest and qualifications for these positions directly to NABP. The Association determines if they meet the criteria to be a candidate. At the Annual Meeting, the membership votes on the slate of candidates, including the open member positions and officer positions of president-elect and treasurer. The president and chairperson positions are progressively assumed.

## *Resolutions*

Members may submit resolutions for consideration by their district during the district meetings. Resolutions may also be submitted outside of the district by any active member board or NABP committee. Resolutions are submitted to NABP and reviewed by the Committee on Resolutions before being voted on at the Annual Meeting. Resolutions have the potential to result in NABP actions such as the development of task forces to explore or address an issue or revisions to the *Model Act*, which provides the boards with model language that may be used when developing state laws or board rules. In addition, once approved by the full membership, resolutions document the Association's stance on issues affecting the practice of pharmacy and public health. They can also express NABP's intention to work with other key stakeholders.

Proposed resolutions are first presented by the Committee on Resolutions chair to attendees during the Annual Meeting's Second Business Session. Delegates receive a copy of the proposed resolutions. The proposed resolutions are also available on the NABP Annual Meeting website on the evening before the Second Business Session.

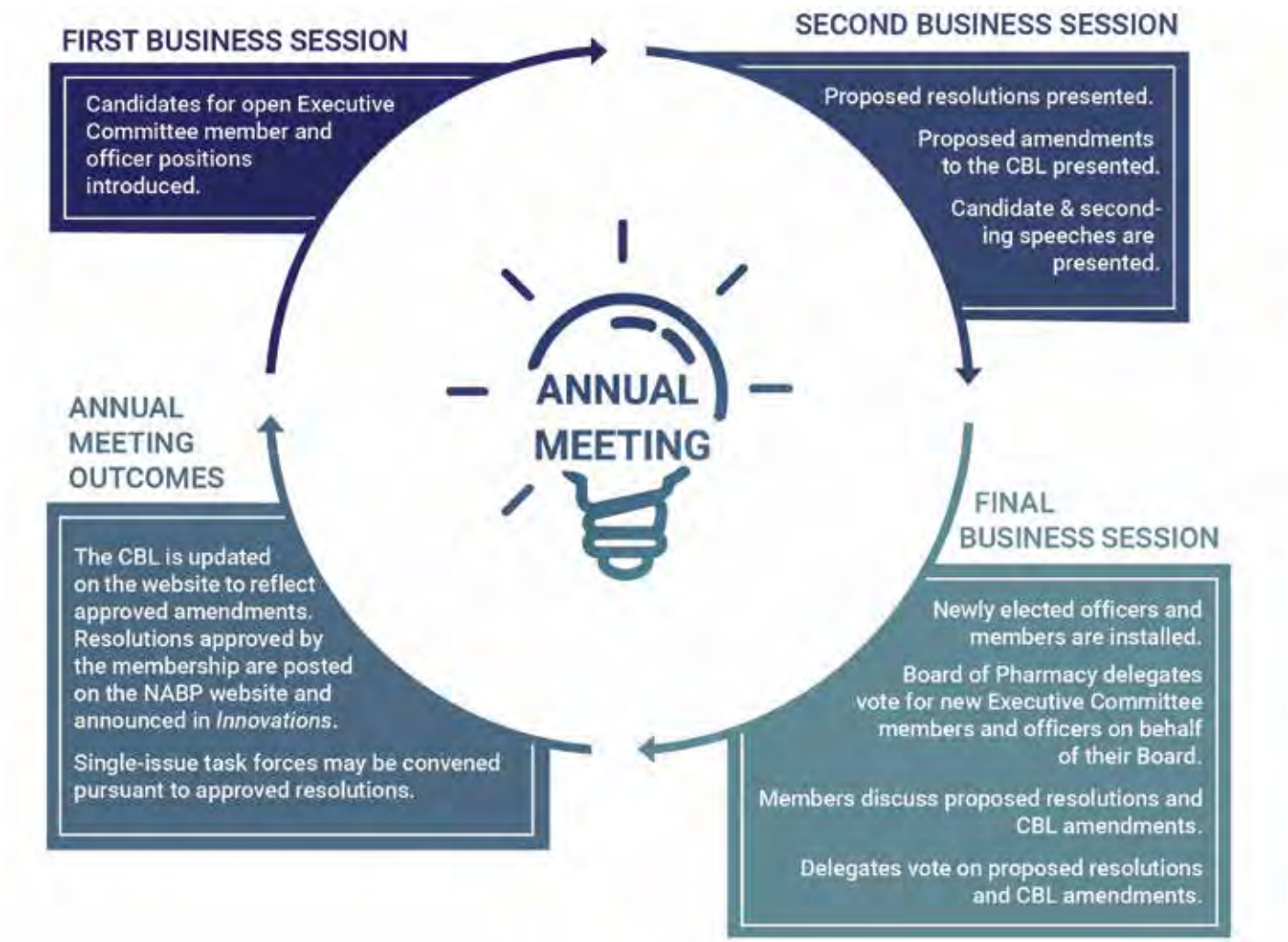
During the Final Business Session of the Annual Meeting, each resolution that was read during the Second Business Session is presented and discussed. As each resolution is presented, members of the Committee on Resolutions, the executive director/secretary, and the NABP president are available to address the resolution or the Committee recommendation. During the discussion on the resolution, only affiliated members of NABP have the privilege of the floor and must follow the Rules of Debate.

