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?