Compounding Special Issues

Inter-governmental Working Meeting on Drug Compounding

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Gail Bormel
Office of Compliance
CDER/FDA

Compounding Special Issues

- Hospital / Health-System Compounding
- Compounding for Long Term Care Facilities
- New /Complex Compounding Practices
- Compounding in Rural Areas
- Compounding of Radiopharmaceuticals

Panel Presentations

- **Gail Bormel, Director, Division of Prescription Drugs, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA**
  - Hospital and Long Term Care Compounding
- **Kari Shanard-Koenders, Executive Director, South Dakota Board of Pharmacy**
  - Long Term Care Compounding
- **Ruey Ju, Senior Advisor for Compounding Compliance and Enforcement, CDER/FDA**
  - Drugs that are difficult to compound, compounded combination products
- **Steve Hart, Executive Director, Kentucky Board of Pharmacy**
  - New or complex compounding technologies and practices
  - Compounding in rural areas
- **Sara Rothman, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA**
  - Compounding of radiopharmaceuticals

Compounding for Hospitals and Long Term Care Facilities

- Stakeholders have expressed concerns that some of FDA's proposed **policies regarding patient-specific prescriptions** for compounded and repackaged drugs could impede practices in the hospital and long term care settings.
- FDA is considering how to address these concerns
- In April 2016 FDA issued a draft guidance that proposes an agency policy for applying section 503A's prescription requirement to drugs compounded by hospital or health system pharmacies.
- In addition, in the agency's January 2017 final guidance on repackaged drugs, FDA indicated the Agency is considering
  - the applicability of the policies described in the guidance to hospitals and health systems, and
  - the applicability of a condition requiring a patient-specific prescription to certain non-sterile drug products for distribution to long-term care facilities.
- FDA intends to address these issues in separate or revised guidance.

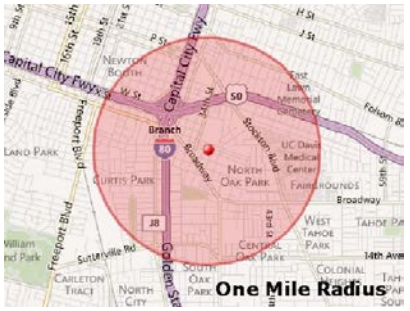
Hospital and Health-System Compounding

- FDA recognizes that hospitals may need to maintain a supply of certain compounded medicines in the hospital but outside the pharmacy, e.g., in ER departments and OR suites, for patients who present with a critical, time-sensitive need for the drug.
- Also, hospital pharmacies have characteristics that differentiate them from conventional pharmacies, and pharmacies not owned and controlled by hospitals – e.g., limits on how drugs are ordered and distributed
- **FDA's April 2016 draft guidance on compounding in State-licensed hospital or health system pharmacies:**
  - FDA sought to address concerns that the prescription requirement could disrupt the hospital centralized compounding model and impede patient care, while also recognizing the risks of compounded drug products.
  - **Proposed 1-mile radius policy**: a hospital pharmacy distributes compounded drug products without first receiving a patient-specific prescription provided they are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a 1 mile radius of the compounding pharmacy, and the products otherwise comply with section 503A and the FD&C Act.

Hospital and Health-System Compounding

Stakeholder concerns regarding the draft guidance and 1-mile radius proposed policy

- The one-mile radius is too limiting, many health systems include a larger geographic area; building redundant facilities to cover a larger area is costly
- Becoming an outsourcing facility is problematic. FDA's draft facility guidance would prevent hospitals from housing 503A and 503B facilities at the same address, and building two facilities would be expensive. And subjecting all products made at a pharmacy to CGMP regulations would be too onerous.



Hospital and Health-System Compounding

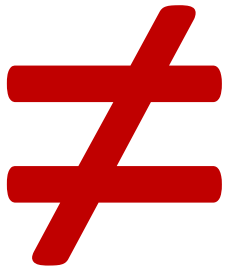
Stakeholder concerns regarding the draft guidance and 1-mile radius proposed policy

- Hospitals will not be able to get all the non-patient-specific drugs they need, in the time they need them, from outsourcing facilities. Outsourcing facilities may also be unable to supply hospitals in times of shortage.
- Placing limitations on hospital centralized compounding could push compounding to the bedside where lower environmental controls could increase contamination risk.

Hospital and Health-System Compounding

Stakeholder concerns regarding the draft guidance and 1-mile radius proposed policy

- The proposed policy is too permissive. FDA should not set a more permissive policy for hospitals and health systems than the policy the Agency applies to other compounding pharmacies that are not registered outsourcing facilities.



Compounding for Long-Term Care

- Over three quarters of the ~625 comments FDA received on our draft guidance on repackaging described implications for long term care facilities.
- Primary Concern: The prescription condition in the draft guidance would prevent long-term care pharmacies from distributing non-sterile repackaged drugs to long term care facilities for emergency boxes or for automated dispensing machines because the pharmacy does not have a patient-specific prescription at the time that it distributes these repackaged drugs to the facility

Compounding for Long-Term Care

- **Emergency kits/boxes**
  - A condition of participation in Medicare Part D is that a network long term care pharmacy provide an "emergency" supply of medications as required by the facility in compliance with State requirements.
  - Emergency kits are used in long term care facilities for patients who are admitted during non-business hours and may prevent re-admission to a hospital.
  - Generally, kits contain non-sterile repackaged prescription drugs (usually no compounded drugs, or sterile repackaged drugs, though kits may contain conventionally-manufactured sterile prescription drugs that are not repackaged).
  - The drugs are removed from the emergency kit and administered to a patient after the receipt of a patient-specific order from a prescriber.

Compounding for Long-Term Care

- **Automated dispensing machines (ADMs)**
  - Machines kept on-site at the long-term-care facility, managed by the long term care pharmacy.
  - Also contain drugs that are commonly used by patients at the facility.
  - Generally contain non-sterile repackaged drugs (usually no compounded drugs, or no sterile repackaged drugs)
  - The pharmacy managing the ADM generally receives a patient prescription before releasing the drug from the machine. But ADMs also have an override function that enables the facility to remove the drug without first sending a prescription or order to the pharmacy.

Breakout Sessions

- **Breakout 1: New compounding practices**
  - Use of new technologies
  - New products or activities that raise potential concerns
  - Compounding of combination products
- **Breakout 2: Hospital and long term care pharmacy compounding**
  - How do states currently oversee these facilities?
  - Are they treated differently than other pharmacies, and if so, why?
- **Breakout 3: Compounding in rural areas**
  - What special issues related to compounding affect rural areas?
  - Greater reliance on nonresident compounding facilities?
- **Breakout 4: Radiopharmaceuticals compounding**
  - Q&A with FDA on radiopharmaceuticals
  - State experiences and feedback