The Impact of FDA's New Compounding Guidance: A Primer

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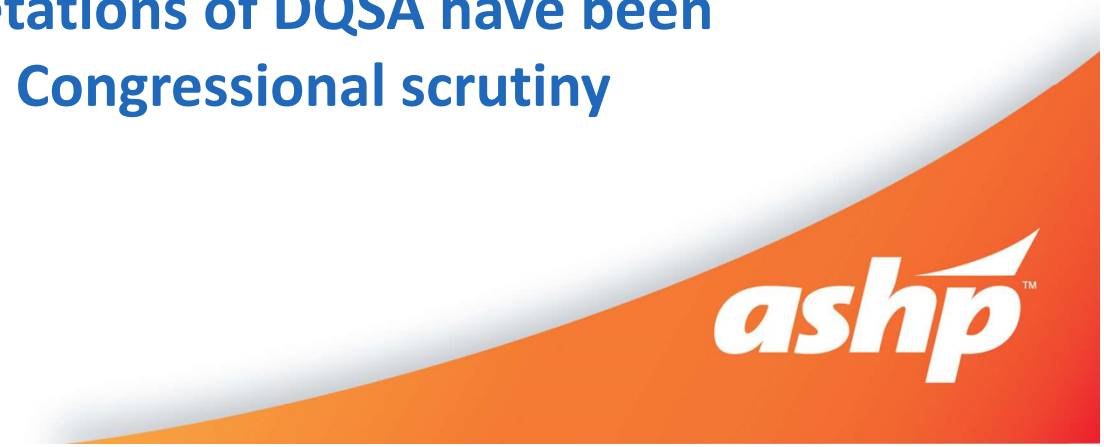
Compounding Recap

- **Drug Quality and Security Act of 2013**
  - Maintained state Boards of Pharmacy oversight of 503A compounding
  - Created 503B "outsourcing facility" designation
- **FDA's implementation of the law is a work in progress**
  - Guidance/policy based approach rather than the formal rulemaking process
  - Stakeholder input gathered through annual listening sessions with Agency staff and comments on draft guidances
- **Current Agency interpretations of DQSA have been controversial, attracting Congressional scrutiny**



Regulatory Implementation to Date

Draft

- **503A**
  - Repackaging (2/15)
  - Biologics (2/15)
  - Memorandum of Understanding (2/15)
  - RX Requirement (4/16)
  - Hospitals and Health Systems (4/16)
- **503B**
  - Facility Definition (4/16)

Interim /Ongoing

- Compounding with Bulk Substances under 503A and 503B
- Lists
  - Bulk Substances Nominations
  - Demonstrably Difficult to Compound
- 503B cGMP Applicability

Final

- **503A**
  - 503A Compounding Guidance (10/15)
- **503B**
  - Considerations for Registration (8/15)
  - Facility Fees (11/14)
  - Registration (11/14)

