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Upcoming Events

September 9-10, 2014
Task Force on Standards for the Use of PMP Data
NABP Headquarters

September 9-10, 2014
Task Force on Prescription Drug Abuse
NABP Headquarters

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

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

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

The Drug Quality and Security Act (DQSA)'s reaffirmation of the modified Section 503A has important consequences for compounding pharmacies that engage in "office use" compounding. Some states' laws that regulate pharmacy practice permit "office use" compounding;[1] other states' laws do not.[2]

Office Use Compounded Drugs Not Exempt From FD&C Act

DQSA now makes clear, however, that as a matter of federal law, **any** compounded drug product prepared and dispensed without a prescription order for an individually identified patient is adulterated and misbranded. This is because "office use" compounded drug products are **not** exempt from the Federal Food, Drug, and Cosmetic (FD&C) Act's labeling, new drug approval, and Current Good Manufacturing Practice (cGMP) requirements.

It is true that Section 503A, as reaffirmed by DQSA, permits "limited" anticipatory compounding "before the receipt of a valid prescription order" for an "individual patient."[3] Still, Section 503A makes

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it clear that a compounded drug product is exempt from federal labeling, new drug application, and cGMP requirements only if dispensed "for an identified individual patient" based on

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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 166, 170, and 172 for further information. This is the second part of a two-part article focusing on the Drug Quality and Security Act. The first part of Mr Campbell's article was published in the August 2014 NABP Newsletter.

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.

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DQSA

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a "valid prescription order," regardless of whether the compounded drug product is prepared upon receipt of that order or in "limited quantities" prior to its receipt.

At some level, the exclusion of "office use" compounding from Section 503A exemptions is not surprising. After all, New England Compounding Center purported to avail itself of state law "office use" compounding authority when preparing large quantities of non-patient-specific compounded drug products and shipping them to clinics and health care facilities around the country. Other recent public health crises caused by compounding pharmacies have likewise involved products prepared and shipped to clinics and health care facilities for "office use" rather than pursuant to individual patient prescriptions.[4]

On the other hand, in the months of debate over the appropriate federal role in compounding pharmacy regulation, some stakeholders stressed that "office use" compounding serves a valuable public health function, particularly when critical medications are in short supply.[5] Accordingly, these stakeholders stressed that pharmacies should retain an ability to engage in some level of "office use" compounding without subjecting themselves to direct regulation by Food and Drug Administration (FDA).[6] At least one compounding bill introduced in Congress expressly preserved some ability for pharmacies to do so, insofar as consistent with pharmacy law in the facility's state of domicile.[7]

DQSA does provide a pathway for the preparation of "office use" compounded drug products – via "outsourcing facilities" explicitly subject to direct federal regulation (discussed on page 170) but outside of this sanctioned pathway, "office use" compounding by pharmacies (that are not also "outsourcing facilities") will run afoul of federal law.[8]

Creation of Methods for State and Federal Authorities to Jointly Monitor Section 503A Compliance

DQSA requires FDA to receive reports from state boards of pharmacy "expressing concerns that a compounding pharmacy may be acting contrary to section 503A . . . "[9] Likewise, FDA is required to "immediately notify" state boards of pharmacy if it "makes a determination that a pharmacy is acting contrary to section 503A . . . "[10] Hence, DQSA is structured to ensure that state boards of pharmacy are not only monitoring compliance with state law governing compounding,[11] but are also actively engaged with

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1. See, eg, 21 NCAC 46.1810 ("Compounded drug products shall not be offered to other entities for resale; however, practitioners may obtain compounded drug products to administer to patients within the scope of their professional practice . . . ")
2. See, eg, Minnesota Board of Pharmacy Urgent Memorandum Regarding Compounding (Nov. 15, 2012) (explaining how Minnesota statute and rules governing the practice of pharmacy prohibit "office use" compounding) (available at *www.pharmacy.state.mn.us/cmpdmemo.pdf*) (accessed Nov. 17, 2013).
3. 21 USC § 353a(a)(2)
4. See, eg, Centers for Disease Control and Prevention, Multistate Investigation of Suspected Infections Following Sterile Injections (available at *www.cdc.gov/hai/outbreaks/TN-pharmacy*) (accessed Nov. 17, 2013).
5. See Testimony of David G. Miller, RPh, chief executive officer and executive vice president of the International Academy of Compounding Pharmacists, to the United States House of Representatives Energy and Commerce Committee (July 16, 2013) (available at *http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Miller-Health-Drug-Compounding-Reform-2013-7-16.pdf*) (accessed Nov. 17, 2013).
6. Id.
7. See, eg, HR 3089, § 2(a)(1)(C), 113th Cong. (2013).
8. Indeed, FDA has begun enforcing the statute according to these terms. See, eg, April 30, 2014 Warning Letter 14-ATL-06 issued by FDA to Blue Ridge Pharmacy and Compounding Center (available at *www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm395820.htm*) (accessed May 9, 2014)
9. DQSA Section 105(a)(2)
10. Id. ¶ (d)
11. DQSA obligates state boards of pharmacy to report to FDA any "actions taken against compounding pharmacies," which includes: issuance of a warning letter, sanctions or penalties for violations of state pharmacy regulations pertaining to compounding; suspension or revocation of a pharmacy license or registration for compounding regulation violations; and any "recall of a compounded drug due to concerns relating to the quality or purity of such drug." DQSA Sections 105(a)(1) and (b).

Interactive Executive Officer Forum Returns This Fall; Interactive Member Forum to Follow

This fall, the NABP Interactive Forums will return and focus on the theme, "Revitalizing Partnerships for Collaboration."

Set to take place October 14-15, 2014, the upcoming NABP Interactive Executive Officer Forum will provide board of pharmacy executive officers the opportunity to network with their peers while discussing challenges faced by their boards on a daily basis. The forum will take place over two days and programming includes presentations on timely and relevant topics developed directly from suggestions submitted by the board of pharmacy executive officers. In addition, NABP support services available to boards of pharmacy will be reviewed. Invitations to attend the Executive Officer Forum were sent in August. As with previous forums, there is no registration fee, and travel, hotel accommodations, and meals will be paid by NABP.

Following the Executive Officer Forum, NABP will hold another forum on December 2-3, 2014, tailored specifically to board of pharmacy members. Invitations for the NABP Interactive Member Forum will be sent to board of pharmacy executive officers in late October. Executive officers are asked to designate one member as the board's attendee. The member forum is held biannually, alternating with the forum for board compliance officers and legal counsel.

The goal of the Interactive Forums is to facilitate interaction among boards from across the country and provide closed sessions to discuss important and timely issues related to pharmacy regulation.

Both forums will take place at the Hilton Chicago/Northbrook in Northbrook, IL.

PCOA Registration Opens Soon for the January 12 to February 6 Testing Window

The deadline for schools and colleges of pharmacy to register their students for the first 2015 Pharmacy Curriculum Outcomes Assessment® (PCOA®) testing window is October 14, 2014.

The testing window runs from January 12 to February 6, and schools and colleges of pharmacy that would like to participate are encouraged to contact Lori Schumacher, FPGEC/PCOA program manager, at 847/391-4438 or via e-mail at PCOA@nabp.net.

Appropriate for administration to students in all professional years, the PCOA is an excellent resource for pharmacy educators as they review pharmacy curricula, design courses, and assess student performance. Please note, effective January 2015, the paper-based format will no longer be available. The PCOA will only be delivered in the computer-based format.

More information, including future PCOA testing windows for 2015, is available in the Programs section of the NABP website at *www.nabp.net*. Registration materials for the 2015 PCOA will be available soon.

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

APPE: A Phailed Pharmacy Education

By Dale J. Atkinson, JD

Applicants for licensure as pharmacists must meet the eligibility criteria set forth in law, usually contained in the pharmacy practice act. Eligibility criteria contain requirements related to education, experience, examination, and likely personal history/moral character. In all of the regulated professions, questions often arise as to the obligations of the academic community to screen its applicants for admission into the program for moral character issues that may affect post-graduate licensure eligibility.

