newsletter

National Association of Boards of Pharmacy®

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Upcoming Events

September 21-24, 2014
NABP/AACP Districts 6, 7, & 8 Meeting
Whitefish, MT

September 27, 2014
DEA National Prescription Drug Take-Back Day

October 5-7, 2014
NABP/AACP Districts 1 & 2 Meeting
Williamsburg, VA

October 7, 2014
FPGEE Administration

October 7-18, 2014
PARE Administration

October 14-15, 2014
NABP Interactive Executive Officer Forum
Northbrook, IL

December 2-3, 2014
NABP Interactive Member Forum
Northbrook, IL

The Drug Quality and Security Act: What Does It Mean for Compounding Pharmacies?

By Jack W. "Jay" Campbell IV, JD, RPh, Executive Director, North Carolina Board of Pharmacy, and Member, NABP Executive Committee

On November 27, 2013, President Barack Obama signed HR 3204, the Drug Quality and Security Act (DQSA). DQSA focuses on two broad issues: (1) the intersection between state and federal regulation of compounding pharmacy practices; and (2) the creation and implementation of a national "track-and-trace" program intended to ensure the integrity of the prescription drug supply chain. This article focuses exclusively on DQSA's changes to compounding pharmacy regulation.

DQSA's alteration of the compounding pharmacy landscape was spurred chiefly by an outbreak of fungal meningitis that sickened hundreds and killed over 60 patients across the United States in the fall of 2012. State and federal public health officials traced the source of the outbreak to contaminated vials of preservative-free methylprednisolone acetate produced by the Massachusetts-based New England Compounding Center.

Federal reaction was swift. Then Representative, and now Senator, Ed Markey of Massachusetts, introduced a bill to grant

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Food and Drug Administration (FDA) significant additional authority over compounding pharma-

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Editor's Note:

Mr Campbell states that the opinions in this article are his own and do not necessarily reflect the opinions of the North Carolina Board of Pharmacy or its members or NABP. In addition, the author has provided footnotes on pages 146, 150, and 152 for further information. This is the first part of a two-part article. The second part of Mr Campbell's article will be published in the September 2014 NABP Newsletter *and it analyzes the modified Section 503A and its "important consequences for compounding pharmacies that engage in 'office use' compounding" as well as requirements for outsourcing facilities under Section 503B.*

In This Issue. . .

The *NABP Newsletter* (ISSN 8756-4483) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 64 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
847/391-4406
www.nabp.net
custserv@nabp.net

Carmen A. Catizone
Executive Director/ Secretary

Deborah Zak
Communications Manager

DQSA

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cies.[1] Two congressional committees – the House of Representatives' Energy and Commerce Committee and the Senate's Committee on Health, Education, Labor and Pensions (HELP) – launched investigations and convened hearings on compounding pharmacy regulation.[2] Members of Congress introduced several alternatives to the Markey bill.[3] DQSA emerged after several rounds of intense negotiation among various stakeholders over a number of months.

Reaffirmation of Section 503A of the FD&C Act and the Effect on Office Use Compounding

In 1997, as part of the Food and Drug Administration Modernization Act (FDAMA)[4], Congress created Section 503A of the Federal Food, Drug, and Cosmetic (FD&C) Act[5]. Section 503A attempted to clarify whether and to what extent drugs compounded by a pharmacy are subject to federal law standards. The DQSA reaffirms Section 503A with one modification.

Section 503A's Exemptions for Patient-Specific Compounded Drugs

Under Section 503A, federal requirements that drugs be produced in compliance with current Good Manufacturing Practices (cGMPs), bear adequate directions for use on the labeling, and be proven safe and effective through the new drug application process "shall not apply" if the "drug product is compounded for an identified individual patient."[6] More specifically, Section 503A states that compounding must be performed by a "licensed pharmacist in a State licensed pharmacy or Federal facility" or a "licensed physician."[7] The compounding must occur "on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs."[8] Section 503A further allows compounding in "limited quantities before the receipt of a valid prescription order for such individual patient" so long as the "limited quantity" is "based on a history . . . [of] receiving valid prescription orders for the compounding of the drug product" that were generated "solely within an established relationship" between the compounder and "such individual patient for whom the prescription order will be provided" or "the . . . licensed practitioner who will write such prescription order."[9]

Importantly, Section 503A does *not* exempt so-called "office use"[10] compounded drug products – eg, those provided to a practitioner's office or a health care facility for administration to a patient without receipt of a prescription order for an "identified individual patient" – from the new drug approval process, labeling, or cGMP requirements of the FD&C Act.

Other Conditions of Exemption

Additionally, Section 503A imposed the following conditions for exemption from these requirements:

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1. HR 6584, 112th Cong. (2012).
2. See US Senate HELP Committee, *The Case for Clarifying FDA Authority: Large-Scale Drug Compounding and the Ongoing Risk to Public Health*, 113th Cong. (May 22, 2013); US Government Accountability Office, *Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight*, GAO-13-702 (July 2013).
3. HR 3089, 113th Cong. (2013); HR 3019, 113th Cong. (2013); HR 2186, 113th Cong. (2013); S.959, 113th Cong. (2013).
4. Pub. L. No. 105-115, 111 Stat. 2296
5. Codified at 21 USC §353a.
6. 21 USC § 353a(a).
7. 21 USC § 353a(a).
8. 21 USC § 353a(a).
9. 21 USC § 353a(a).
10. The term "office use" does not appear in Section 503A. The plain text of Section 503A, however, grants exemptions to certain FD&C Act requirements to products compounded upon receipt of a prescription order for an "identified individual patient." "Office use" is simply a shorthand phrase commonly used for compounded products that are *not* produced upon receipt of a prescription order for an "identified individual patient."

NABP Interactive Forums Tailored for Executive Officers and Members Return

Offering continued opportunities for collaboration and networking, the NABP Interactive Forum series will return this fall. Held as two separate forums, the first will be tailored to board of pharmacy executive officers and will be held in October. The second will be customized for board members and will be held in December.

The NABP Interactive Executive Officer Forum and the NABP Interactive Member Forum will each take place over two days. Both forums will also include presentations on timely and relevant topics developed from suggestions submitted by attendees in advance of the meeting.

Executive Officers

The NABP Interactive Executive Officer Forum will take place October 14-15, 2014. Each state board of pharmacy executive officer is invited to attend the forum at no charge. As with the previous forums, travel, hotel accommodations, and meals will be paid by NABP. In addition, there is no registration fee for the meeting.

Members

NABP invites each executive officer to select one member from his or her board to attend the Interactive Member Forum at no charge. Like the Executive Officer Forum, travel, hotel accommodations, and meals will be paid by NABP and there is no registration fee for the meeting. During the forum, which will be held December 2-3, 2014, attendees will have the chance to meet with their peers to discuss regulatory trends and challenges faced by their boards.

Information on registering for the Executive Officer Forum will be sent to the board of pharmacy executive officers by mid-August. Participation requests for the Member Forum will be sent to executive officers by late October. Both meetings will be held at the Hilton Chicago/Northbrook in Northbrook, IL.

The forums were first announced in 2010 at the NABP 106th Annual Meeting, as part of an initiative to provide additional support and resources to the member boards of pharmacy. A forum for board compliance officers and legal counsel is scheduled to return in fall 2015. For more information about the interactive forums, contact exec-office@nabp.net.

Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

Briargrove Pharmacy
Houston, TX

Citizens Pharmacy Services, Inc
Havre de Grace, MD

City Pharmacy
Martinsburg, WV

Halliburton Professional Pharmacy
Hacienda Heights, CA

Prescription World
Far Rockaway, NY

UI Healthcare-Iowa River Landing Pharmacy
Coralville, IA

A full listing of over 500 accredited DMEPOS companies representing nearly 27,500 facilities is available on the NABP website at *www.nabp.net.*

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NABP Executive Committee elections are held each year at the Association's Annual Meeting.

Subpoena CURES Disclosure

By Dale J. Atkinson, JD

The issue of weighing patient confidentiality with the public protection aspects of a regulatory scheme will always create interesting legal questions. This is especially true where administrative prosecutions by regulatory boards involve the health care practitioner as a respondent and not necessarily the patient. Indeed, the patient may be unwilling to cooperate with the board's investigation based upon privacy issues. In some cases, patients may be implicit in the alleged wrongful acts, creating additional motivation to not cooperate or to refuse to agree to the release of relevant records.

Administrative prosecutors have at their disposal certain subpoena power that may be effective in compelling cooperation. Recipients of subpoenas have a mechanism to dispute the validity of the subpoena to protect not only their rights as a respondent, but also the rights of their patients. Consider the following.

The Medical Board of California (Board) received information that a licensed physician (Licensee) was possibly prescribing excessive medications to patients in violation of the Medical Practice Act (Act). A Board investigator obtained a Controlled Substance Utilization Review and Evaluation System (CURES) report of the Licensee's prescribing history between August 2009 and February 2012. In addition, the investigator obtained CURES reports of five of the Licensee's patients over a 12-month period and the corresponding pharmacy records.

A medical expert conducted an independent review of the CURES reports and the pharmacy records and identified significant concerns and irregularities in the prescribing practices of the Licensee. Such irregularities included prescribing large quantities of addictive narcotics, prescribing highly unusual combinations of drugs, prescribing buprenorphine to patients concurrently receiving opioids from several other physicians, and prescribing at irregular time intervals and lengths. The medical expert referred to the Licensee's prescribing practices as "alarming and difficult to justify."

In February 2012, the investigator sent letters to the five patients seeking authorization for the release of their medical records regarding their treatment by the Licensee. The Licensee also received a subpoena to produce such records. After the patients were notified of the subpoenas, they objected to the release of the records and refused authorization. Based upon the patients' objections, counsel for the Licensee objected to the release of the medical records.

In December 2012, the Board filed a petition to compel compliance with the subpoenas. The Board argued that the medical records were needed to properly assess whether the Licensee was prescribing within the standards of care and practice and were "reasonably tailored to seek only the records that are necessary and material to the Board's investigation." The Licensee objected and argued that his refusal to produce was based upon the patients' rights to privacy and their rights to not be subjected to unwarranted search and seizure. In April 2013, the trial court granted the Board's petition to compel compliance. The Licensee appealed the lower court ruling.

On appeal, the Licensee argued that CURES reports

were obtained in violation of his patients' rights to privacy under Article I, section 1 of the California Constitution. He argued that the Board was given "unfettered and extensive access to two-and-a half years' worth of all his patients' CURES prescription information." In addressing these arguments, the court of appeals analyzed the CURES statute, the Board, and the constitutional principles propounded by the Licensee.

Regarding the CURES statute, the court noted that the prescribing and dispensing practices of controlled substances (CS) are strictly regulated and monitored by the Department of Justice (DOJ). Specifically, the CURES statute provides for the reporting of prescription records to the DOJ and permits the DOJ to disclose such records to state enforcement and regulatory agencies. The DOJ maintains a database of information regarding the prescribing and dispensing of Schedule II, III, and IV CS by all practitioners authorized to prescribe and dispense such CS. It noted that the primary purpose of CURES is to assist "law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of . . . controlled substances." The court emphasized that it is undisputed that the Board qualifies for authorization under the CURES statute to access and review prescription records for CS. Indeed, the CURES statute does not require the Board to obtain either patient consent or judicial approval prior to accessing CURES data, but the statute does require the database to "operate under existing provision to safeguard the privacy and confidentiality of patients" and prohibits the disclosure, sale, or transfer of patient data to any third party.

Turning its attention to the Board, the court cited a previous California Supreme Court case that provided a useful overview of the public protection role of the Board. The Board is authorized to license and discipline medical practitioners, and the right to investigate relevant matters is integral to this authority. Board investigators have a wide range of powers, inclusive of issuing subpoenas. In fact, the Board can issue investigative subpoenas prior to any formal accusation or scheduling of a formal hearing. Rather than challenging the Board's investigative powers, the Licensee asserts that the privacy rights of the patients were violated. Under previous case law, a physician has the right to assert the privacy interests of his/her patients.

Article I, section 1 of the California Constitution includes a specific right to privacy that was added by voter initiative in 1972. Subsequent jurisprudence identified a three-part test in analyzing an invasion of privacy claim. First, the claimant must possess a legally protected privacy interest. Second, the claimant's expectation of privacy must be reasonable. Finally, the invasion of privacy alleged must be serious in both its nature and scope. If the claimant establishes all three elements, the strength of the privacy interest is balanced against countervailing interests. This balancing test is not addressed unless the claimant satisfies all three elements. The right to privacy has been interpreted to include not only medical records, but also prescription records. However, the constitutional right to privacy is not absolute.

Identifying a legitimate, albeit competing, state interest, the court clearly noted that Board review of CURES data is justified. "Invasion of a privacy interest is not a violation of the state constitutional right to privacy if the invasion is justified by a competing state interest." Based upon the furtherance of a legitimate and important public protection interest, the balance of the interests favors disclosure to the Board. Citing a United States Supreme Court case that upheld a similar law

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Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, outside counsel for NABP.

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- The compounder must use ingredients meeting United States Pharmacopeia (USP) standards or contained in an FDA-approved drug.[11]
- The drug must not appear on an FDA-established list of products removed or withdrawn from the market for safety or efficacy reasons.[12]
- The compounded product must not be "essentially [a copy] of a commercially available drug product."[13]
- The drug must not be identified by FDA as "present[ing] demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product."[14]

Section 503A also prescribes compliance with USP Chapters <795> and <797> as a condition of exemption. Provisions of Section 503A dealing with compounding from bulk drug substance and ingredients other than bulk drug substance specify that an exempted compounded product must comply with "the United States Pharmacopeia chapter on pharmacy compounding."[15] FDA's draft guidance on implementation of Section 503A through the DQSA notes that, since Section 503A's original enactment in 1997, "the USP moved its chapter on pharmacy compounding to chapter <795> and added chapter <797>, which specifically addresses sterile compounding and is referenced in chapter <795>."[16]

Although individual states vary in their approaches to enforcement of USP standards for compounding (eg, prescribed by statute, prescribed by rule, enforced as a standard of care, silence on issue), Section 503A appears to resolve any question of these standards' application to compounded drug products as a matter of federal law. [17]

Section 503A also limits the ability of compounding pharmacies to ship products in interstate commerce. Individual state boards of pharmacy may enter into a "memorandum of understanding" (MOU) with FDA to police the "distribution of inordinate amounts of compounded drug products interstate." Obviously, the term "inordinate" is not self-defining, and it remains to be seen how that term will be applied. If a state has not entered into an MOU concerning "inordinate" interstate distribution, a compounding pharmacy may not cause more than five percent of its total compounded drug products to be distributed interstate. Efforts to produce a draft MOU are currently underway.