Full list:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm

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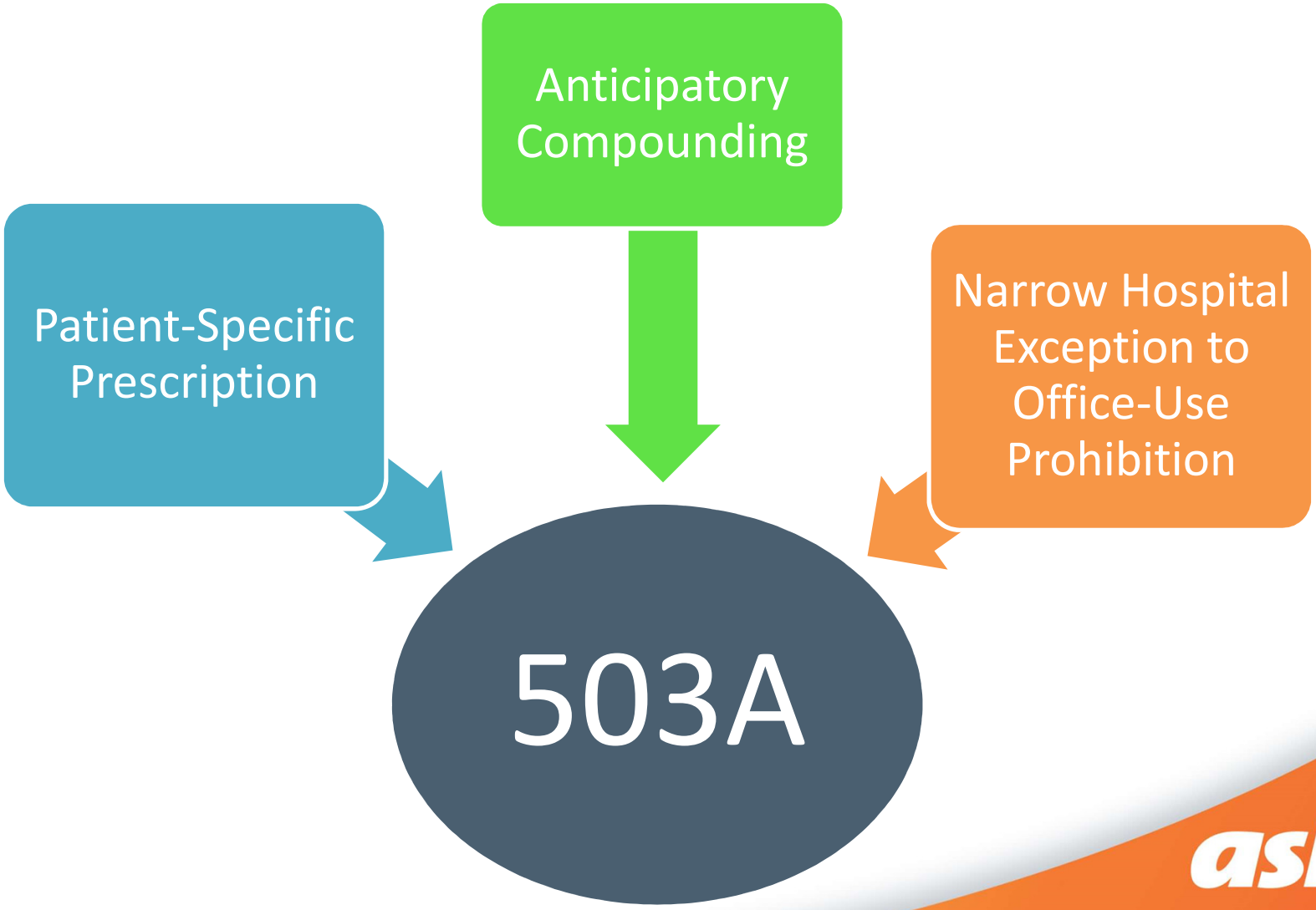
Compounding Draft Guidances

- **Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act**
- **Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act**
- **Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act**
  - Released on April 15, 2016
  - Comments due July 18, 2016

Compounding Paradigm Shift



Prescription Requirement

- **Guidance's requirements apply to all 503A non-sterile and sterile compounding, regardless of setting**
- **FDA firmly situates a patient-specific prescription as the "hallmark" of 503A compounding**
  - Prescription or order must be received prior to dispensing or distributing compounded medication
- **Compounding for office use/office stock strictly prohibited**
  - Unequivocal ban rather than implied requirement
- **Compounding in anticipation of a prescription allowed under limited circumstances**

Anticipatory Compounding

- **Limited by relationship and amount**
  - Prescriber and compounder must have an “established relationship”
    - Compounders must maintain appropriate documentation
  - Compounder may prepare no more than 30 days’ supply of product
    - Supply is based on the amounts historically provided to the prescriber
- **Compounder must receive the prescription or order prior to dispensing or distributing anticipatorily-compounded medication**
  - This does not allow for traditional non patient-specific office-use, even for hospitals and health systems