Furthermore, academic programs adhere to standards designed to distinguish between students who successfully matriculate through the curriculum and those that do not. As readers are aware, licensure eligibility criteria include both education and examination components. The education component provides an educational foundation and academic basis for a career in pharmacy, while the licensure examination provides an entry-level competence determination based upon a practice analysis that is statistically validated based upon performance of the exam questions.

Not all students successfully complete the academic program and, as a result, do not graduate from the program. There are a host of reasons why students may not successfully complete the academic program and an equal number of legal challenges that may result. Consider the following.

After receiving a bachelor of arts degree in business from a university in China, a student (plaintiff) attended the California Polytechnic State University in Pomona, CA, where she earned her bachelor of science with a major in microbiology and a minor in chemistry. Thereafter, she was admitted to and attended the Skaggs School of Pharmacy and Pharmaceutical Science at the University of California, San Diego (School). During her attendance at the School from fall 2006 through November 2011, the plaintiff received two failing grades from classroom courses. She remediated those failing grades and was thus allowed to proceed to the clinical rotations.

In the clinical rotations, the Plaintiff was required to pass seven Advanced Pharmacy Practice Experiences (APPE) consisting of four required rotations and three elective rotations. Students take one APPE at a time which lasts approximately six weeks. The School's progression policy provides that students receiving an F or U for a specific APPE will be allowed to continue the remaining scheduled APPEs, and that upon completion of the last scheduled APPE, the student will repeat and pass the previously failed APPE, or complete and pass an equivalent APPE experience. A student may only repeat and pass a failed APPE or complete and pass an equivalent APPE *after* the student finishes all other remaining scheduled APPEs.

The progressive completion and/or repeating of APPEs is necessary because of the complex scheduling of APPEs which use over 100 locations and over 150 instructors that supervise students. In fact, each student's seven APPEs are scheduled before he or she begins the first rotation. As a matter of policy, the School determined that it would be disruptive to allow or require immediate remediation of failed APPEs.

The plaintiff failed an acute care APPE in spring 2011. Because this was her first failed APPE, the plaintiff was allowed to continue with her scheduled

APPEs. In September 2011, she failed an ambulatory care APPE. As a result of her second failed APPE, the plaintiff was subject to dismissal from the School. An academic committee hearing was held and evidence of the plaintiff's failed courses and APPEs were presented. Testimony questioning her academic performance and ability to calculate doses, her confusion of medications, and her lack of critical thinking were introduced. The plaintiff presented her evidence and the Committee, after "considerable discussion," unanimously voted to dismiss her from the School.

In its dismissal letter of November 2011, the School stated, "The main reason for this decision of dismissal included a history and pattern of poor academic performance, in the first three years of the curriculum as well as two failures during the [APPE], a fundamental lack of clinical and medication knowledge leading to the concern for patient safety, and a lack of professionalism. [The school] has an obligation to ensure competence of our trainees and graduates."

The plaintiff's internal appeal to the Dean of the School was denied. The denial on appeal contained the School's justification for its decision of dismissal and referenced both academic failures and lack of professionalism as grounds for the decision. The Dean noted but rejected the plaintiff's arguments that non-academic factors were inappropriately used as a basis for dismissal. Indeed, the Dean referenced that such allegations had been previously investigated and satisfactorily concluded. Finally, the Dean rejected arguments that the School failed to follow its own policies regarding an alleged lack of completion of a professionalism evaluation form (PEF), noting that such forms are not mandatory and are new to the faculty. In the end, the Dean concluded that the plaintiff was adequately informed of the professionalism issues necessary to defend herself and the dismissal results would not have changed even if the PEF had been completed.

The plaintiff filed a petition for a writ of mandamus seeking reinstatement to the program. The circuit court ruled in favor of the School on all claims, holding that the plaintiff "failed to establish that the School acted arbitrarily, capriciously or in bad faith when it dismissed her without issuing a PEF." After entry of the final judgment, the plaintiff appealed the matter to the Court of Appeals.

On appeal, the court first disposed of some procedural arguments related to the timeliness of the appeal. Next, the court identified its standard of review as assessing whether the School's actions were arbitrary or capricious, were entirely lacking in evidentiary support, or whether it failed to follow proper procedures or failed to give notice as required by law. As noted by the court, ". . . courts rarely intervene in a university's academic affairs." The academic decisions of a private university are given highly deferential treatment and subject to a limited standard of review. The court noted that "… university faculties must have the widest range of discretion in making judgments as to the academic performance of students."

Turning its attention to the merits of the case, the court first addressed the argument that the failure to complete the PEF constituted grounds for the mandamus. Even assuming that the PEF was mandatory, the court held that academic reasons support the dismissal decision of the School. The PEF process applies to deficiencies in professionalism, not academics. Academic deficiencies are not ignored if a PEF is not prepared. The record supports the academic failures of the plaintiff and the failure to provide a PEF is, according to the court, "of no moment."

Next, the plaintiff argued that School policy requires two non-remediated failing grades in required courses during the same year before dismissal is

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

DQSA

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FDA to monitor and enforce compliance with Section 503A.

"Outsourcing Facilities" the Sole Source of Drug Products Compounded For "Office Use"

In addition to reaffirming a modified Section 503A, DQSA adds new Section 503B to the FD&C Act. This section charts a federally-authorized pathway for "office use" compounding. Section 503B exempts "a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility" from the new drug approval and adequate directions for use labeling requirements of the FD&C Act.[12] In contrast to pharmacies preparing patient-specific compounds in compliance with Section 503A, outsourcing facilities preparing "office use" compounded drugs in compliance with Section 503B are **not** exempted from cGMP mandates.

DQSA defines an "outsourcing facility" as "a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of [Section 503B]."[13] An outsourcing facility is "not required to be a licensed pharmacy,"[14] although, as noted above, any drug compounded at an outsourcing facility must be prepared "under the direct supervision of a licensed pharmacist."

Furthermore, an outsourcing facility "may or may not obtain prescriptions for identified individual patients."[15] Hence, unlike a pharmacy operating under the requirements of Section 503A, an outsourcing facility can avail itself of the labeling and new drug approval exemptions (but not the cGMP compliance exemption) when preparing compounded products for "office use."

Some early commentary on DQSA has made much of the "voluntary" nature of outsourcing facility registration. Why, some have asked, would a facility "voluntarily" subject itself to federal regulation?[16] The straightforward answer is that any pharmacy (or other facility) that wishes to provide "office use" compounded drug products can only do so legally if it is registered as an outsourcing facility. As mentioned, Section 503A does not exempt "office use" compounded drug products from federal labeling, new drug application, and cGMP requirements. Accordingly, "office use" compounded products are adulterated and misbranded unless produced by an "outsourcing facility" in compliance with Section 503B and in compliance with cGMP requirements.

To be sure, both FDA and state boards of pharmacy must devote enforcement resources sufficient to ensure that "below the radar" facilities are not permitted to evade the law. However, Section 503B is not drained of effect simply because it characterizes registration as an outsourcing facility to be "voluntary."

Compliance Standards for "Outsourcing Facilities"

As noted, outsourcing facilities do not enjoy an exemption from federal cGMPs, and Section 503B delineates a number of other specific requirements and compliance standards for outsourcing facilities.

