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Pharmacy Compounding Legislation and Implementation

National Conference of State Legislatures Fall Forum Meeting

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Summary of Presentation

- Overview of legislation
- How states and FDA can work together

Drug Quality and Security Act (DQSA)

- Amends the Federal Food, Drug, and Cosmetic Act (FDCA) with respect to human drug compounding and drug supply chain security
- Title 1, the *Compounding Quality Act*, contains provisions relating to the oversight of compounding of human drugs

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Section 503A

- 503A describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA requiring:
  - FDA approval prior to marketing (section 505)
  - Compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); and
  - Labeling with adequate directions for use (section 502(f)(1))
- Pharmacies that qualify for the exemptions are primarily regulated by the states, although some Federal requirements still apply (e.g., no insanitary conditions)

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Compounding Quality Act

- Removes certain provisions from section 503A related to solicitation of prescriptions and advertising and promotion that were found to be unconstitutional by the U.S. Supreme Court in 2002.
- Clarifies that section 503A will be applicable to compounders nationwide
- Adds new section 503B: “Outsourcing Facilities”

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New Category of Outsourcing Facilities

- Hospitals and other health care providers that have patients with medical needs that cannot be met by FDA-approved products can purchase compounded drugs from an outsourcing facility, which is subject to CGMP requirements and increased federal oversight.

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A Registered Outsourcing Facility

- Must comply with CGMP requirements;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products it compounds
- Beginning 10/1/14, must pay user fees at the time of registration and annually, and upon certain reinspections

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Outsourcing Facility

- Is engaged in the compounding of STERILE drugs
- Has elected to register as an outsourcing facility
- Complies with all of the requirements in section 503B
- NOT required to be a licensed pharmacy, but compounding must be by or under the direct supervision of a licensed pharmacist
- May or may not obtain prescriptions for identified individual patients

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What about a pharmacy that doesn't register as an outsourcing facility?

- If a compounder chooses NOT to register as an outsourcing facility, the compounder could qualify for the exemptions under section 503A of the Act
- **Otherwise, it would be subject to all of the requirements in the FDCA applicable to conventional manufacturers.**

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The New Law Leaves Some Issues Unresolved

- Compounders may seek to hide out in the traditional compounding category and escape detection
- The lack of clarity in section 503A over whether a state or FDA has primary responsibility over a particular pharmacy remains

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Working With The States

- State partners participated in many recent inspections of compounders; some were initiated at a state's request
- December, 2012, FDA convened a 50 State meeting
- States provided suggestions, and one idea discussed was the need for clarifying legislation
- FDA to hold another 50 State meeting in the first quarter of 2014 to discuss plans for implementing the law and get input from the states on how best to partner to improve oversight of the compounding industry

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States Have A Critical Role

- Identify pharmacies that may be in violation of the law because:
  - They may be making drugs in insanitary conditions
  - They may not be meeting the conditions in section 503A or 503B necessary to qualify for the exemptions
    - for example, if they are making drugs that appear on the list of drugs withdrawn or removed from the market for safety reasons or using bulk drug substances that are not from registered establishments

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Enhanced Communication with States

- The new law requires the Secretary to establish a mechanism to receive submissions from state boards of pharmacy concerning certain actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to section 503A
  - FDA to consult with NABP on implementation of this section
- State boards of pharmacy must be notified when the Secretary receives certain state submissions or makes a determination that a compounding pharmacy is acting contrary to section 503A

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FDA Can Receive Submissions Now

- FDA has set up a mailbox for states: statecompounding@fda.hhs.gov
- FDA will acknowledge submissions and tell states how they were resolved
- FDA will work with NABP on how the process should work going forward

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Memorandum of Understanding With States

- To qualify for the exemptions under section 503A, a compounding pharmacy cannot ship compounded drugs interstate that exceed 5% of the total prescription drugs dispensed or distributed unless the state in which it is located has signed an MOU with FDA
- The MOU must address the distribution of inordinate amounts of compounded drug products interstate and provide for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside the state

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Memorandum of Understanding

- In consultation with NABP, FDA will develop a standard MOU that states can sign
- FDA does not intend to enforce this provision until 90 days after the MOU is available to sign.

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Inspection and Enforcement: Moving Forward

- FDA has been conducting inspections of compounding pharmacies for cause (in response to serious adverse event reports, reports of quality problems, and state requests)
- FDA has also been conducting proactive inspections to identify pharmacies with deficient sterile practices
- FDA will continue these efforts as available resources permit

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