Advertising Restrictions Eliminated; "Severability" Issue Resolved

Section 503A, as originally enacted, also specified that any prescription order authorizing a compounded drug product must be "unsolicited" and that the compounder must "not advertise or promote the compounding of any particular drug, class of drug, type of drug." In 2001, a group of pharmacies mounted a legal challenge to these advertising restrictions in *Western States Medical Center v. Shalala*, asserting that they ran afoul of the First Amendment's commercial speech doctrine. The US Supreme Court ultimately held Section 503A's speech restrictions as unconstitutional.[18]

In some respects, however, *Western States* created more questions than it answered. Substantial uncertainty remained about whether *any* of Section 503A's other provisions remained viable. The US Court of Appeals for the Ninth Circuit had held, under the "severability" doctrine, that Congress did not intend that the remainder of Section 503A stand if its advertising restrictions were struck down. Hence, under the Ninth Circuit's reasoning, Section 503A was void *in toto*.[19] The Supreme Court, while noting the Ninth Circuit's severability holding, did not rule on that issue.[20] In contrast, in 2008, the US Court of Appeals for the Fifth Circuit, "differing with the . . . Ninth Circuit,"

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11. 21 USC § 353a(b)(1)(A)
12. 21 USC § 353a(b)(1)(C)
13. 21 USC § 353a(b)(1)(D) and (b)(2)
14. 21 USC § 353a(b)(3)(A)
15. 21 USC § 353a(b)(1)(A)(i)(I) & (b)(1)(B).
16. Pharmacy Compounding of Human Drug Products Under Section 503A of the federal FD&C Act at 4 n.5 (Dec. 4, 2013) (available at *www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377052.pdf*) (accessed May 9, 2014)
17. These provisions of Section 503A are somewhat awkward in their phrasing. Some may argue that the references to the "United States Pharmacopeia chapter on pharmacy compounding" are only intended to speak to ingredient selection. That is a possible reading, but one that would appear to render much of the chapter reference superfluous. In all events, FDA's guidance documents make clear FDA's interpretation that Section 503A's exemptions are conditioned on the compounder's overall compliance with USP compounding standards. Even if these statutory provisions can be said to be ambiguous, *Chevron* deference to FDA's interpretation would likely resolve the issue in any court challenge.
18. *Thompson v. Western States Medical Center,* 535 US 357 (2002).
19. *Western States Medical Center v. Shalala,* 238 F.3d 1090, 1096-98 (9th Cir. 2001), *aff'd* 535 US 357 (2002).
20. 535 US at 366 ("We granted certiorari to consider whether FDAMA's prohibitions on soliciting prescriptions for, and advertising, compounded drugs violate the First Amendment. Because neither party petitioned for certiorari on the severability issue, we have no occasion to review that portion of the Court of Appeals' decision.").

Access to PMPs Grows as Several States Enact Legislation to Establish Programs and Expand Use

In 2014, at least six states and the District of Columbia enacted legislation designed to establish, expand, or enhance state prescription monitoring programs (PMPs). Although the scope of these programs varies by state, all PMPs are designed to track prescribing and dispensing of certain controlled substances (CS) to help prevent abuse and diversion of such drugs, and, where state laws allow, to help health care providers make the most appropriate prescribing and dispensing decisions. In the face of the prescription drug abuse epidemic that has been linked to more than 15,500 annual overdose deaths, many state and federal agencies, health care advocates, and regulatory bodies have recognized PMPs as a vital tool in efforts to reduce rates of misuse and abuse.

To date, 49 states and the District of Columbia have either established or passed legislation allowing the establishment of some form of PMP. In addition, many states have passed legislation to refine or enhance PMPs in order to better serve the needs of their states. Bills passed in 2014 include acts to establish a new PMP in Washington, DC, allow pharmacists and other health care providers to delegate PMP access in two states, and to create a new category of monitored drugs in Virginia. Summaries of each of the laws follow.

DC Law Authorizes Establishment of PMP

In the District of Columbia, the Prescription Drug Monitoring Program Act of 2013 (B20-0127) authorizes the creation of a new PMP under the regulatory oversight of the district's Department of Health. Once the system is implemented, pharmacies must report each sale of a Schedule II through V CS to the database within 24 hours. The data reported will include information about the patient, details of the prescription, the amount of drugs dispensed, details of payment, and other data yet to be determined by the department. Authorization to access the database and to use the data will be governed by confidentiality rules outlined in the bill. The act also allows the district's Department of Health to enter into information sharing agreements with states that have similar programs. NABP is in discussions with the district regarding participation in the NABP PMP InterConnect® program once the new PMP is operational. NABP InterConnect facilitates the transfer of PMP data to authorized users across state lines and is provided at no cost to the states.

Privacy Protections

Florida's HB 7177 tightens up requirements related to privacy and the disclosure of information from the state's PMP, which was established in 2009. Under the new law, signed by Governor Rick Scott on June 13, 2014, direct access to Florida's PMP is limited to a defined list of health care providers including medical doctors, dentists, and pharmacists. Law enforcement agencies are not allowed to directly access the database, and may only receive information relevant to a specific investigation, with all non-relevant information redacted by the state's Department of Health. Law enforcement agencies wishing to acquire such data must enter into a user agreement with the Florida Department of Health.

Mandatory Use and Registration Laws

Idaho and Virginia have passed legislation making registration or use of their state's PMP mandatory.

In Idaho, H 396 now requires prescribers to annually register with Idaho's medical board to obtain access to the Controlled Substances Prescriptions Database, the state's PMP, during annual license renewal or initial licensure.

Similarly, Virginia's HB 1249 and SB 294 require certain prescribers to be registered with the state's Department of Health Professions to use the PMP. The bill requires prescribers, prior to writing a prescription for a benzodiazepine or opiate for a quantity expected to last more than 90 days and for which a treatment agreement is entered into, to request information from the PMP to determine what, if any, other covered substances are currently being prescribed. Pain management relating to dialysis or cancer treatment is exempt. The bill also authorizes Virginia's Secretary of Health and Human Resources to identify and publish a list of benzodiazepines and/or opiates that have a low potential for abuse by patients. Drugs on this list will not require the prescriber to check the PMP. HB 1249 has a delayed effective date of July 1, 2015. Additionally, prior to prescribing a CS approved for the treatment of opioid addiction, such as Suboxone®, a prescriber must query the PMP to determine what, if any, other CS the patient may be taking.

Monitoring "Drugs of Concern"

Another Virginia law, HB 874, allows the Virginia Board of Pharmacy to identify "drugs of concern" to be reported to the PMP. The legislation specifically states that any material, compound, mixture, or preparation that contains tramadol, a Schedule VI CS prescription medication used to treat pain, will be

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Trimester-Based NAPLEX and MPJE Score Reports Now Available for Download in Board e-Profile Connect

To improve access and security, boards of pharmacy can now use the Board e-Profile Connect to review North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®) summary score reports on a trimester basis. Previously, a trimester-based report distribution system was available through a separate service. This enhancement of Board e-Profile Connect will allow authorized users to access this information using interface and login credentials that are consistent with other score reporting features already available through the online portal. Pending operational agreements, NABP anticipates that colleges of pharmacy will also be able to access the score reporting feature by the end of 2014, allowing for more efficient communication.