Section 503B limits the use of bulk drug substances by outsourcing facilities to those that:

- Appear on an FDA-created list of bulk substances for which there is a clinical need – whether pursuant to FDA rulemaking or to appearance on FDA's drug shortage list,[17]

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12. 21 USC § 353b(a) (exempting such drugs from the requirements of 21 USC §§ 352(f)(1), & 355. DQSA also exempts such drugs from certain provisions of Title II, the Drug Supply Chain Security Act. The so-called "track and trace" program created by DQSA is outside the scope of this paper.
13. 21 USC § 353b(d)(4)(A); see also 21 USC § 353b(b)(1) (setting forth an annual registration requirement "upon electing and in order to become an outsourcing facility").
14. 21 USC § 353b(d)(4)(B). This provision at least raises a question of whether federal law defining an outsourcing facility can be said to preempt state law defining what is and is not a pharmacy. For example, under North Carolina law, a pharmacy is "any place where prescription drugs are dispensed or compounded." NCGS § 90-85.3(q). Thus, an "outsourcing facility" would, by dint of its compounding activities alone, be a "pharmacy" under North Carolina law and required to obtain the requisite permit. See NCGS §§ 90-85.21(a), 90-85.21A(a). Does DQSA preempt North Carolina law and relieve the outsourcing facility of the need to obtain a state pharmacy permit? DQSA appears to answer in the negative, albeit indirectly. The statute provides that "[p]ayment of the [federal registration] fee . . . shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees." DQSA Section 353b(d). It appears, then, that if the facility's state of domicile deems it a pharmacy, registration as an outsourcing facility does not nullify the facility's obligation to be permitted as such. On the other hand, if a state's law did **not** deem a facility engaged in compounding, but not dispensing, to be a pharmacy, the lack of a pharmacy permit would not prohibit the facility from registering as an outsourcing facility under federal law. NABP is drafting a brief memo on this issue, encouraging states whose current statutory definition of a pharmacy does not include an outsourcing facility to find a way to license these facilities either as pharmacies or as a new type of licensee so that patients may still be protected at the state level.
15. 21 USC § 353b(d)(4)(C)
16. See, eg, Letter from Edith A. Rosato, RPh, IOM, chief executive officer, Academy of Managed Care Pharmacy, to Senator Tom Harkin (Oct. 8, 2013) ("A company that is engaging in the unauthorized manufacturing of drugs is not going to volunteer to register with the FDA.") (available at *www.amcp.org/WorkArea/DownloadAsset.aspx?id=17285*) (accessed Nov. 17, 2013).
17. 21 USC § 353b(a)(2)(A)

NABP *Model Act* Updated to Assist Boards of Pharmacy in Developing Laws and Rules to Protect the Public Health

To assist the state boards of pharmacy in developing state laws or board rules in their efforts to protect the public health, NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).* Changes made to the *Model Act* were incorporated as a result of the Executive Committee-approved recommendations of the Task Force on Pharmacy Licensure Standards, the Task Force on the Regulation of Pharmacy Benefit Managers, resolutions adopted at the 109th Annual Meeting, and the recommendations of the 2013-2014 Committee on Law Enforcement/Legislation.

Pharmacy Licensure

As suggested by the Task Force on Pharmacy Licensure Standards, the *Model Act* was updated to clarify resident and nonresident pharmacy licensure standards and pharmacy inspections. The Committee on Law Enforcement/Legislation agreed with the task force that nonresident pharmacies should be licensed by every state in which they provide pharmacy services. In addition, the committee noted that individual pharmacists need only to obtain licensure in those states in which they are actively engaged in the practice of pharmacy and providing those services. Further, the committee added a statement to the introductory comment in the *Model Act* to note that the *Model Act* is written in a first-person point of view for a resident board of pharmacy. Also in this provision, the *Model Act* was updated to remove "Persons" from the Manufacturer and/or Distributor licensing authority in an effort to avoid confusion as to who was required to obtain the license.

Also related to pharmacy licensure, the *Model Act* was updated to clarify definitions in the Notifications section, including what is considered a quality-related event versus an adverse drug reaction, and in what circumstances either should be reported to the board of pharmacy. In addition, the *Model Act* now includes a definition for a "Significant Quality Related Event," as the committee reasoned that such events are often preventable and therefore should be under the boards' purview.

Also, as recommended by the task force, the *Model Act* was updated to include the requirement that boards should be provided with a report of any inspection of their licensees conducted by any state or federal agency or their authorized agent. Specifically, the *Model Act* now clarifies that a pharmacy must notify either the board or the board's authorized agent that the inspection was conducted and submit the report and applicable documents, including those related to corrective actions.

PBM-Related Updates

The *Model Act* was also revised based on suggestions from the Task Force on the Regulation of Pharmacy Benefit Managers. Based on the task force's recommendations, the language in the Comment section was generalized to avoid the implication that the listed activities always constitute the practice of pharmacy by pharmacy benefit managers (PBMs). In addition, language related to formularies was broadened to include all aspects of formulary management, not just interventions. Lastly, in recognition of the fact that many PBMs design the clinical programs for their associated mail order and/or network pharmacies, direction and design of clinical programs for pharmacies was added to the list of activities that may constitute the practice of pharmacy by PBMs.

Adopted by Resolution

Several amendments to the *Model Act* were also implemented as a result of the resolutions adopted at the NABP 109th Annual Meeting. Resolution 109-2-13 proposed amendments be made to address five percent rules. The Committee on Law Enforcement/Legislation noted that the previous *Model Act* language limited the amount of product that a pharmacy can transfer to another pharmacy to five percent of its total prescription drug sales revenue. However, some committee members noted that Drug Enforcement Administration (DEA) controlled substance (CS) regulations limit the transfer of CS between DEA registrants to five percent of dosage units distributed or dispensed (versus five percent of sales revenue). To avoid conflict on this issue, the *Model Act* was amended to include verbiage stating, "providing that such transfers are compliant with federal law."

Also stemming from resolutions adopted at the 109th Annual Meeting, the *Model Act* was updated to address performance metrics and quotas. Reflecting Resolution 109-7-13, the *Model Act* now states that requiring pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety may be grounds for discipline. Further, language was added to clarify that this addition does not include performance metrics that may be related to the ability and competency of pharmacy personnel, as these types of evaluations are important to professional development and patient safety.

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DQSA

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- Comply with any applicable compendium monograph,[18]
- Are manufactured in an FDA-regulated facility, and[19]
- Are accompanied by a "valid certificate of analysis."[20]

Non-bulk drug substance ingredients must comply with applicable monograph standards.[21]

Specific safety standards govern an outsourcing facility's compounding. Outsourcing facilities may not compound drugs that have been withdrawn or removed from the market for safety or efficacy reasons.[22] Similarly, outsourcing facilities may not compound drugs that present "demonstrable difficulties for compounding" that would likely, on balance, outweigh the product's safety or effectiveness.[23] And, for any product compounded "from a drug that is the subject of a risk evaluation and mitigation strategy," the outsourcing facility must "prior to compounding" demonstrate to FDA that it will "utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy."[24] Adverse events involving drugs compounded by an outsourcing facility must be submitted to FDA.[25] Outsourcing facilities may not compound drugs that are "essentially a copy" of an approved drug product.[26] If, however, an approved drug appears on FDA's drug shortage list, an outsourcing facility may compound a "copy."[27]

While DQSA generally exempts compounded drug products prepared by an outsourcing facility from federal "adequate directions for use" labeling requirements, it imposes a number of other labeling requirements, including:

- The statement "This is a compounded drug" or an FDA-approved alternative,[28]
- Identifying information for the outsourcing facility,[29] and
- Identifying information for the drug product, including a "Not for resale" caution and, if not dispensed pursuant to an individual patient prescription, an "Office Use Only" disclaimer.[30]

Upon initial registration and twice annually thereafter, an outsourcing facility must supply FDA with a report identifying all drugs compounded, as well as specific information about each drug's ingredients, strength, dosage form, packaging, and volume produced.[31] Outsourcing facilities are subject to FDA inspection, and FDA is directed to develop a risk-based inspection schedule.[32]

Finally, DQSA prohibits outsourcing facilities from wholesaling. A facility's compounded drug product "will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug."[33] The wholesaling prohibition does not, however, "prohibit administration of a drug in a health care setting."[34] Accordingly, it appears that "hub" or "enterprise" pharmacies that provide non-patient-specific compounded drug products for administration within a hospital system, for example, may continue to do so as long as they register as an outsourcing facility and comply with applicable standards.

