Implementing the Drug Quality and Security Act

On Nov. 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA), amending the Federal Food Drug, and Cosmetic Act (FDCA). The act addresses issues related to oversight of the practice of drug compounding, and incorporates a national prescription drug “track and trace” system inclusive of standards for prescription drug wholesale distributors and third-party logistics providers (3PLs).

It establishes a category of “outsourcing facilities” under which pharmacies conducting large-scale compounding of sterile drugs could voluntarily register and become subject to oversight by the Food and Drug Administration (FDA). It also imposes certain labeling requirements for compounded products. Traditional compounding pharmacies will remain under the oversight of state boards of pharmacies, as the law strives to improve communication between federal and state entities.

The measure also preempts state laws that establish requirements for tracing drugs through the distribution system that are inconsistent with or more stringent than, or in addition to, any ‘track and trace’ standards of the enacted provisions.

The FDA has begun the implementation process with the release of several guidance documents related to compounding practices:

- FDA Implementation of the Compounding Quality Act
- Compounding and the FDA Questions and Answers
- Interim Product Reporting for the Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
- Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

State/Federal Communications: Conclusions from an Inter-governmental Working Meeting March 2014

The DQSA requires the FDA and state boards of pharmacy to collaborate in their efforts to monitor compliance of compounding pharmacies. State regulators will not only have oversight of compliance with state laws governing compounding, but will be actively engaged with the FDA to monitor and enforce compliance with the DQSA. During an inter-governmental meeting of representatives from the state boards of pharmacy, the National Association of Boards of Pharmacy (NABP), the Association of State and Territorial Health Officials (ASTHO), and the National Conference of State Legislators (NCSL) and the FDA in March 2014, participants discussed how DQSA requirements would affect the existing systems for oversight of pharmaceutical compounding.

Barriers to Information Sharing

State and federal governments must develop a framework for information-sharing to avert and respond to adverse events. Although the Freedom of Information Act (FOIA) provides for disclosure of many FDA records with the public, there are exemptions to the FOIA, as well as other laws and regulations governing disclosure, under which the FDA either can or must withhold information (e.g., confidential commercial, trade secret, pre-decisional, personal privacy and law enforcement records). Certain non-public information can be shared with state officials who are either commissioned by FDA or have signed a “20.88” confidentiality agreement.

State officials expressed concerns that the current framework for sharing information is too limiting. For example, many states operate under their own disclosure laws, such as “sunshine” laws, which can present challenges to entering into 20.88 agreements or complying with federal non-disclosure rules. In addition, the commissioning route for disclosure was
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described as limiting because the person who is commissioned cannot further disclose the information to their superiors if they are not commissioned, or use it to bring a state enforcement action.

Furthermore, the 20.88 agreements contain strict non-disclosure language that states the disclosure of certain shared information could be a criminal violation of federal law. Some state officials are reluctant to enter into 20.88 agreements because of this. Some state officials noted that although the states could conduct their own inspections, it is not efficient for the states to have to duplicate FDA inspection efforts to obtain information necessary to bring an enforcement action. They cited duplicating product sampling and laboratory testing of the samples as one example of this. They also cited the need to obtain the information in a timely way to support immediate action when necessary. Several state officials indicated they need more clarity on what constitutes confidential commercial information (CCI).

FDA and state officials agreed to work together to explore better ways to share information consistent with federal and state law. Specifically, FDA will reexamine the language in 20.88 agreements to determine whether it can be modified in any way to remove disincentives to signing such agreements. FDA also will work with the states to determine what types of information gathered during or after an FDA inspection might be necessary for a state to take rapid enforcement action to protect the public health, and explore whether that information can be made available more quickly so the states can use it.

FDA will reexamine the language in 20.88 agreements to determine whether it can be modified in any way to remove disincentives to signing such agreements. The FDA also plans to work with states to determine ways to streamline communications; for example, delegating one point of contact for coordination of inspections while providing advanced notification of scheduled inspections.

State Legislation/Regulation

Some states are moving toward comprehensive legislation to provide oversight of compounding, while others are waiting for the FDA to implement the DQSA before changing their own laws. Meanwhile, some states have enhanced their pharmacy board capacities through additional funding and staffing. Some of the issues that states are grappling with include:

1. whether to permit office use compounding,
2. labeling of compounded products,
3. licensure requirements for firms registered with the FDA,
4. exemptions for ophthalmologists and oncologists, and
5. what quality standards to impose on sterile compounding (e.g., most require compliance with USP 797 standards).

State officials also reported that they use terminology, definitions, and categories in their legislative and regulatory frameworks for pharmacy compounding that differ from the FD&C Act. Some states have restructured terminology, definitions and categories to align with those established under the FD&C Act.

The outcome of the meeting discussion is that much still needs to be done to remove barriers to a collaborative oversight program including training of state

Interim Guidance for Human Drug Compounding Outsourcing Facilities

In July of 2014, the FDA issued interim guidance describing their expectations regarding compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs and register with the FDA as
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outsourcing facilities. The guidance is intended to be taken only as recommendations, unless specific regulatory or statutory requirements are cited. It makes nonbinding recommendations on the following issues:

1. Design of Facilities Used in the Manufacture, Processing, Packaging, or Holding of Drug Products,
2. Control Systems and Procedures for Maintaining Suitable Facilities,
3. Environmental and Personnel Monitoring,
4. Controls Over Equipment Used to Compound, Containers, and Closures,
5. Quality of Care Components,
6. Production and Process Controls,
7. Release Testing,
8. Laboratory Controls,
9. Stability/Expiration Dating,
10. Packaging and Labels, and
11. Quality Assurance Activities/Complaint Handling.

The FDA intends to develop specific CGMP regulations applicable to outsourcing facilities. Until those new regulations are promulgated, this guidance describes FDA’s expectations regarding outsourcing facilities and the CGMP requirements.

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