In order to help boards adapt to changes in the system, NABP will continue to offer webinar training opportunities for boards to review new Board e-Profile Connect features. Information on upcoming webinars will be sent to board executive officers as trainings become available. In addition, an updated Board e-Profile Connect user manual will soon be available to assist board of pharmacy staff. To request training or additional information, contact Neal Watson, member liaison, by sending an e-mail to nwatson@nabp.net.

As NABP continually refines and enhances the Board e-Profile Connect system, the Association is also partnering with member boards of pharmacy to identify what features will best support their licensure needs.

More information about Board e-Profile Connect's current and forthcoming features is available in the April 2014 issue of the *NABP Newsletter.*

States' PMP Legislation

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considered a drug of concern. The new law became effective on July 1, 2014.

Access for Assigned Delegates

Also in Virginia, HB 539 passed with near unanimous support from the state's legislature, and allows prescribers or dispensers who are authorized to access the PMP to delegate this authority to certain health care providers employed at the same facility and under their direct supervision. The bill also changes the categories of individuals to whom such authority may be delegated by prescribers or dispensers to include health care providers licensed, registered, or certified by a health regulatory board in another state and employed at the same facility and under their direct supervision.

A similar law in Arizona, SB 1124, allows the Arizona State Board of Pharmacy to release data from its PMP, the Controlled Substances Prescription Monitoring Program, to a delegate who is authorized by the prescriber or dispenser.

Interstate Data Exchange

Iowa and Oklahoma both passed laws allowing for interstate exchange of PMP data under certain conditions. Iowa's SF 2080 allows the Iowa Board of Pharmacy to enter into an agreement with a prescription database or monitoring program operated in any bordering state – Minnesota, Wisconsin, Illinois, Missouri, Nebraska, and South Dakota – as well as Kansas. Oklahoma's HB 2665 allows the state to share PMP data with other states who have a reciprocal agreement in place. As with the District of Columbia, these laws may allow for increased participation in NABP InterConnect. Additional information about NABP InterConnect is available on page 158 of this *Newsletter.*

NABP will continue to monitor important legislative trends related to PMPs and provide updates.

DQSA

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concluded in a similar case, *Medical Center Pharmacy v. Mukasey,* "that the invalidated portion of [Section 503A] is severable and that its surviving portions therefore remain in effect."[21]

DQSA resolves this uncertainty. DQSA amends Section 503A by removing the solicitation and advertising restrictions deemed unconstitutional by the Supreme Court in *Western States.*[22] In other words, there can no longer be any doubt as to Congress' view of the "severability" question. Congress has severed the advertising restrictions, reaffirmed the remainder of Section 503A, and added a severability clause to Section 503A to avoid similar questions in the future.

21. *Medical Center Pharmacy v. Mukasey,* 536 F.3d 383, 401 (5th Cir. 2008).
22. DSQA Section 106.

More Than 170 VPP Facility Inspections Completed or Underway

Program Continues to Evolve with Input from Member Boards

Since the launch of the Verified Pharmacy Program™ (VPP™), inspections of 174 facilities have either been completed or are scheduled, and VPP inspection reports continue to be available to authorized users in order to assist member boards' licensure decisions. Developed in partnership with member boards of pharmacy, VPP facilitates the communication of essential inspection and licensure information between the state boards and serves as an information hub that provides verified data to support boards' licensure decisions for nonresident pharmacies.

Basic licensure and demographic information for nearly every pharmacy in the United States has been added to e-Profiles created by NABP, and boards may now access certain inspection reports. By the end of 2014, NABP anticipates that boards will be able to access complete pharmacy e-Profiles directly through Board e-Profile Connect, including inspection reports, executive summaries, and related licensure information.

Each participating facility is inspected using a uniform pharmacy inspection form. In addition, facilities that engage in compounding may also be inspected for applicable sterile and nonsterile compounding requirements, primarily in compliance with US Pharmacopeia Chapters <795> and <797>, through the use of specialized "modules."

At press time, at least 174 facilities have either been inspected, or are scheduled to be inspected. Of those, 76 facilities were inspected specifically for nonsterile compounding requirements, 15 pharmacies were inspected specifically for sterile compounding requirements, and 56 pharmacies were inspected for both nonsterile and sterile compounding requirements. The remaining pharmacies were not compounding and received only the general pharmacy inspections. Inspections have taken place in nearly 31 states.

As VPP continues to be enhanced, NABP has expanded its outreach efforts and is partnering closely with the state boards of pharmacy. For example, to implement a 2013 law requiring nonresident pharmacies to be inspected by the board or an entity approved by the board as a requirement of initial licensure or renewal, Virginia became the first state to formally recognize and accept VPP inspections for this purpose. Working closely with the Virginia Board of Pharmacy, more than 120 inspections were successfully conducted in less than 90 business days to meet a renewal deadline.

In addition to inspection reports completed through VPP, boards of pharmacy in several states have begun uploading their own completed inspection reports into the NABP inspection sharing network. By August 2014, more than 6,200 uploaded state reports from Kansas, Louisiana, Oklahoma, Nevada, and South Dakota are expected to be available in the inspection sharing network.

Through Board e-Profile Connect, state boards can access and view reports in the inspection sharing network, utilizing this verified data to assist when making licensure decisions for a pharmacy. By the end of 2014, NABP intends to make available an executive summary function to the system so that boards may quickly view the most relevant information for a VPP facility.

VPP executive summaries will provide essential demographic and operational information about a particular pharmacy, including location, pharmacy activities, and abbreviated summaries highlighting the pharmacy's most recent inspection results, including deficiencies, compliance issues, and existing disciplinary actions.

At the NABP 110th Annual Meeting, a prototype of the Board e-Profile Connect system focusing on integrated access to VPP was provided as a demonstration to the boards of pharmacy as an example of how the final version would function. NABP also plans to hold a working group session with stakeholders to gather additional feedback on how the program can best meet the needs of the state boards of pharmacy.

More information about the launch of VPP, including additional background, is available in the November-December 2013 and the April 2014 issues of the *NABP Newsletter*. Member boards with questions about VPP or the inspection sharing network may contact the Member Relations and Government Affairs Department at GovernmentAffairs@nabp.net.

Newly Accredited VAWD Facilities

The following facilities were accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

AnovoRx Distribution, LLC
Memphis, TN

Smith Medical Partners, LLC
Wood Dale, IL

Sonexus Health Distribution Services, LLC
Lewisville, TX

A full listing of more than 530 accredited VAWD facilities is available on the NABP website at *www.nabp.net*.

Physician Investment in Pharmacies Raises Legal and Ethical Concerns

Compounding pharmacies have drawn significant attention from regulators and lawmakers since the tragic 2012 deaths caused by contaminated injectables compounded by the New England Compounding Center. Most of the attention has focused on regulation to ensure the safety of compounding practices, but another potentially troublesome issue has come to the attention of some boards of pharmacy: pharmacies, commonly compounding pharmacies, soliciting physician investment in their practices. While the custom nature of compounded drugs may, at times, encourage greater collaboration between physicians and pharmacists, recent reports have revealed that financial collaborations can sometimes be problematic.