As with any new legislation, interpretation and application issues will arise. This article sets forth a basic overview of the intersection of DQSA and state laws governing compounding pharmacy practice.

Compounding pharmacies in states that permit "office use" preparations may be surprised to learn that the DQSA reaffirmation of Section 503A effectively prohibits such practice. Section 503A does not grant a pharmacy exemption from federal labeling, new drug approval, and cGMP requirements unless, among other things, it dispenses compounded drug products after receipt of an individual patient prescription.

The sole pathway to "office use" compounding now runs through the creation of "outsourcing facilities" under a new Section 503B of the FD&C Act. Compliance with Section 503B exempts compounded products prepared by the outsourcing facility from the federal new drug application process and certain labeling requirements. Such facilities are not, however, exempt from cGMP requirements, and those pharmacies that can meet cGMP standards will also be required to meet a number of production and labeling standards specific to "office use" compounded drug products.

Effective and rational implementation of DQSA will depend on close cooperation among federal and state regulatory authorities, and, indeed, DQSA creates information-sharing mechanisms designed to maximize such cooperation.

18. 21 USC § 353b(a)(2)(B)
19. 21 USC § 353b(a)(2)(C)
20. 21 USC § 353b(a)(2)(D)
21. 21 USC § 353b(a)(3)
22. 21 USC § 353b(a)(4)
23. 21 USC § 353b(a)(6); see also 21 USC §§ 353b(c)(1) & (c)(3) (setting forth the procedure for FDA's creation of a list of "difficult to compound" drugs).
24. 21 USC § 353b(a)(7)
25. 21 USC § 353b(b)(5)
26. 21 USC § 353b(a)(5)
27. 21 USC § 353b(d)(2)(A)
28. 21 USC § 353b(a)(10)(A)(i)
29. 21 USC § 353b(a)(10)(A)(ii)
30. 21 USC § 353b(a)(10)(A)(iii)
31. 21 USC § 353b(b)(2)(A)
32. 21 USC § 353b(b)(4)
33. 21 USC § 353b(a)(8)
34. 21 USC § 353b(a)(8)

States Pass New Legislation for Oversight of Compounding Facilities

As United States Food and Drug Administration (FDA) continues with steps to implement Title I of the Drug Quality and Security Act (DQSA), state lawmakers have been developing and enacting legislation to bring state law into harmony with the new federal law. State legislation passed or under consideration in 2014 includes laws relating to requirements for compounding practice and outsourcing facilities, as well as provisions for inspection requirements and stronger penalties for compounding violations.

Compounding Oversight

On July 10, 2014, Massachusetts Governor Patrick Deval signed into law H 4235, which includes varied provisions related to the oversight of compounding practice. Under the legislation, pharmacies engaged in sterile compounding must pass an inspection as a requisite for license renewal. In addition, the Massachusetts Board of Registration in Pharmacy will conduct random inspections of such licensees. Further, Board inspectors must be trained in sterile compounding and nonsterile compounding practices, and the training shall include, but not be limited to, any programs offered free of charge by NABP. Pharmacies found to be in violation of compounding regulations could face fines of up to $25,000 per violation and up to $1,000 for each day that a violation continues.

Under the law, four new licensure categories will be established for the following specialities: retail sterile compounding, retail complex nonsterile compounding, institutional pharmacy, and nonresident pharmacy. In addition, the law requires a portion of continuing education requirements to be in the area of sterile compounding for those pharmacies engaging in or supervising sterile compounding. The law also requires pharmacies to inform prescribed users and practitioners whether their medication is a sterile or nonsterile compounded drug.

Further, the law includes provisions requiring the Board to participate in any national data reporting system that provides information on individual pharmacies, pharmacists, and pharmacy technicians, such as those maintained by NABP and FDA. Finally, under the bill, the Board would be composed of eight registered pharmacists practicing in varied areas (including one sterile compounding pharmacist), one pharmacist technician, one public member, and three members from other health care professions.

In Michigan, two bills to increase regulation of compounding pharmacies and increase penalties for compounding violations were signed into law by Governor Rick Snyder on June 28, 2014. Specifically, SB 904 establishes criminal penalties for cases of patient harm linked to compounding violations. Sentences could allow up to 15 years in jail for convictions of patient death due to a compounding violation. Michigan's SB 704 increases regulatory oversight of compounding pharmacies by prohibiting the compounding of commercially available products unless there is a significant difference or unavailability of the drug. The law also requires pharmacies to notify the Michigan Board of Pharmacy of any complaint filed with another state or federal agency or an accrediting body for violation of pharmacy laws or standards. Further, out-of-state pharmacies must reimburse the Board for any expenses incurred for inspections or investigations. Last, pharmacies compounding sterile products must obtain national accreditation or provide other Board-approved proof of compliance with United States Pharmacopeia (USP) standards for compounding of sterile products.

Both laws went into effect on July 16, 2014.

Outsourcing Facility Oversight

Several states have enacted laws to define and establish requirements for outsourcing facilities.

Michigan's SB 704 requires outsourcing facilities to be licensed in Michigan as pharmacies. The leg-

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FDA Releases Final Guidance for Human Drug Product Compounding

Food and Drug Administration (FDA) has released its final guidance for pharmacies and individuals that intend to compound drugs under Section 503A of the Federal Food, Drug, and Cosmetic (FD&C) Act, now that it has been amended by the federal Drug Quality and Security Act. The document "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" restates the provisions of Section 503A, describes FDA's interim policies with respect to specific provisions that require implementing regulations or other actions, and contains a non-exhaustive list of potential enforcement actions against pharmacies or individuals that compound human drug products in violation of the FD&C Act.

The final guidance document may be viewed at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf.*

State Legislation

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islation also establishes a regulatory framework and standards for those pharmacies compounding without a prescription to include maintaining a list of pharmacists and pharmacies approved to compound drugs for physicians, health facilities, or agencies without a prescription.

New York passed legislation (A 9205) that includes a definition of an "outsourcing facility" that is similar to the DQSA definition. The law requires such facilities to register with the New York State Board of Pharmacy, and, as a prerequisite, to register with FDA. Registration with the Board as an outsourcing facility requires a fee of $825. Both resident and nonresident facilities will be required to register.

Similarly, a new law in Minnesota defines "outsourcing facility" as an entity thus licensed under federal law. However, Minnesota's HF 2402 includes outsourcing facilities as a type of manufacturer and these entities must be licensed as such with the Minnesota Board of Pharmacy. Outsourcing facilities must also show evidence of registration with FDA, and be inspected by an approved entity.

Legislation in Connecticut (HB 5262; PA 14-224) amended the state's Pharmacy Practice Act and Department of Consumer Protection statutes to require nonresident pharmacies to have a manufacturing license to ship non-patient-specific drugs into Connecticut. The law also requires nonresident pharmacies practicing sterile compounding to submit written proof that they have passed an inspection by an appropriate agency of the state in which the pharmacy is located to show compliance with USP standards.

> Several states passed laws addressing the practice of compounding non-patient-specific drug products for use in medical offices.

Legislation in Florida and Utah also addresses registration and inspection requirements for outsourcing facilities. Florida passed a law (HB 7077) requiring nonresident pharmacies or outsourcing facilities to obtain a special nonresident sterile compounding permit. Any resident or nonresident pharmacy or any outsourcing facility (whether in-state or nonresident) registered with FDA will also be required to have this permit. The bill also requires that facilities pass an inspection within six months for new permits and one year for renewals. Inspections may be conducted by the resident jurisdiction, by the Florida Board of Pharmacy, by an entity contracted by the Board, or by an entity approved by the Board in rule. For outsourcing facilities, Florida will accept an FDA inspection. The law will go into effect on October 1, 2014.