## *NABP Annual Meeting Business Processes*

### NABP/AACP District Meetings

Members nominate individuals to run for the open Executive Committee positions in their district.

Members discuss and vote on proposed resolutions to be submitted to NABP for consideration by the full membership.



## 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 board member who is a relative or close friend of an individual being subjected to possible disciplinary action; or
- 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 their 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.

## *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.

## *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.

### *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.
- 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.
- Participation at NABP/AACP District Meetings and the NABP Annual Meeting are an opportunity to collaborate with members from other boards and guide NABP policy. Key activities include nominating candidates and voting for open officer and member positions, submitting and voting on resolutions, and voting on proposed amendments to the NABP Constitution and Bylaws.
- 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.
- 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 their official capacity and exercising accepted skills in the performance of their 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."

# CHAPTER 3
# LICENSURE

## 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:

- Submitting a written application in a form prescribed by the board of pharmacy;
- Attaining the age of majority;
- Demonstrating good moral character and temperate habits;
- Graduating and receiving the appropriate professional degree from a board-approved pharmacy degree program;
- 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;
- Successfully passing any examinations required by the board of pharmacy; and
- 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 their conduct reflects detrimentally upon ther 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 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 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 the offense should be considered in determining moral character and, if it should, whether 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 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.

## 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 Accreditation Council for Pharmacy Education (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, United States 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. The scope of practice is defined in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (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.***

References to other defined terms, rules, and background information are also made to provide additional guidance.

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's active member boards have agreed to permit licensure transfer pursuant to standards established by the statutory law of the state and that are compatible with the NABP Constitution and Bylaws. 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.

Licensure transfer is initiated through NABP, which acts as a clearinghouse for participating states. Applicants for licensure transfer:

- may be subject to interview by the state in which they are seeking a license.
- may be required to take a jurisprudence examination to demonstrate an understanding of laws of the state into which they are transferring. In 49 jurisdictions, the Multistate Pharmacy Jurisprudence Examination® (MPJE®) is recognized and used to assess candidates' knowledge of state pharmacy law.
- are screened for disciplinary actions through the NABP Clearinghouse, which is a national database of disciplinary information on pharmacists practicing in NABP's member states and jurisdictions and intended to aid boards of pharmacy in

determining the acceptability and qualifications of candidates requesting the transfer of licenses into their jurisdictions. Active member boards are required to submit disciplinary information to the NABP Clearinghouse.

## 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 their conduct was detrimental to their 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 exemplified in the *Model Act*. Such definitions can empower the board to discipline unlicensed personnel who are engaged in the practice.
- 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, MPJE, and Clearinghouse – pharmacy enjoys the finest system of licensure transfer among all the health professions.