Physicians, generally speaking, may hold an ownership stake in a health care facility (including pharmacies) without necessarily violating federal or state laws, or the American Medical Association's Code of Medical Ethics. The arrangements coming to light, however, raise a number of legal and ethical concerns for both pharmacies and physicians, from violations of state and/or federal anti-kickback laws to conflict-of-interest rules and patient-care standards.

An Attractive Investment?

Taking an ownership stake in a pharmacy provides one possible route to diversify a physician's business and increase income, but being reimbursed for providing referrals to a given pharmacy may be legally and ethically concerning, and sometimes illegal. From the compounding pharmacy's perspective, a deeper relationship with a physician could increase its business by creating greater awareness of the compounding pharmacy's services and, more problematically, providing incentives to physicians to prescribe that pharmacy's custom-made medications. In some cases, physicians seem to be actively seeking investment opportunities in pharmacies. In others, compounding pharmacies are reportedly seeking out receptive physicians to invest in their business, or to refer patients for prescriptions, or to participate in medication trials.

Both federal and state governments have a number of laws in place that are intended to cut back on potential abuses that may result from such arrangements. The federal Anti-Kickback Statute, for example, prohibits paying or receiving remuneration for referrals of business reimbursed by federal health care programs, and the federal "Stark Law" prohibits a physician who has a financial relationship with an entity from making referrals to that entity for services that are reimbursed by a federal health care program. Both laws allow exceptions, however, and some compounding pharmacies reportedly seek to avoid law violations (not always successfully) by not accepting federal reimbursement.

State laws vary, meanwhile, though many do incorporate language similar to the federal anti-kickback and anti-fraud and anti-abuse laws. In Florida, for example, one state law prohibits health care providers from referring patients to an entity in which the provider is an investor, although exceptions are permitted assuming certain requirements are met. In addition, an anti-kickback law makes remuneration for referrals illegal, without listing exemptions. In Texas, a physician must disclose to patients that the physician has a financial relationship with a pharmacy to which the physician is referring patients, but does not completely disallow the referral. The Georgia State Board of Pharmacy's Code of Professional Conduct prohibits pharmacies from entering into pay-for-referral agreements with physicians if "in any way a patient's free choice of a pharmacist or licensed pharmacy is or may be limited."

Because of the dangers of running afoul of state or federal laws, many lawyers advise caution to physicians considering investing in pharmacy ownership or tempted to establish a formal referral relationship. This does not seem to be halting physician or pharmacy interest in seeking such opportunities, however. Representatives from the Texas State Board of Pharmacy and the Texas Board of Medical Examiners appeared before the state legislature's House Committee on Public Health in April 2014 and discussed, in part, the ongoing concerns in that state over physician ownership of pharmacies and some of the difficulties investigating the physician-pharmacy relationships.

The same month, after fielding a number of inquiries on the topic, the North Carolina Board of Pharmacy reminded its licensees that such practices are illegal in that state:

> A health care provider shall not financially compensate in any manner a person, firm, or corporation [for referrals] . . . No health care provider who refers a patient of that health care provider to another health care provider shall receive financial or other compensation from the health care provider receiving the referral as a payment . . .

The Board of Pharmacy also reminded licensees of relevant language from the North Carolina Medical Board, which had reminded physician licensees that they "may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist . . . for prescribing or referring a patient to said source."

Some observers have pointed out that, even when physician-owned health care entities, including compounding pharmacies, stay within the letter of the law, they may nonetheless raise ethical concerns.

News reports focusing on pharmacy-physician liaisons in Texas note that the Board of Pharmacy was in part hampered in investigating the relationships because the Pharmacy Act prohibits the Board from inspecting financial records unless the pharmacy consents in writing to the inspection. Gay Dodson, executive director of the Texas State Board of Pharmacy indicates that the Texas Board must depend on the Texas Attorney General's office to investigate and prosecute these types of cases.

Given the potential financial rewards for both parties when physicians invest in or develop another financial relationship with compounding pharmacies, it seems likely that parties on both sides will continue to seek these liaisons. Boards of pharmacy may wish to remind licensees of any state laws or regulations that would render such activities illegal.

Register Now for the October 7, 2014 FPGEE Administration

Registration is now available for the next Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) that will be administered on **October 7, 2014**. Foreign Pharmacy Graduate Examination Committee™ candidates who have been accepted to take the FPGEE may register using the link in the FPGEE section of the NABP website.

Within one week of registering with NABP, candidates will receive an Authorization to Test, and they may then schedule their test location with the NABP test vendor, Pearson VUE. Candidates have from July 15, 2014 to September 30, 2014, to schedule an appointment with Pearson VUE. NABP encourages early registration for optimal scheduling options as certain test centers fill up quickly.

To prepare for the FPGEE, NABP recommends that candidates take the Pre-FPGEE®, the practice examination for the FPGEE designed to help familiarize candidates with the types of questions on the actual examination.

Additional information about the FPGEE is available in the Programs section of the NABP website at *www.nabp.net.*

Next PARE Testing Window: October 7-18, 2014

The next available Pharmacist Assessment for Remediation Evaluation™ (PARE™) testing window is scheduled during the two-week time period of **October 7-18, 2014.**

Member boards of pharmacy are encouraged to take advantage of this web-based assessment that was created to assist the boards as part of their decision-making process when considering cases of remediation or brief departures from practice. To pre-register an individual for the PARE, boards of pharmacy may use the NABP Clearinghouse via Board e-Profile Connect or contact the NABP Competency Assessment Department at NABP_Comp_Assess@nabp.net.

More information about PARE is available in the Programs section of the NABP website at *www.nabp.net.*

Legal Briefs

(continued from page 149)

(*Whalen v. Roe*, 429 US 589 (1977)), the court of appeals compared the CURES statute with that of a New York law whereby physicians were required to forward prescription records with detailed patient information to a centralized databank.

Finally, the court distinguished cases cited by the Licensee in that such facts involved an absence of good cause. In the current case, the Board and its medical expert established reasonable cause. The court concluded that while patients have a reasonable expectation of privacy of prescription records, balancing the substantial societal interests in reducing the illegitimate use of dangerous, addictive drugs weighs in favor of disclosure under these circumstances and the enforcement of the subpoenas did not violate the California Constitutional right to privacy. Accordingly, the lower court ruling mandating compliance with the subpoenas was affirmed.

This case presents a thorough overview of the California CURES statute and how the balance of interests supports the right of regulatory boards to obtain access to patient information under certain circumstances.

Medical Board of California v. Chiarottino, 225 Cal. App. 4th 623 (App. Ct. CA 2014)

NABP Seeks Volunteer Item Writers to Develop New Examination and Assessment Questions for the NAPLEX, MPJE, FPGEE, PCOA, and PARE

NABP is seeking volunteers to serve as item writers for the Association's examinations and assessments. The opportunity to participate in item writing workshops is currently available for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), the Pharmacy Curriculum Outcomes Assessment® (PCOA®), and the Pharmacist Assessment for Remediation Evaluation™ (PARE™) programs.

Pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply.