A new law in Utah includes provisions that would appear to possibly require licensure of nonresident outsourcing facilities as Class C pharmacies. Specifically, "Mail-Order Wholesale Drug Amendments" (HB 114) redefines a Class C Pharmacy, removing the wording "located in Utah," and replacing the definition as "a pharmacy that engages in the manufacture, production, wholesale, or distribution of drugs or devices in Utah." The bill was signed into law by Governor Gary Herbert on April 1, 2014, and became effective July 1, 2014.

Compounding for Office Use

Several states passed laws addressing the practice of compounding non-patient-specific drug products for use in medical offices.

Maryland's HB 1088 allows for limited compounding for office use for ophthalmologists, and requires that the identity of the patient is submitted back to the pharmacy after administration. In addition, another bill passed by the Maryland legislature (SB 1108) exempts mixing by oncologists, hematologists, and rheumatologists from the definition of compounding, and therefore also exempts them from having to comply with USP standards for compounding. The bill calls for a study group to report back on these exemptions.

Utah enacted a law (SB 77) that allows for office use compounding by pharmacies, provided the compounded preparation does not contain a controlled substance, it is labeled for office use only, and is used for administration by the practitioner within the office or facility, subject to rules promulgated by the Utah Board of Pharmacy. The law became effective on July 1, 2014.

Focusing on veterinary compounding, HB 1035 in Virginia provides that a veterinarian may dispense a 72-hour supply of a compounded drug product for a companion animal that is his or her patient, and when timely access to a compounding pharmacy is not available. The bill also requires the Virginia Board of Pharmacy to convene a work group to explore and clarify issues related to the compounding of drugs for human and veterinarian use.

More information about federal requirements for outsourcing facilities and for office use compounded products is provided in the cover story article "The Drug Quality and Security Act: What Does It Mean for Compounding Pharmacies?" in this *Newsletter*. NABP will continue to provide updates on new legislation and regulations for compounding practice.

Responses to Survey on Actions Related to Inappropriate Social Media Behavior Vary Among State Boards of Pharmacy

Misleading product claims posted by pharmacists on social media sites were likely to result in an investigation, agreed 78% of boards of pharmacy participating in a survey conducted by researchers at the McWhorter School of Pharmacy at Samford University. The purpose of the study was to determine how often boards of pharmacy receive complaints related to licensees' online behavior, and what types of online behaviors may prompt an investigation of a licensee. Survey participants answered questions about the most common types of unprofessional online behavior, whether such behaviors were addressed by current rules or policies, and whether any related actions had been taken. In addition, survey participants were asked how their board would respond to 10 scenario-based "vignettes" depicting questionable online behaviors. The survey questions and the varied responses may assist boards of pharmacy that are considering regulations and policies related to online behavior.

On behalf of the researchers, NABP distributed the survey via e-mail to boards of pharmacy located in the 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, eight Canadian provinces, Australia, and New Zealand. Responses were received from 14 boards of pharmacy, representing six of NABP's eight districts. Based on the range of responses received, the authors indicate that the sample is "reflective of current board of pharmacy policies both nationally in the US and internationally."

The researchers found that inappropriate use of the Internet for clinical practice (unapproved online pharmacy activity) and inappropriate online communication or contact with patients in a sexual or other inappropriate context were the most commonly reported kinds of unprofessional online behavior. The participating boards also reported that inappropriate behavior was most commonly identified through investigation of other complaints against the same licensee, or through direct reporting from other pharmacy personnel. For licensees who were disciplined for such conduct, the boards indicated the most common types of disciplinary action involved license revocation (21%), monetary fines (14%), and other measures such as temporary restriction of licensure (14%). Of the boards that responded to the survey, 60% reported that their board has been involved in managing a complaint regarding the online behavior of a licensee, and that disciplinary actions including revocation or suspension of license, letter of reprimand, and monetary fines have been taken.

Nearly four out of five (79%) of the boards who responded to the survey indicated that their board enforces existing rules and statutes that specifically address issues of Internet use and unprofessional behavior online. Almost all of the respondents (93%) indicated that there were no current plans to develop policies to address the issues of Internet use and online unprofessional behavior. However, the study also indicates "general uncertainty" among the boards when asked whether they had the ability to effectively deal with future cases of unprofessional online behavior from licensees.

When asked whether individual or constitutional rights would prevent their boards from pursuing warranted charges of unprofessional conduct online, 57% of respondents said no. Another 43% were "generally unsure." The majority of responding boards indicated that they were not concerned (46%) or only moderately concerned (46%) about incidents of unprofessional online behavior by pharmacists in their jurisdictions.

In addition to questions regarding current policies and recent actions, boards were asked to respond to 10 scenario-based vignettes

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depicting licensees' online behavior. Participants were asked to imagine each scenario was a real complaint that had been brought to their board and to indicate how likely their board would be to investigate using a five-point scale ranging from "very unlikely" to "very likely." For example, one vignette described misleading claims made about a compounded product on a pharmacist's website and resulted in a high consensus, with 78% of boards indicating that they would be "likely" or "very likely" to investigate further.

Vignettes with moderate consensus involved posting an image online of a patient receiving vaccine therapy without explicit consent (57%), images depicting inappropriate use of alcohol in the workplace (57%), and misrepresentation of professional credentials (64%). Vignettes with a low consensus for investigation involved complaints of discriminatory speech (28%), placement of potentially identifiable protected health information on a blog (43%),

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Legal Briefs

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permitted. She argued that she remediated her failed acute care APPE and thus, did not meet the School policy for dismissal. Specifically, the plaintiff argued that she remediated her failed acute care APPE by completing an APPE at a local children's hospital. The court rejected this argument, noting that the School policy requires remediation of a failed APPE *after* completion of all remaining APPEs. The court noted that while the remediation of an academic course (rather than an APPE) is allowed during the next available course offering, only allowing remediation of an APPE upon completion of all remaining APPEs is an academic program decision not to be disturbed by the court.

As a result of not recognizing the remediated APPE, the plaintiff did, indeed, have two F's on her academic record in one year and the School policy allowed for dismissal. The fact that the policy allowed opportunities for the plaintiff to remediate did not mean that she could not be dismissed from the program.

Boards of pharmacy require an educational component as a prerequisite to licensure. It is incumbent on the schools/programs to not only thoroughly vet applicants seeking admission into the school, but to also dismiss students who do not meet the academic and/or professional rigors of the program. Licensure eligibility and public protection are at stake.

Yang v. The Regents of the University of California, 2013 Cal. App. Unpub. LEXIS 6801 (App. Ct. CA 2013)

Model Act

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Additional Updates

After reviewing information about medication synchronization and noting that it may help benefit the patient by improving medication adherence, the Committee on Law Enforcement/Legislation recommended that the *Model Act* be updated to include a definition for the practice, and that NABP convene a task force to further review the issue.

As recommended by the committee, the *Model Act* was also updated to include language that would require annual inspections for pharmacies that compound sterile pharmaceuticals and require inspections not more than every 24 months for all others. In addition, the *Model Act* now includes language that would require the state board of pharmacy to collect the NABP e-Profile IDs of pharmacies and pharmacists-in-charge upon licensure renewal to help facilitate inspection processes and communication of information among boards.

The committee also suggested that the *Model Act* be updated to reference the National Council for Prescription Drug Programs' Universal Medication Schedule White Paper and that NABP should take a leadership role in the development of standardized labels, as there are varying labeling standards among states, which may negatively impact patient safety.

Lastly, the *Model Act* was updated in order to consolidate information in an effort to increase readability. Such changes include removing the Comments sections and placing that text as footnotes for ease of reference.

The updated *Model Act* will soon be available for free download in the Publications section of the NABP website at *www.nabp.net*.