# CHAPTER 4
# EXAMINATIONS

## PURPOSE OF THE EXAMINATION

Every jurisdiction in the United States requires that a candidate successfully pass an examination 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 NABP developed the North American Pharmacist Licensure Examination® (NAPLEX®). NABP initiated studies and surveys to ascertain the competencies necessary for entry into the practice and developed the NAPLEX blueprint. This process is revisited regularly to ensure the continued viability of the examination. 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 Executive Committee establishes policies pertaining to the programs, and the Advisory Committee on Examinations advises the Executive Committee.

*Every five years, NABP reevaluates the competency statements and passing standard for the NAPLEX in accordance with commonly held practices in licensing testing. The NAPLEX competency statements undergo periodic reviews by a committee of subject matter experts.*

NABP utilizes the expertise necessary to ensure the highest professional standards and the appropriate technical procedures for the examination. A uniform method for determining the results of the licensing examination is also used. As a result, boards may assure the public and the candidate that successive examinations are equivalent and are appropriately geared to measure competencies necessary for a sufficiently knowledgeable candidate entering the practice of pharmacy.

The NAPLEX is a 225-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 Multistate Pharmacy Jurisprudence Examination® (MPJE®), which is currently offered in 48 jurisdictions as a means of assessing a licensure candidate's knowledge of state and federal pharmacy law. Item development for the 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.

## 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 accommodation requests in consultation with NABP. Testing accommodations for candidates with disabilities will be made only with the authorization of the board of pharmacy. All states whose eligibility is managed by NABP 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 (TOEFL iBT) developed and administered by ETS. 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.

## 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 determining the results 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 FPGEE, and pass the TOEFL iBT.

# CHAPTER 5
# RULEMAKING

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:

- implements, interprets, or prescribes law or policy; or
- 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:

- a brief description of the agency;
- 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;
- a similar breakdown of the staff units or sections and/or bureaus of the agency;
- address of the home office and any field offices, and specifically, where needed forms and information may be obtained; and
- citation to all applicable statutes and rules relating to the agency's operation and how to practice before the agency.

## 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:

- the rule is an invalid exercise of validly delegated legislative authority;
- the rule is an exercise of invalidly delegated legislative authority; or
- 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 United States 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.

## 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.

# CHAPTER 6
# DECLARATORY STATEMENTS

## DECLARATORY STATEMENTS

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:

- the applicability of a statute, agency rule, or an order;
- the question of the invalidity of a rule; or
- 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.

# CHAPTER 7
# ADJUDICATION PROCEEDINGS

## ADJUDICATION PROCEEDINGS

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 their 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:

- Full opportunity of the affected person or persons to respond.
- The right to bring or compel by subpoena witnesses at the hearing.
- The right to present evidence and/or argument on all issues involved.
- The right to conduct cross-examination and submit rebuttal evidence.
- The right to submit proposed findings of fact, conclusions of law, and orders.
- The right to file exceptions to any order or recommended order, as the case may be.
- The right to continuance where justified.
- 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 they allege 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 their 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:

- The subpoena or order directing discovery was unlawfully issued.
- The subpoena or order is unreasonably broad in scope.
- 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:

- administering of oaths;
- 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;
- ruling upon motions and other evidentiary matters; and
- 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:

- Irrelevant, immaterial, or unduly repetitious evidence should be excluded.
- 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.
- Verified copies of documentary evidence are generally admissible if the original is not readily available.

## 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:

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

- findings of fact;
- conclusions of law;
- interpretation of administrative rules, if applicable;
- recommended discipline or penalty, if applicable; and
- 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:

- The agency or board may adopt the recommended order as its final order without a review of the record.
- 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.
- 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.
- 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:

- the presiding officer or board notifies the licensee or permittee that a default order will be considered at a certain time and place.
- that the licensee or permittee is afforded an opportunity to present evidence in opposition to or in mitigation of the proposed default.
- 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 they have 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.