Item writers will be selected based on the specific needs of the programs. Those who are selected will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item development process and content-related requirements for their designated examination program. Item writers will then engage in the development of new test items that will be considered for inclusion in NABP licensure, certification, and assessment examination programs.

The NAPLEX focuses on content domains relating to the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes,
- Assess safe and accurate preparation and dispensing of medications, and
- Assess, recommend, and provide health care information that promotes public health.

The MPJE combines federal and state-specific questions that test an individual's knowledge in pharmacy jurisprudence and includes the following areas:

- Legal aspects of pharmacy practice,
- Licensure, registration, certification, and operational requirements, and
- Regulatory structure.

Writers for the MPJE are typically assigned by the participating jurisdiction; however, individuals may be selected to participate independent of board of pharmacy affiliation.

The FPGEE content domains cover curricula of accredited United States pharmacy schools including:

- Basic biomedical sciences,
- Pharmaceutical sciences
- Social/behavioral/administrative, and pharmacy sciences
- Clinical sciences.

The PCOA is administered to pharmacy students in all four professional years. The assessment follows a blueprint that is representative of curricula of accredited US pharmacy schools, including:

- Basic biomedical sciences,
- Pharmaceutical sciences,
- Social/behavioral/administrative pharmacy sciences, and
- Clinical sciences.

The PARE is a multidimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist remediations or brief departures from practice. The content areas are:

- Medication safety and the practice of pharmacy,
- Professional ethics/pharmacist judgment, and
- Clinical Pharmacy.

How to Apply

Interested individuals should complete the online NABP Item Writer Volunteer Interest Form on the NABP website at *www.nabp.net/meetings/examination-meetings*, and upload a current résumé or curriculum vitae.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years.

The blueprint for each examination and assessment program may be found in the Programs section of the NABP website at *www.nabp.net*. For more information about item writing, contact NABP at NABP_Comp_Assess@nabp.net.

Twenty-Six States Securely Sharing Prescription Drug Data Via NABP PMP InterConnect; Participation Expected to Grow

Participation in the NABP PMP InterConnect® program continues to grow with twenty-six states live as of July 2014.

Currently, the following participating state prescription monitoring programs (PMPs) are using NABP InterConnect in the fight against the prescription drug abuse epidemic: Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wisconsin.

Since launching, NABP InterConnect has processed more than 6,000,000 requests, with an average total wait time of 7.5 seconds for a consolidated multistate PMP report.

NABP InterConnect is expected to see continued growth in 2014 as additional states have executed a memorandum of understanding (MOU) to participate, and other states are currently reviewing their MOUs. In addition, legislative changes in some jurisdictions may open the gate for more prospective NABP InterConnect participants in the future. (See "Access to PMPs Grows as Several States Enact Legislation to Establish Programs and Expand Use" on page 151 for more information.)

In July 2014, the NABP PMP InterConnect Steering Committee convened at NABP Headquarters to discuss the program's recent updates and other information as it relates to the administration and function of the program. Exclusively composed of representatives of PMPs that participate in the NABP InterConnect program, the Steering Committee serves as the governing advisory body of the program. The committee meets at least once per calendar year in person or by teleconference. Additional members will join as they agree to participate and execute an MOU with NABP.

More detailed information about the Steering Committee meeting will be available in future NABP communications.

Launched in 2011, NABP InterConnect was designed to facilitate interoperability and interstate data sharing between state PMPs by providing a secure communication platform for participating states. The system does not house any data and ensures that each state's data access rules are enforced.

States seeking further information about the NABP InterConnect may contact NABP Member Relations and Government Affairs staff at GovernmentAffairs@nabp.net or by calling 847/391-4406. More information about the program, including the most up-to-date information on state participation, is available in the Programs section of the NABP website at *www.nabp.net.*

NABP PMP InterConnect Steering Committee Gathered at NABP Headquarters in July 2014

The NABP PMP InterConnect® Steering Committee met at NABP Headquarters July 8-9, 2014, to discuss recent state participation updates and issues related to the administration and function of the program. More information about the meeting is forthcoming in future NABP communications.

NABP Holds .Pharmacy Supporter Advisory Committee Meeting to Further Program's Policies and Partnerships

To review policy and foster partnerships for the .Pharmacy generic Top-Level Domain (gTLD) Program, NABP held its second .Pharmacy Supporter Advisory Committee meeting on July 21-22, 2014, at NABP Headquarters. Comprised of pharmacy regulatory authorities, industry leaders, patient advocacy groups, enforcement authorities, and Internet technology experts from around the globe, the committee was developed to make recommendations for the program's governance model and for developing, implementing, and upholding international best practices for the use and operation of the .pharmacy gTLD.

Meeting Overview

During the July 21-22 meeting, the advisory committee reviewed implementation plans for .pharmacy governance, and reviewed program policies and universal baseline standards that must be met by all domain name registrants that will use the .pharmacy gTLD.

Also during the meeting, the committee continued to discuss and develop recommendations for collaborative efforts with international partners. For example, NABP is working closely with several international groups, including the International Pharmaceutical Federation (FIP) and National Association of Pharmacy Regulatory Authorities (NAPRA), to establish ad hoc national standard setting committees to help define supplementary specifications appropriate to particular geographic areas. Other participants in these discussions included pharmacy regulatory authorities and stakeholder groups from France and the United Kingdom. In addition, NABP is working to finalize relationships with partners to assist in such areas as the initial screening of applicants, the domain name registration process, and the provision of a web-based WHOIS service (a public record of all registrants that will use the gTLD).

Among the global coalition of stakeholders supporting the .pharmacy initiative are the Alliance for Safe Online Pharmacies, Eli Lilly and Company, European Alliance for Access to Safe Medicines, Food and Drug Administration, Gilead Sciences, Inc, FIP, INTERPOL, Janssen Pharmaceuticals, Inc, LegitScript, Merck & Co, Inc, NAPRA, Pfizer, and state boards of pharmacy.

.Pharmacy Moves Closer to Launch

NABP's efforts to own and operate the .pharmacy gTLD have taken major strides in the past year. In June 2014, the Association executed a Registry Agreement with the Internet Corporation for Assigned Names and Numbers (ICANN) to become the registry operator of the .pharmacy domain, which will be available only to legitimate online pharmacies and related entities located in the United States and other countries. The Registry Agreement with ICANN serves as the framework for operating the .pharmacy domain and includes a number of safeguards intended to protect consumers around the world.

NABP plans to launch the .pharmacy gTLD by fall 2014, and is currently operationalizing policies to ensure that only legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and to which they sell medicine will be able to register domain names in .pharmacy. For example, a pharmacy that is licensed in another country and is selling prescription drugs to patients in the US would not be eligible for .pharmacy because it is violating US federal law that prohibits importation. These eligibility requirements for the .pharmacy gTLD were developed in partnership with NABP's global coalition of stakeholders and address a shared concern about illegal online drug sellers distributing products that endanger patient health worldwide.

To help inform potential registrants and the general public about the .pharmacy initiative, NABP launched an informational website at *www.dotpharmacy.net*. The site provides program updates and explains .pharmacy's mission. In addition to the new website, NABP continues to raise global awareness of the .pharmacy gTLD through the AWAR$_X$E® Prescription Drug Safety Program. The ultimate goal of the .Pharmacy gTLD Program is to provide a powerful tool to educate consumers, distinguish legitimate Internet pharmacies from the thousands of rogue Internet drug outlets, and reinforce the value of purchasing medication only from trustworthy online sources.