Hospital and Health System Exception

- **Unless the hospital or health system meets FDA's narrow exemption criteria, it will be bound by the general prescription and anticipatory compounding requirements**
- **Hospitals/health systems may only dispense compounded drugs without a prescription if the:**
  - Pharmacy and the health care facility are jointly owned and under common control;
  - Pharmacy is within a 1-mile radius of the health care facility; and
  - Compounded drugs will be dispensed for use within the health care facility's walls (i.e., no discharge prescriptions)

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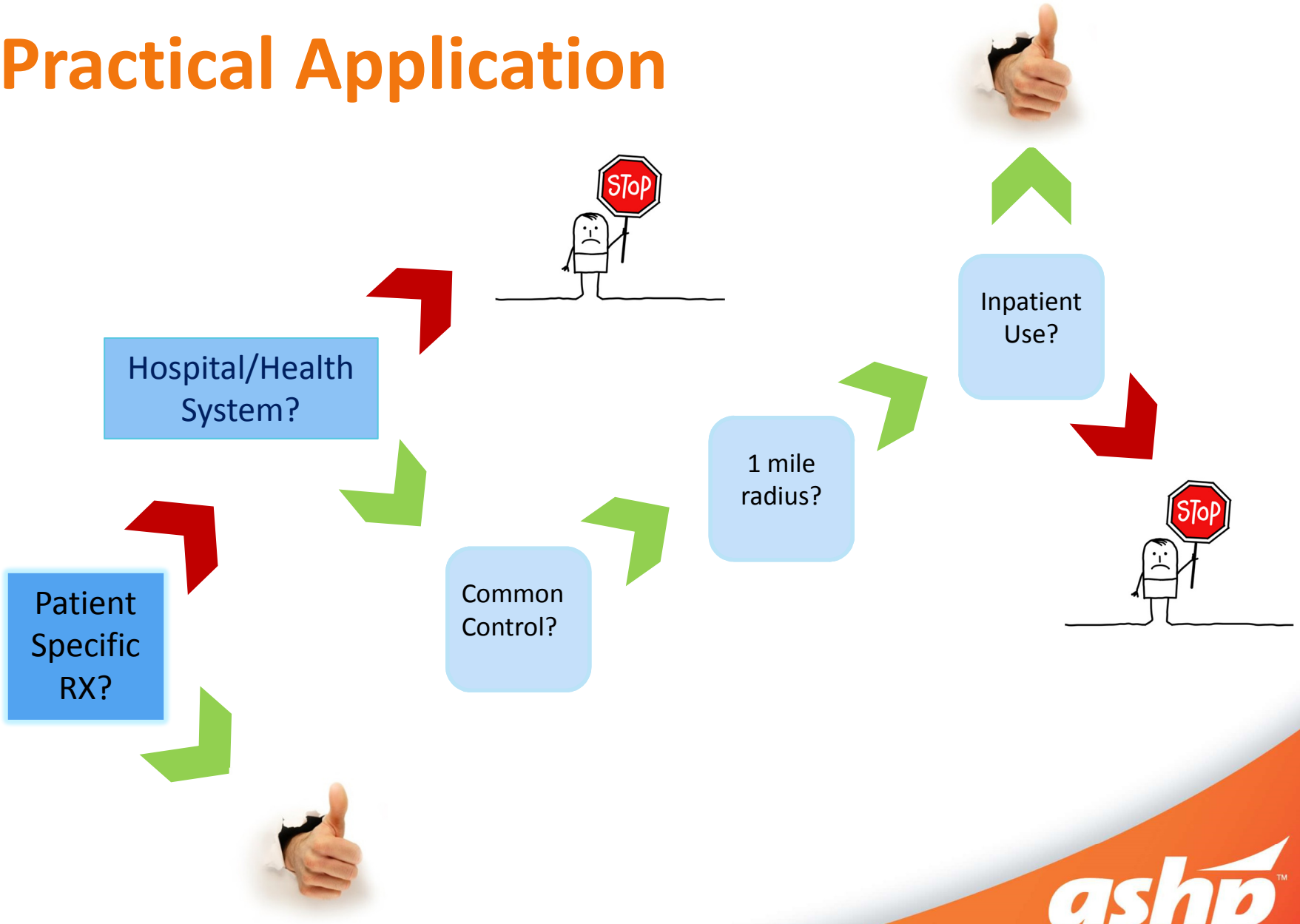
Practical Application