## 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:

- a conclusion of the investigation with an agency finding of no probable cause;
- a determination by the agency that further information is necessary and that the investigation must be continued; or
- 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 their 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 their 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.

## CHAPTER SUMMARY

- 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 55).
- Members of hearing panels must ensure that the license holder is afforded the minimum procedure requirements provided in this chapter (see page 56).
- The “right to discovery” is a tool used by the regulant to assist in the preparation of their defense to the board’s allegations or to seek dismissal of charges. Such their 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 page 60 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. 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 they may 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

## 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 their 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 their 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 their 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 their 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 they consider 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 their 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 their 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.

# CHAPTER 9
# SUNSHINE LAWS

## SUNSHINE LAWS

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 their 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

## SUNSET LAWS

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:

- 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.
- All complaints from consumers and law enforcement agencies will be directed to the master agency.
- Employees of the master agency will investigate all of the complaints.
- 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.

- 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."
- 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

- 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.
- 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.
- 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

- All examinations for licensure would be prepared, administered, and scored by the master agency.
- 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 they, of course, have 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:

- Rules discussions
- Presentations to the board
- 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:

- Completed investigations to be acted upon by the board.
- Unsigned telephone contacts that might warrant a board instituted complaint (investigation).

### *Audits:*

- authorized;
- completed pending board action;
- pre-hearing conferences;
- hearings;
- court actions; and
- follow-ups.

*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.*

## VIII. OLD BUSINESS

## IX. UNFINISHED BUSINESS

## X. ADJOURNMENT

# CHAPTER 12
# PARLIAMENTARY PROCEDURE

## FOR BOARD MEMBERS

- Familiarize yourself with the rules of order and policies and procedures.
- 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.
- You may only speak after receiving permission from the chair; be courteous to the chair or anyone else.
- Determine the proper method of introducing a motion and restrict your remarks to issues rather than personalities.
- 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.
- 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*

- Familiarize yourself with current standing rules and policies of the board.
- Review for yourself basic parliamentary procedures and terminology, particularly dealing with motions.
- 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).
- Determine necessity for formal action on agenda items as opposed to indicating what the “board noted,” or other designations.
- Identify potential trouble spots in agenda and develop alternate plans for handling these matters.
- Identify members of the board qualified to lead discussion and make appropriate motions when needed.