Coinciding with the .pharmacy gTLD launch, NABP expects to start accepting applications for applicants interested in obtaining the .pharmacy domain in fall 2014.

More information about the .Pharmacy gTLD Program, including information on how to apply for the .pharmacy domain, is available at *www.dotpharmacy.net.*

AWARXE PSAs Return to Indianapolis 500 and Brickyard 400, Sharing Medication Safety Messages With Millions

For the third consecutive year, more than one million racing fans at the Indianapolis 500 received information about the realities of prescription drug abuse and counterfeit medications in the form of public service announcements (PSAs) from the AWARXE® Prescription Drug Safety Program. The 15-second PSAs played a total of 319 times during the Indianapolis 500, which took place the weekend of May 23-25, 2014. AWARXE PSAs also returned to the Brickyard 400 on July 24-27, 2014, for a second year, potentially reaching an additional one million attendees.

Viewers of the advertisements were warned about the presence of glue, chalk, rat poison, and other dangerous substances in counterfeit drugs sold by rogue online drug sellers. Another PSA alerted viewers that such medications often contain too much, too little, or the wrong amount of the active ingredient required for the drug to work properly. In addition, AWARXE PSAs featured important information about the prescription drug abuse epidemic, including the following facts:

- Prescription drugs are among the drugs most commonly abused by 12-to 13-year-olds.
- Over 50% of prescription drug abusers get the drugs from family or friends.

Community Outreach

Closer to NABP Headquarters, AWARXE continues to educate consumers through partnerships with local law enforcement officers, educational leaders, and other awareness groups that support prescription drug safety awareness at local events. In the spring and summer months of 2014, AWARXE attended multiple events reaching varied audiences.

At the HERO and HELPS Will County community forum event, held in Romeoville, IL, on May 17, 2014, AWARXE representatives provided a resource table to answer questions and to share flyers about how to safely dispose of unwanted, unneeded, or expired prescription drugs, and how to safely acquire and use prescription and over-the-counter medications. Speakers at the event included state and local government officials. An estimated 200 people attended.

A similar resource table was provided at the Lake County Opioid Initiative held in Grayslake, IL, on May 28, 2014. There, approximately 75 people attended the program, which featured speakers from Drug Enforcement Administration, county and local law enforcement officials, and health care organizations.

AWARXE attended and provided resources at several other events through the spring and summer of 2014, including a resource table at "It Couldn't Happen Here . . . The Realities of Heroin Addiction in our Community" in Villa Park, IL, on March 11, 2014, and a presentation at the Penray Companies, Inc, in Wheeling, IL, on June 3, 2014.

Additionally, AWARXE provides flyers, bookmarks, posters, and other educational materials to community leaders and educators in support of their efforts to combat prescription drug abuse. AWARXE materials for board of pharmacy or community events may be requested by sending an e-mail to AWARERX@NABP.NET.

AWARXE PSAs Displayed for Race Fans at 2014 Indianapolis 500

AWARXE® public service announcements (PSAs) were displayed for race fans throughout the Indianapolis 500 weekend on May 23-25, 2014. The PSAs were ran a total of 319 times on the jumbotron at the entrance to the Indianapolis Motor Speedway.

New Jersey Implements New Sterile Compounding Requirements

A new regulation in New Jersey (NJAC 13:39-11.14) addresses the cleansing and garbing requirements for personnel who engage in compounding sterile preparations.

- 13:39-11.14(a) defines the cleansing and garbing requirements for such personnel before entering the buffer area.
- 13:39-11.5(b) defines the steps that must be taken once inside the buffer area.
- 13:39-11.12(c) defines the steps required for disposal of garb upon exiting the cleanroom.

In addition, the new regulation, NJAC 13:39-11.15, defines the cleaning and disinfection requirements for the cleanroom, buffer area, and ante area. The rule requires that all cleaning and disinfection procedures be performed consistent with the standards established in United States Pharmacopeia Chapter <797>, Appendix II.

New Jersey's substantially modified NJAC 13:39-11 (Compounding Sterile and Non-Sterile Preparations in Retail and Institutional Pharmacies) can be accessed through the "Pharmacy Regulations" hyperlink at *www.njconsumeraffairs.gov/pharm/phar_rules.htm*.

Delaware Amends CS Regulations

Delaware Controlled Substance Rules and Regulations were amended pursuant to 29 Del. C. §10118. The amendments reorganize the rules for greater clarity and expand the rules to incorporate pertinent provisions from Chapter 47 of Title 16.

Rule 8.0 is added to address dispensing by practitioners, and Rule 3.0 was amended to require initial and biennial credits of controlled substances (CS) continuing education to enhance practitioner competence for greater protection of the public.

The rules pertaining to security in dispensing, now set forth in Rule 7.0, are amended for greater public protection. They include, but are not limited to, Regulation 7.1.2, which states that unless otherwise authorized by the Office of Controlled Substances, all CS storage area or areas shall be provided with electronic intrusion detection equipment to all sections of the said area or areas where CS are stored, so as to detect four-step movement. "Four-step" movement is the movement of a person walking not more than four consecutive steps at a rate of one step per second. Such four-step movement shall constitute a "trial," and a sufficient number of detection units shall be installed so that, upon test, an alarm will be initiated in at least three out of every four consecutive "trials" made moving progressively through the protective area. Electronic intrusion detection equipment shall be installed using equipment that must be UL-approved and listed. The said system must be capable of transmitting a local alarm to an outside audible device that shall comply with UL Standards. Rule 7.1.3 requires that the immediate area in a pharmacy remodeled or newly constructed after July 31, 2011, containing dispersed, controlled drugs must be secured in a manner approved by the Office of Controlled Substances that will prevent entry by unauthorized persons. Such a manner includes, but is not limited to, the implementation of a floor to ceiling physical barrier limiting access to the pharmacy area, motion detectors, strategically placed surveillance cameras, and backup alarm systems.

More information is available on the Delaware State Board of Pharmacy's website at *www.dpr.delaware.gov.*

New Security Prescription Blanks Now Required in New Jersey

The New Jersey Office of the Attorney General has published new mandatory security requirements for prescription blanks. All state-approved printer vendors of prescription blanks will stop selling the old blanks and will begin to exclusively sell the new blanks. State-licensed prescribers must stop writing prescriptions on the old blanks no later than August 18, 2014. Pharmacists will likely begin to see the new prescription blanks prior to the enactment date, but physicians can continue to write valid prescriptions using the old blanks until August 18, 2014. Enhanced security measures for the new prescription blanks are summarized below:

- A small "Rx" on the front written in thermochromic (heat-activated) ink that changes color or disappears as the prescription is handled;
- A line of microprint on the front that becomes illegible when scanned or photocopied;
- A hollow "VOID" that is invisible on a genuine prescription blank but will be visible on a scanned or photocopied prescription;
- A unique identification number for each blank; and
- A scannable barcode matching the unique identification number that allows the prescription to be identified in the New Jersey Prescription Monitoring Program.

The new blanks will be green on the front and blue on the back, and will have a complete list of security enhancements printed on the back.