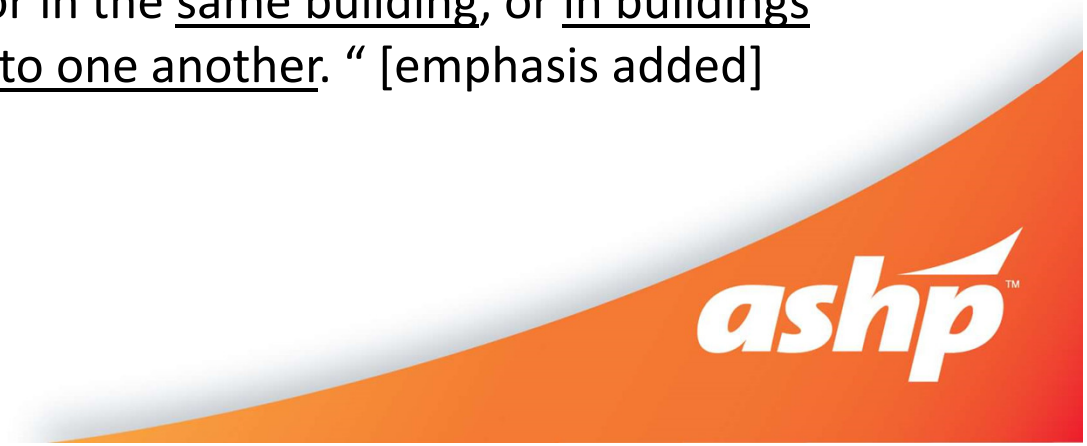


Weighing Options

- **What happens when you don't meet the hospital/health system criteria?**
  - Contract with an outsourcing facility
  - Register as an outsourcing facility
  - Reconfigure pharmacy operations
- **All of these options raise logistical, quality, and patient safety concerns**

503B Definition Guidance

- **503B registration is "facility-specific"**
  - 503Bs must compound at least some sterile medications
- **FDA clarifies that any compounded medications produced by an outsourcing facility must meet 503B standards**
- **"Facility" defined very broadly:**
  - "The agency considers all activities, equipment, appurtenances, and materials part of such a facility if they are related to human drug compounding under the supervision of the facility's management at the same street address, or in the same building, or in buildings located in close proximity to one another. " [emphasis added]



Member Feedback

- **ASHP convened two calls with a cross-section of members including urban and rural hospitals and large health systems**
- **Participants identified serious negative implications related to the guidances:**
  - Decreased care quality
    - Care delays
    - Pushing compounding to the bedside and out of specialized facilities/technologies
    - Lack of choice in outsourcing facilities
  - Patient access problems
    - Potential for recalls and shortages
    - Rural specialty care may be impacted

ASHP Next Steps

- **Continue to gather member feedback to incorporate into formal comments to FDA**
  - Comments/input can be sent to Jillanne Schulte at jschulte@ashp.org
- **Attend FDA listening sessions for pharmacy organizations and hospitals/health systems**

Additional Training Resources

ASHP Sterile Product Preparation Training and Certificate Program

- **Launched Monday, May 16th, 2016**
- **Curriculum:**
  - Importance of appropriate aseptic processing for safe and effective preparation of sterile products
  - Appropriate use and maintenance of equipment and facilities
  - Behaviors and skills required of compounding personnel
- **8 Modules**
  - Recorded presentations
  - Videos
  - Readings
- **17.25 CE hours**
- **Optional practice-based exercises for Professional Certificate**
  - Upload videos demonstrating practice skills
  - Validation by supervisor
- Prerequisite to Advanced Certificate (Launching November 2016)

Questions?