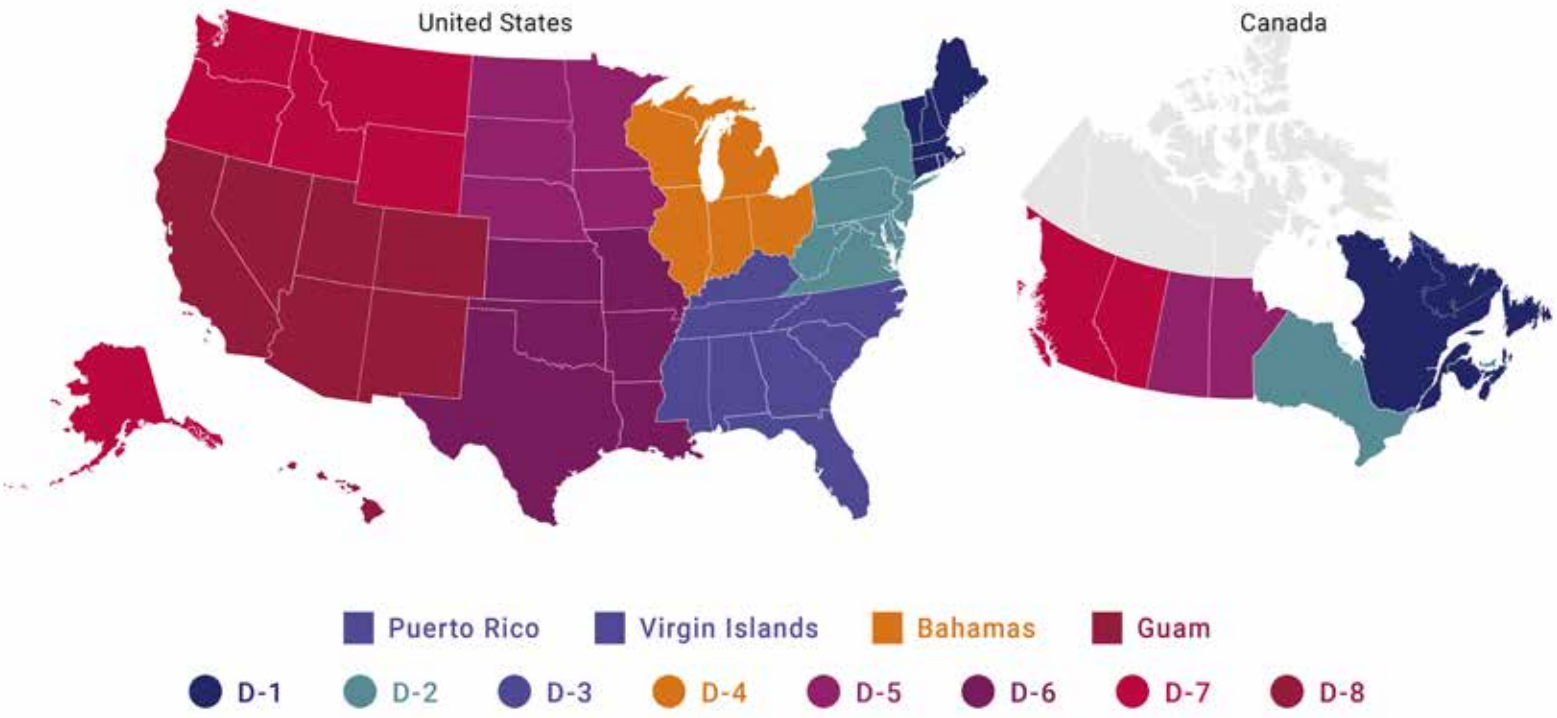
- Anticipate agenda items that might require further study and identify members likely to fulfill this assignment. Contact these members ahead of the planned meeting, if possible, or at least before the specific item on the agenda is due to be discussed.
- Determine what items not already on the agenda might be addressed in an informal manner, if time permits, and how much time could be allowed.
- Determine what items can be handled by consent rather than a vote (ie, “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*

- 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.
- The chair should refrain from strong, argumentative, partisan views.
- Keep discussion focused on the agenda item, allowing only one person to speak at a time, but refrain from becoming dictatorial.
- 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.
- 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.
- Attempt to handle as many matters as possible by consent.
- 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.”
- Remember that all of your rulings are designated as from the “chair,” not “I” or “we.”
- Remain helpful to board members in the proper method of framing and presenting their motions.
- 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.

APPENDIX

# NABP DISTRICT COMPOSITION




## GLOSSARY

***Following are commonly used acronyms in pharmacy:***

| | |
|---|---|
| **AMCP** | Academy of Managed Care Pharmacy |
| **ACPE** | Accreditation Council for Pharmacy Education |
| **ASOP Global** | Alliance for Safe Online Pharmacies |
| **AACP** | American Association of Colleges of Pharmacy |
| **ACA** | American College of Apothecaries |
| **AFPE** | American Foundation for Pharmaceutical Education |
| **AIHP** | American Institute of the History of Pharmacy |
| **APhA** | American Pharmacists Association |

