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Sterile Compounding: Where Do We Stand?
Sterile Compounding: Highlights of the New Law

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Please explain the difference between Sections 503A & 503B of the Drug Quality and Security Act.
When a 503B outsourcing facility is registered with FDA, is a pharmacist required to be on site to oversee the sterile compounding processes?
Can you clarify: does Section 503B apply to both sterile and non-sterile compounding?

How does the new law apply to the preparation of investigational drugs?
We are an inpatient pharmacy that mixes BCG for the hospital’s own urology practice. Is it OK to do so? Or do the office personnel have to mix the BCG before administering to their in-office patient.
Please discuss further how Section 503B of the new law applies to central-fill hospital pharmacies that compound *only* for facilities under common ownership and *not* for distribution across state lines.
Would allergy antigen testing kits be required under Section 503B of the Drug Quality and Security Act?
I seemed to hear contradictory information about whether full cGMPs are required for outsourcing facilities that are registered under Section 503B. Can you clarify?
- Under Section 503B, does an outsourcing facility need to apply for an NDC number?
- How long must they maintain a product for sterility testing?
How does the use of USP-grade vs. commercial-grade chemicals affect high-risk compounding?
How do hospitals obtain instructions to compound preservative-free ophthalmic sterile preparations?
USP <797> does not have adequate standards to ensure compounding of either single-dose or multiple ophthalmic sterile drugs. What is the best source or reference to use?
How can a pharmacy obtain a list of hazardous drugs?
- If nuclear pharmacies are used by the hospital, what should the hospital pharmacy have on file?
- Should the pharmacy visit the nuclear facility that provides the outsourced product and inspect?
State Boards of Pharmacy and NABP Efforts Related to the New Law
What is meant by “nonresident pharmacy” in a particular state?
Which 2 states require pharmacies to be in the Verified Pharmacy Program (VPP)?
Due to lack of resources, many state boards of pharmacy do not conduct on-site inspections of existing pharmacies. In many cases, these BOPs rely on a self-assessment by the Pharmacist-in-Charge. How does this affect the VPP program?
What is the difference between VPP and VIPPS?

What is the cost of VPP?
Can anyone access the VPP information or only state boards of pharmacy?
How can a pharmacist become an NABP compliance officer?
Can hospitals or pharmacists gain access to NABP’s inspection reports after its oversight of compounding facilities?
I work with many pharmacies in both acute care and alternate-site settings throughout the U.S. and have noticed that only a minority of pharmacists supervising sterile compounding operations have the education, experience, or skill set to perform this responsibility effectively. Therefore, they tend to rely on the most experienced pharmacy technician or the way they have always done things.

- What is FDA, NABP, or others doing to address this weakest link in our sterile compounding system?
How can we obtain the assessment guide used by the NABP to inspect compounding pharmacies?
Outsourcing of Sterile Compounding: The Experience at UC Health
How are extended stabilities validated, supported, and documented by outsourcing pharmacies?
Are outsourcing facilities required to use pharmacists for compounding their sterile products?
What ongoing quality assurance should facilities require from an outsourcing facility?

- For non-sterile, such as LET gel
- For sterile, such as phenol
Please discuss further the regulatory requirement that each facility must perform a stability study. Is this a facility policy, state rule, or law?
In reference to the outsourcing facilities used by UC Health hospitals:

- Were their policies, procedures, and practices significantly better than those that are commonly found in hospitals?
Just because a facility is registered with the FDA does not ensure that an inspection has taken place. Also, cGMPs are complex, and compliance may require months or even a year or two. Do you wish to comment?