Online Behavior

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placement of potentially identifiable information about a patient on a blog (0%), and unwelcomed advances directed toward a patient in an online chat room (28%). In addition to mixed responses to the vignettes, participating boards of pharmacy were also of mixed certainty about existing policies and statutes, with several boards indicating "not sure" in response to multiple questions about about existing statutes.

The authors concluded that the varied responses to the vignettes suggest that existing policies may vary widely among pharmacy boards, and that these results may indicate a lack of specific guidance on social media interactions by both licensing boards and national pharmacy organizations. The study concluded that dialogue on online professionalism should be expanded to obtain broader consensus on which behaviors are considered appropriate and which are inappropriate.

The results of the survey are available in "Social Media and Unprofessional Pharmacist Conduct: A Cross-Sectional Survey of Boards of Pharmacy," published in *Innovations in Pharmacy,* 2013, Volume 4, Number 3, available online at *www.pharmacy.umn.edu/innovations.*

.Pharmacy Supporter Advisory Committee Meets in July 2014

On July 21-22, 2014, the .Pharmacy Supporter Advisory Committee met at NABP Headquarters to review policies, discuss universal standards, and foster partnerships for the .Pharmacy generic Top-Level Domain (gTLD) Program. 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. 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. Coinciding with the .pharmacy gTLD launch, NABP expects to start accepting applications for Internet pharmacies interested in obtaining the .pharmacy domain in the fall 2014. More information about the .Pharmacy gTLD Program is available at *www.dotpharmacy.net.*

Back row pictured from left to right: Ronald F. Guse, BScPharm, College of Pharmacists of Manitoba; Mark Hardy, PharmD, North Dakota State Board of Pharmacy; Malcolm J. Broussard, RPh, Louisiana Board of Pharmacy; Luc Besançon, MS, PharmD, International Pharmaceutical Federation; Walt Slijepcevich, RPh, Pfizer Inc; Bruce Longbottom, JD, Eli Lilly and Company; LCDR Eleni Anagnostiadis, RPh, Food and Drug Administration; Tucker Johns, FairWinds Partners, LLC; Josh Bourne, FairWinds Partners, LLC; and Michael Kitcoff, MBA, Neustar, Inc. Front row pictured from left to right: Virginia Herold, MS, California State Board of Pharmacy; Jeff Neuman, JD, Neustar, Inc; Rashi Rai, Merck & Co, Inc; Isabelle Adenot, Ordre National des Pharmaciens; Kasie Gorosh, JD, Alliance for Safe Online Pharmacies; and Tatiana Luchian, LegitScript.

VPP Continues to Assist Boards with Nonresident Licensure Decisions; More Than 170 Facilities Inspected

Verified Pharmacy Program™ (VPP™) inspection reports continue to be available through the secure inspection sharing network in an effort to assist member state boards of pharmacy in making appropriate licensure decisions for nonresident pharmacies. As of press time, at least 175 nonresident facilities have either been inspected or are scheduled to be inspected. The 175 facilities were or will be inspected for the following:

- 81 facilities for nonsterile compounding requirements;
- 17 pharmacies for sterile compounding requirements; and
- 57 pharmacies for both sterile and nonsterile compounding requirements.

Twenty pharmacies were not compounding and received only the general pharmacy inspections.

Developed by NABP in partnership with member boards of pharmacy, VPP facilitates the communication of important inspection and licensure information between the state boards of pharmacy and serves as an information hub that provides verified data to support boards' licensure processes for nonresident pharmacies.

NABP has created e-Profiles containing basic licensure and demographic information on nearly every pharmacy in the United States. It is anticipated that by the end of 2014, boards will be able to access complete pharmacy e-Profiles, including inspection reports and related licensure information, directly through the VPP section of Board e-Profile Connect.

For more information about VPP or the inspection sharing network, contact the Member Relations and Government Affairs Department at GovernmentAffairs@nabp.net. Additional information is also available in the Programs section of the NABP website at *www.nabp.net.*

Board of Pharmacy Staff Attend Annual Program Review and Training to Network and Learn About NABP Programs and Services

To further familiarize themselves with NABP programs and services, board of pharmacy staff – both new employees and those seeking a refresher course – attended the NABP Annual Program Review and Training session on July 22-23, 2014, at NABP Headquarters.

Ten participants representing nine state boards of pharmacy attended this two-day interactive session that provided board staff with information about NABP's examinations, licensure transfer, accreditation programs, and more. In addition, these informational sessions provided board staff with a unique opportunity to network with other board of pharmacy staff.

The event began with a group dinner on July 22, which provided the board of pharmacy staff the opportunity to network with each other and NABP representatives.

On July 23, both groups convened for breakfast and a brief welcome. After the welcome, the educational portion of the meeting began, which provided attendees with an overview of the following NABP programs and services:

- Electronic Licensure Transfer Program® (e-LTP™), license verification, e-mail, and data transfer functions
- NABP Clearinghouse/ National Practitioner Data Bank (NPDB) reporting
- Verified Pharmacy Program™ (VPP™)
- Application and certification processes for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program, including information on the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and the Pre-FPGEE®
- North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®), including eligibility and score reporting and the Pre-NAPLEX®
- Pharmacist Assessment for Remediation Evaluation™ (PARE™)
- Pharmacy Curriculum Outcomes Assessment® (PCOA®)
- CPE Monitor® service and board access through Board e-Profile Connect
- AWAR$_X$E® Prescription Drug Safety Program
- Verified Internet Pharmacy Practice Sites® (VIPPS®), Vet-VIPPS®, Verified-Accredited Wholesale Distributors® (VAWD®), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation programs, and the NABP e-Advertiser Approval℠ Program
- Internet Drug Outlet Identification program and .pharmacy generic Top-Level Domain (gTLD)
- NABP PMP InterConnect®
- NAR$_X$CHECK®
- Professional Affairs
- Member Relations and Government Affairs
- Communications

For more information about future training sessions or to obtain training materials provided at the session, please contact NABP at custserv@nabp.net.

Networking Opportunities
(Above) The Program Review and Training offered attendees the opportunity to network with other board of pharmacy staff about important issues related to their fields. Pictured above: Hannah Abel, administrative coordinator, Louisiana Board of Pharmacy (left) and Beth O'Halloran, RPh, individual licensing manager, Virginia Board of Pharmacy (right).

Board of Pharmacy Staff Get Informed on NABP Programs and Services
(Below) During the training, attendees were provided with informational materials detailing all of NABP programs and services to accompany the presentations made by NABP staff throughout the day. Pictured below: Penny Woodberry, staff officer, Mississippi Board of Pharmacy (left) and Jennifer Mitchell, MS, executive secretary, Arizona State Board of Pharmacy.

Two Cleveland-Based Top Hospitals to Deploy NAR$_X$CHECK, Making PMP Data More Accessible to Providers

Building on the success of pilots with a number of hospitals in Indiana and Ohio, NAR$_X$CHECK®, the software tool that generates risk-based scores reflecting a patient's controlled substance (CS) prescription medication history, will soon be deployed into the provider workflow of two of the largest hospitals in Cleveland, OH – Cleveland Clinic and MetroHealth.

Top Hospitals Deploy Software

Beginning in fourth quarter 2014, NAR$_X$CHECK will be made available to prescribers at Cleveland Clinic – one of the nation's top-rated hospital care systems – to assist its health care providers in making the most appropriate prescribing and dispensing decisions. Known by many independent organizations for the quality of patient care it provides, Cleveland Clinic is a nonprofit, multispecialty academic medical center that integrates clinical and hospital care with research and education. Cleveland Clinic was highlighted as one of the "U.S. News Best Hospitals 2013-2014," earning honors as the 4th ranked hospital in the United States. In addition, Cleveland Clinic has earned the number one spot as the top hospital for cardiac care for the past 20 years. Ten other Cleveland Clinic specialities were also ranked in the Top 10, including urology, diabetes and endocrinology, and gastroenterology.