Around the Association

Executive Officer Changes

- **Patrick Kennedy, MA,** is now serving as executive director of the Florida Board of Pharmacy, replacing Mark Whitten. Prior to this position, Kennedy served in executive leadership positions with the Florida Medical Association, North Carolina Medical Society, North Carolina Chapter of the American Academy of Pediatrics, American Heart Association, and Florida's Agency for Health Care Administration. Kennedy received both his bachelors and master's degree in economics from the University of Florida.
- **Peter Ragosta, RPh,** is now serving as the chief administrative officer of the Rhode Island Board of Pharmacy, replacing Catherine Cordy. Prior to this position, Ragosta worked in field management for Brooks Pharmacy and Brooks/Eckerd Pharmacy, which later became Rite Aid. He later went on to serve as both project manager and operations manager for Lifespan Pharmacy. Early in his career, he served as a staff pharmacist and pharmacy manager. Ragosta received his bachelor of science degree in pharmacy from the University of Rhode Island College of Pharmacy.

Board Member Appointments

- **Gregory Murphy, MS,** has been appointed a public member of the California State Board of Pharmacy. Murphy's appointment will expire June 1, 2017.
- **Allen Schaad, RPh,** has been appointed a member of the California State Board of Pharmacy. Schaad's appointment will expire June 1, 2015.
- **Anthony Perrone, MD, MBA, RPh,** has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Perrone's appointment will expire December 1, 2018.
- **Richard Tinsley, MBA, MEd,** has been appointed a public member of the Massachusetts Board of Registration in Pharmacy. Tinsley's appointment will expire December 1, 2014.
- **Calliope "Cali" Alexander** has been appointed a government representative of the New Jersey State Board of Pharmacy. Alexander is serving at the discretion of the appointing body.
- **Carol Jacobson, RPh, Esq,** has been appointed a public member of the New Jersey State Board of Pharmacy. Jacobson's appointment will expire May 13, 2018.
- **Mitch Sobel, MAS, RPh,** has been appointed a member of the New Jersey State Board of Pharmacy. Sobel's appointment will expire May 31, 2016.
- **Linda Witzal, RPh,** has been appointed a member of the New Jersey State Board of Pharmacy. Witzal's appointment will expire March 11, 2019.
- **Kyle Whitehead, DPh,** has been appointed a member of the Oklahoma State Board of Pharmacy. Whitehead's appointment will expire June 30, 2019.

Board Member Reappointments:

- **Gavin Meshad** has been reappointed a public member of the Florida Board of Pharmacy. Meshad's appointment will expire October 31, 2017.
- **Justin Barnes, PhD,** has been reappointed a public member of the Minnesota Board of Pharmacy. Barnes' appointment will expire January 1, 2018.
- **Laura Schwartzwald, RPh,** has been reappointed a member of the Minnesota Board of Pharmacy. Schwartzwald's appointment will expire January 1, 2018.
- **Margherita Cardello, RPh,** has been reappointed a member of the New Jersey State Board of Pharmacy. Cardello's appointment will expire May 31, 2017.
- **Richard Palombo, RPh,** has been reappointed a member of the New Jersey State Board of Pharmacy. Palombo's appointment will expire May 31, 2018.
- **Jeffrey Nielsen, RPh,** has been reappointed a member of the South Dakota State Board of Pharmacy. Nielsen's appointment will expire October 1, 2016.
- **Lisa Rave, MBA,** has been reappointed a member of the South Dakota State Board of Pharmacy. Rave's appointment will expire October 1, 2016.

Board Officer Changes:

The Kentucky Board of Pharmacy has elected the following officers to the Board:

- **Cathy Hanna, PharmD,** President
- **Deborah Brewer, RPh,** Vice President

- The Maine Board of Pharmacy has elected the following officers to the Board:

- **Joseph Bruno, MBA, RPh,** President
- **Paul Chace, RPh,** Vice President

The Massachusetts Board of Registration in Pharmacy has elected the following officers to the Board:

- **Karen Ryle, MS, RPh,** President
- **Patrick Gannon, MS, FABC, RPh,** President-Elect
- **Edmund Taglieri, MSM, NHA, RPh,** Secretary

The Wisconsin Pharmacy Examining Board has elected the following officers to the Board:

- **Thaddeus Schumacher, PharmD,** Chairperson
- **Franklin LaDien, RPh,** Vice Chairperson
- **Philip Trapskin, PharmD, BCPS,** Secretary

New Recommended Starting Dose for Lunesta to Avoid Morning Impairment

Food and Drug Administration (FDA) has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes. More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Soliris Lots Recalled Due to Presence of Visible Particles

In June 2014, Alexion Pharmaceuticals of Cheshire, CT, initiated a voluntary recall for certain lots of Soliris® (eculizumab) 300 mg/30 mL concentrated solution for intravenous infusion due to the presence of visible proteinaceous particles detected in one lot during periodic testing. The affected lot is #10007A. The other recalled lots are:

- 10002-1
- 00006-1
- 10003A
- 10005A
- 10005AR
- 10006A
- 10008A

All recalled lots were manufactured using a process component during vial filling identified in a November 2013 recall to the hospital/user level and were distributed only in the United States. Additional details, including expiration dates, shipping dates, and instructions for returning the products, are available in a press release available on FDA's website at *www.fda.gov/Safety/Recalls/ucm399527.htm*. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

CPE Credit Offered for Online FDA "Bad Ad" Course

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing pharmacy education (CPE) course through its Bad Ad Program. Pharmacists may receive CPE credit by taking this course. Learning objectives, faculty information, and other details are available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one contact hour (0.1 CEU) of Accreditation Council for Pharmacy Education-accredited CPE credit.

Yellow Jug Medication Disposal Program Expands to Indiana and Ohio

Indiana and Ohio have joined Michigan, Illinois, and Wisconsin in allowing local pharmacies to participate in the Yellow Jug Old Drugs Program, a community prescription drug disposal program. The program was created by the Great Lakes Clean Water (GLCW) Organization in order to provide a secure and responsible method for consumers to dispose of unwanted medications and to prevent such drugs from entering the water supply. Individuals who wish to dispose of their medications in these states can look for the yellow jugs at participating pharmacies. A map of participating disposal locations can be found at the GLCW website. To date, the program has safely disposed of over 45 tons of unwanted medications. Note that pharmacies participating in the program are currently unable to take controlled substance medications. Pharmacies wanting to participate in the program can visit the Pharmacists page of the GLCW website at *www.greatlakescleanwater.org/pharmacist*.

Newly Approved e-Advertisers

The following entities were granted approved e-Advertiser status through the NABP e-Advertiser Approval[CM] Program:

Florida Cancer Specialists, LLC, dba Florida Cancer Specialists Rx to Go
www.flcancer.com

Grand Medicine Health Sciences Pharmacy Ltd dba Grand Medicine Health Sciences Pharmacy
www.gmhs.ca

London Drugs Ltd
www.londondrugs.com

PetFlow.com dba VetSource Home Delivery
www.petflow.com

Price Chopper Supermarkets
www.pricechopper.com

Whitman-Walker Health, LLC
www.whitmanwalkerpharmacy.com

A full listing of NABP approved e-Advertisers is available on the NABP website at *www.nabp.net*.

nabp newsletter

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

NABP Seeks Your Input on the *NABP Newsletter*

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