



Outsourcing Facility Registration Issues

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An Outsourcing Facility

- Is defined as a facility that:
 - 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
- In addition, an outsourcing facility:
 - is 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

Issues

- Different treatment of outsourcing facilities under different state laws:
 - Some states require a pharmacy license; other states will not license them as pharmacies
 - Some states are calling them “wholesalers”; others are calling them “manufacturers”
 - How will the guidance for outsourcing facilities affect state approaches to regulation of outsourcing facilities?
- What does “under the supervision of a licensed pharmacist” mean?
 - Where does the pharmacist have to be licensed and located?
 - What does this mean for a foreign outsourcing facility?

Timing of Re-registration

- Fiscal year 2015 registration valid from 10/1/2014 (or whenever they registered) through 12/31/2015
- Most outsourcing facilities did not re-register and pay fees by the 12/31/2014 deadline, so they came off the list for some period of time
- How will facilities be regulated if there is a period during which they are not registered as a outsourcing facilities?