Also helping Cleveland Clinic stand out among the nation's top health care systems is the hospital's approach to improving patient care and patient satisfaction through utilizing the latest tools and technologies. This includes its use of Epic as its primary electronic health record (EHR) vendor. Epic specializes in integrated software for health care providers that supports functions related to patient care, including registration and scheduling, and clinical systems for doctors, nurses, emergency personnel, and other care providers.

> [NAR$_X$CHECK] will soon be deployed into the provider workflow of two of the largest hospitals in Cleveland, OH – Cleveland Clinic and MetroHealth.

With the integration of NAR$_X$CHECK through Epic, Cleveland Clinic, providers will be able to seamlessly access a patient's CS medication history through a single click. The integration eliminates the need for a separate login to the state's prescription monitoring program (PMP) and the manual search function to obtain a patient's medication history. Now, with a single click, providers will be able to obtain access to a patient's risk assessment score, CS history over the last two years, and complete records of patient's CS prescriptions, as well as providers, and pharmacies, and additional data analysis.

NABP notes that the use of NAR$_X$CHECK with Epic can be replicated at other Epic facilities, which is good news for health care systems using Epic as their primary EHR vendor nationally. More information about NAR$_X$CHECK and Epic integration is available in the June-July 2014 *NABP Newsletter*.

In addition to the Cleveland Clinic integration, NAR$_X$CHECK will also soon be deployed into the provider workflow of MetroHealth. This Cleveland-based hospital is one of the largest, most comprehensive health care providers in northeast Ohio and serves the medical needs of the greater Cleveland community. MetroHealth's main campus – MetroHealth Medical Center – receives nearly 900,000 visits each year in its outpatient centers, and exceeds 104,000 patient visits each year to the emergency department. In addition to its main campus, MetroHealth also has an additional 16 health centers and ambulatory clinics throughout the Cleveland area in Cuyahoga County. Similar to the implementation at Cleveland Clinic, NAR$_X$CHECK will be integrated directly into the EHR software at MetroHealth, allowing providers to easily access patients' CS medication history.

PMP Legislation

The improved delivery of PMP data into provider workflow has become imperative for many health care systems as they seek to meet the nationally growing mandatory PMP use requirements. Responding to the prescription drug abuse epidemic, many states are now mandating that providers access PMP data prior to prescribing or dispensing a CS. Currently, 49 states have established or have passed legislation allowing the establishment of some form of PMP. Of those states, 18 states require PMP use under certain circumstances; 15 states require mandatory PMP registration, and five states are considering, or have considered legislation that would prompt some form of PMP use requirement. Most recently, Ohio passed HB 341, which mandates the review of PMP data before initially prescribing a CS prescription. The law goes into effect on April 1, 2015.

NAR$_X$CHECK has generated a great deal of interest among health care providers and may assist providers in meeting these

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AWARXE Website Now Mobile Friendly; New Video PSAs Available Soon

The AWARXE® Prescription Drug Safety Program's website is now mobile friendly following the incorporation of responsive design elements, which automatically adjust content to fit any screen. These updates improve accessibility and readability for people who access the website using smartphones, tablets, and other mobile devices. Mobile users who visit the website can now navigate the website and access important information and other AWARXE resources as easily as readers using a desktop or laptop computer.

In addition, AWARXE is currently developing a new resources section of the website, which will provide a central location for consumers, pharmacists, and other health care providers to download flyers and other AWARXE materials. Currently, these materials may be requested by sending an e-mail to AWARERX@nabp.net. Additional information on this and other website enhancements will be provided in future updates.

New Video PSAs

The AWARXE program is producing eight new public service announcement (PSA) videos that will feature important facts about the prescription drug abuse epidemic and the risks of buying medication from rogue Internet drug sellers. Seven 15-second videos will be aimed to alert viewers to a medication safety fact, to raise awareness about prescription drug abuse and dangerous counterfeit drugs. One video will highlight the link between prescription opioid abuse, heroin use, and opioid overdoses. Another will indicate that counterfeit medications, which are often sold online, may contain too little, too much, or the wrong type of active ingredient, which could make the medication ineffective and dangerous to take.

In addition, because rogue Internet drug sites contribute to the prescription drug abuse epidemic by distributing controlled substance medications without requiring valid prescriptions, a double-length 30-second PSA will feature educational information about the new .pharmacy generic Top-Level Domain (gTLD). The timely video will help consumers understand that soon-to-be-available website addresses ending with ".pharmacy" are safe and legitimate. Additional information about NABP's new .Pharmacy gTLD Program is available at *www.dotpharmacy.net*.

The PSA videos will be released in September 2014 and may be accessed through the AWARXE YouTube channel, and will be featured through AWARXE Facebook and Twitter posts, as well as during future awareness and social media campaigns.

GET INFORMED | *WWW.AWARERX.ORG*

Newly Approved e-Advertisers

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

Denver Health and Hospital Authority
www.denverhealth.org

Dobbs Ferry Pharmacy
www.dobbsferrypharmacy.com

Erene Limited, LLC, dba Apotheca Compounding Pharmacy
www.apothecapharmacy.ca

Naz's Pharmacy No 3 Ltd
www.yeswellness.com

PharmEZ Medical, LLC
www.pharmez.com

Select Care Benefits Network
www.scbn.org

Walmart Stores, Inc, dba samsclub.com
www.samsclub.com

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

Vermont Restricts Prescribing of Single-Ingredient Hydrocodone Products

On April 3, 2014, the Vermont Department of Health (DH) issued an emergency rule to restrict how health care providers prescribe certain single active ingredient hydrocodone products such as Zohydro™ ER. Among other restrictions, the new rule requires prescribers to:

- Conduct and document a thorough medical evaluation;
- Conduct and document a risk assessment;
- Document in the medical record that the prescription of a hydrocodone medication without an abuse-detterent formulation is required for the management of pain (ie, nothing else will effectively manage the severe pain);
- Receive a signed informed consent form including information from the drug insert;
- Receive from the patient a Chronic Controlled Substance Treatment Agreement that shall include conditions such as urine screening, pill counts, safe storage and disposal, and other appropriate conditions as determined by the prescriber;
- Query the Vermont Prescription Monitoring System;
- Determine a maximum daily dose or a "not to exceed value" for the prescription to be transmitted to the pharmacy; and
- Schedule and undertake periodic follow-up visits, evaluations, and referrals.

The complete text of the rule is available on the Vermont DH website at *http://healthvermont.gov/regs/documents/hydrocodone_emergency_rule.pdf.*

Collaborative Pharmacy Practice Law Adopted in Tennessee

The Tennessee General Assembly voted unanimously to give Tennessee-licensed pharmacists the ability to enter into collaborative pharmacy practice agreements with prescribers to improve the health, safety, and quality of care for their patients.

According to the Tennessee Pharmacists Association, studies have consistently shown that patient health improves significantly when pharmacists work in collaboration with physicians and other health care providers to manage the care of patients. In the past, the Pharmacy Practice Act has included the ability to obtain a "medical order" for vaccines, medication therapies, and other patient care services. On April 29, 2014, Governor Bill Haslam signed this bill into law as Public Chapter (PC) 832, which became effective on July 1, 2014. Under the law, "collaborative pharmacy practice" is defined as:

> the practice of pharmacy whereby one (1) or more licensed pharmacists licensed in this state, jointly and voluntarily work with one (1) or more prescribers licensed in this state, under a collaborative pharmacy practice agreement to provide patient care services, to achieve optimal medication use and desired patient outcomes.

The law also defines "collaborative pharmacy practice agreement" as:

> a written and signed agreement entered into voluntarily between one (1) or more licensed pharmacists in this state, and one (1) or more prescribers licensed in this state, each of whom is in active practice in this state providing patient care services in this state, that provides for collaborative pharmacy practice, as defined by law.