| | |
|---|---|
| **APHA** | American Public Health Association |
| **ASCP** | American Society of Consultant Pharmacists |
| **ASHP** | American Society of Health-System Pharmacists |
| **ASPL** | American Society for Pharmacy Law |
| **CMS** | Centers for Medicare & Medicaid Services |
| **CHPA** | Consumer Healthcare Products Association |
| **CPSC** | Consumer Product Safety Commission |
| **DEA** | Drug Enforcement Administration |
| **FDA** | Food and Drug Administration |
| **HDA** | Healthcare Distribution Alliance |
| **ISMP** | Institute for Safe Medication Practices |
| **JCPP** | Joint Commission of Pharmacy Practitioners |
| **NACDS** | National Association of Chain Drug Stores |
| **NAPRA** | National Association of Pharmacy Regulatory Authorities (Canada) |
| **NCPA** | National Community Pharmacists Association |
| **NCPDP** | National Council for Prescription Drug Programs |
| **NPC** | National Pharmaceutical Council |
| **PCMA** | Pharmaceutical Care Management Association |
| **PhRMA** | Pharmaceutical Research and Manufacturers of America |
| **HHS** | United States Department of Health and Human Services |
| **USP** | United States Pharmacopeia/United States Pharmacopeial Convention |

***The following abbreviations are for NABP programs and services:***

| | |
|---|---|
| **ACE** | Advisory Committee on Examinations |
| **CBL** | Constitution and Bylaws |
| **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-MPJE®** | Pre-Multistate Pharmacy Jurisprudence Examination |
| **Pre-NAPLEX®** | Pre-North American Pharmacist Licensure Examination™ |
| **VPP®** | Verified Pharmacy Program® |

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.

### *CSA*

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 contendre 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:

- implements, interprets, or prescribes law or policy; or
- 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 NABP

## NABP MISSION STATEMENT

NABP is the independent, international, and impartial Association that assists its member boards in protecting the public health.

## VISION STATEMENT

Innovating and collaborating today for a safer public health tomorrow.

## NABP MEMBER BOARDS OF PHARMACY

Alabama State Board of Pharmacy
Alaska Board of Pharmacy
Arizona State Board of Pharmacy
Arkansas State Board of Pharmacy
California State Board of Pharmacy
Colorado State Board of Pharmacy
Connecticut Commission of Pharmacy
Delaware State Board of Pharmacy
District of Columbia Board of Pharmacy
Florida Board of Pharmacy
Georgia State Board of Pharmacy
Guam Board of Examiners for Pharmacy
Hawaii State Board of Pharmacy
Idaho State Board of Pharmacy
Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy
Indiana Board of Pharmacy
Iowa Board of Pharmacy
Kansas State Board of Pharmacy
Kentucky Board of Pharmacy
Louisiana Board of Pharmacy
Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy
Maryland Board of Pharmacy
Massachusetts Board of Registration in Pharmacy
Michigan Board of Pharmacy
Minnesota Board of Pharmacy
Mississippi Board of Pharmacy
Missouri Board of Pharmacy
Montana Board of Pharmacy
Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit
Nevada State Board of Pharmacy
New Hampshire Board of Pharmacy
New Jersey State Board of Pharmacy
New Mexico Board of Pharmacy
New York State Board of Pharmacy
North Carolina Board of Pharmacy
North Dakota State Board of Pharmacy
State of Ohio Board of Pharmacy
Oklahoma State Board of Pharmacy
Oregon State Board of Pharmacy
Pennsylvania State Board of Pharmacy
Puerto Rico Board of Pharmacy
Rhode Island Board of Pharmacy
South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy
South Dakota State Board of Pharmacy
Tennessee Board of Pharmacy
Texas State Board of Pharmacy
Utah Board of Pharmacy
Vermont Board of Pharmacy
Virgin Islands Board of Pharmacy
Virginia Board of Pharmacy
Washington State Pharmacy Quality Assurance Commission
West Virginia Board of Pharmacy
Wisconsin Pharmacy Examining Board
Wyoming State Board of Pharmacy

***Bahamas:***

Bahamas Pharmacy Council

***Canada:***

Alberta College of Pharmacy
College of Pharmacists of British Columbia
College of Pharmacists of Manitoba
New Brunswick College of Pharmacists
Newfoundland and Labrador Pharmacy Board
Nova Scotia College of Pharmacists
Ontario College of Pharmacists
Prince Edward Island College of Pharmacy
Quebec Order of Pharmacists
Saskatchewan College of Pharmacy Professionals