Furthermore, according to Section 4, Tennessee Code Annotated, Title 63, Chapter 10, Part 2 (amended), the Tennessee Board of Pharmacy will promulgate rules:

> establishing appropriate minimum standards applicable for provisions to be contained in any collaborative practice agreement, including, but not limited to, provisions regarding drugs or drug categories such as controlled substances covered under the collaborative pharmacy practice agreement.

The complete amendment and PC may be viewed on the Tennessee Department of State-Division of Publications website at *http://tnsos.org/acts/PublicActs.108.php?showall.*

Kansas Pharmacy Practice Act Now Includes Collaborative Drug Therapy

Signed by Governor Sam Brownback on April 11, 2014, and effective July 1, 2014, Amendments to KSA 65-1626a expanded the definition of the practice of pharmacy to include the performance of collaborative drug therapy management. A pharmacist in Kansas may perform pharmaceutical-related patient care when physicians delegate those responsibilities through a collaborative practice agreement. Pharmacists and collaborating physicians will need to have a written protocol that outlines conditions or limitations to the collaborative practice agreement. Pharmacists may not act outside of their scope of practice, including altering physicians' orders or directions, diagnosing and prescribing drugs, or practicing independently. Physicians are responsible for the care of the patient at diagnosis and supervising the pharmacist throughout the drug therapy management process. The collaborative practice agreement must also be within the physicians' scope of practice and appropriate for the pharmacist's training and experience.

A complete summary of the amendments and revisions to the Kansas Pharmacy Practice Act is included in the June 2014 *Kansas State Board of Pharmacy State Newsletter*, available in the Publications section of the NABP website at *www.nabp.net.*

Around the Association

Executive Officer Changes

- **Robert "Rob" Kendall** is now serving as director of the Indiana Board of Pharmacy, replacing Gregory Pachmayr, JD, MPA.

Board Member Appointments

- **Percy Malone, PD,** has been appointed a member of the Arkansas State Board of Pharmacy. Malone's appointment will expire June 30, 2015.
- **Goar Alvarez, PharmD, CPh, FASCP,** has been appointed a member of the Florida Board of Pharmacy. Alvarez's appointment will expire October 31, 2017.
- **Patrick Greene, Esq,** has been appointed a public member of the Pennsylvania State Board of Pharmacy. Greene is serving at the discretion of the appointing body.

Board Member Reappointments:

- **Anne Gruening** has been reappointed a public member of the Alaska Board of Pharmacy. Gruening's appointment will expire March 1, 2018.

Board Officer Changes:

The Arkansas State Board of Pharmacy has elected the following officers to the Board:

- **Larry Ross, MSEd,** President
- **Stephanie O'Neal, PD,** Secretary
- **Lenora Newsome, PD,** Vice President

The North Carolina Board of Pharmacy has elected the following officers to the Board:

- **Robert "Joey" McLaughlin, Jr, RPh,** President
- **Ellis Marks, RPh,** Vice President

The Ohio State Board of Pharmacy has elected the following officers to the Board:

- **Michael Moné, JD, RPh, FAPhA,** President
- **Kilee Yarosh, RPh,** Vice President

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

- **Ellen Shinaberry, PharmD,** Chairperson
- **Empsy Munden, RPh, CGP,** Vice Chairperson

NAR$_X$CHECK

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stringent legislative requirements. In the last two years, NAR$_X$CHECK has delivered over 8.5 million NAR$_X$CHECK Scores and Reports to providers, and has facilitated interoperability in health care systems in two states with plans for pilots in an additional five states by the end of 2014.

Future Projects

In an effort to ensure NAR$_X$CHECK software tools are providing the most value to health care providers accessing PMP data to assist with appropriate prescribing and dispensing decisions, NABP Foundation™ and The Jewish Hospital – Mercy Health in Cincinnati, OH, are partnering to conduct research on provider use of NAR$_X$CHECK and the clinical outcomes that follow. The research will provide insight into how workflow-ready access to PMP data impacts patient care. Updates on this research project will be provided in future NABP communications.

NAR$_X$CHECK is currently only configured to work with select state PMPs, and is available as a subscription-based service to health care providers either registered with PMPs in participating NABP PMP InterConnect® states, or agreeing to ensure compliance with PMP laws and regulations when providing access to users.

More information about NAR$_X$CHECK and its services may be found at *www.narxcheck.com.*

Oregon Board Wins Survey of Pharmacy Law Luncheon Drawing

NABP would like to congratulate the Oregon State Board of Pharmacy for winning the 2015 *Survey of Pharmacy Law* Luncheon Drawing. The Board was awarded $175 toward a Board member and staff luncheon for returning updates to the *Survey* by the July 16 deadline. These important updates are requested annually by NABP from all boards of pharmacy for inclusion into each updated issue of the *Survey.* NABP would like to thank all boards for their participation, which makes the publication a valuable resource for many.

Revised and published each December, the *Survey of Pharmacy Law* serves as a convenient reference source for individuals seeking an overview of laws and regulations that govern pharmacy practice in 53 jurisdictions. For more information about the *Survey,* visit the Publications section of the NABP website at *www.nabp.net.*

Lidocaine Should Not Be Used to Treat Teething Pain in Children

Food and Drug Administration (FDA) is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates an FDA Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication. More information may be found in the safety announcement at FDA's website, *www.fda.gov/Drugs/DrugSafety/ucm402240.htm.*

Hidden Drugs in Bee Pollen 'Supplements', FDA Warns

Noting that more than 50 adverse event reports associated with the use of certain bee pollen products have been submitted to FDA, the agency released a Consumer Update in June 2014, warning that such products, marketed as dietary supplements, often contain hidden drug ingredients that can be harmful. Adverse events reported in association with bee pollen products include at least one death.

FDA recently warned consumers to stop taking Zi Xiu Tang Bee Pollen after multiple samples of the supplement were found to contain both sibutramine and phenolphthalein. The Consumer Update names 11 other products that include bee pollen in the list of ingredients and have been found to contain hidden sibutramine and/or phenolphthalein.

Consumers are advised to use caution before purchasing any supplements marketed for sexual enhancement, weight loss, and body building. Consumers and health care providers are encouraged to report any adverse events or quality problems experienced with the use of these products to FDA's MedWatch Adverse Event Reporting Program. The Consumer Update can be accessed in the Consumer Updates section of the FDA website at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm401676.htm.*

Coalition Reports on Acetaminophen Overdose

Reviewing the dosing behaviors that can lead to acetaminophen overdose, a report and educational resource aimed at encouraging safe and appropriate use of the United States' most common drug ingredient was released by the Acetaminophen Awareness Coalition in summer 2014. "Acetaminophen: How It's Used, Preventing Overdose and What We Can Do to Promote Safe Use" reviews research related to common dosing mistakes that lead some people to exceed the labeled maximum daily dose of 4,000 mg a day. The report finds that 72% of those who exceeded the maximum dose took a new dose too soon, and that 59% were using multiple products containing acetaminophen at the same time. The report also highlights recent research showing that educational efforts are having an impact on consumer knowledge and perceptions surrounding acetaminophen safety.

More information on safe acetaminophen use is available on the Know Your Dose website, *www.knowyourdose.org.*

DSCSA Draft Guidance Webinar Available to Assist Small Businesses

The FDA Center for Drug Evaluation and Research Small Business and Industry Assistance hosted a webinar to provide an introduction and overview of FDA's recently issued draft guidance, "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification." The webinar shared information for small pharmaceutical businesses and industry members about FDA, the Drug Supply Chain Security Act (DSCSA) guidance, and basic drug regulation. A recording of the webinar is posted on the FDA website at *www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm402366.htm.*

Newly Accredited DMEPOS Facility

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

Gloversville Pharmacy
Gloversville, NY

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

nabp newsletter

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