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**“A Conversation About
Compounding Pharmacies”**

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What is “Compounding”?

Compounding is standard pharmacy practice

- Compounding is the preparation / formulation of medication not available from a manufacturer
- Pharmacists combine different prescription and /or non-prescription ingredients to formulate a therapy which better suits a patient’s needs

Why is Compounding necessary?

Some products from manufacturers are not in the preferred dosage / administration form

- Pre-filled syringes, single-dose vials
- Pre-mixed IV bags
- Dosing strength needs to be less or more
- An additional ingredient needs to be added
- Unstable therapies are formulated as needed
- Available product formulations do not suit a patient and/or needs to be administered differently

What products are often Compounded?

Medications compounded and dispensed via:

- IV bag
- Syringe
- Single-dose vial
- Creams, ointments, solutions
- Suppositories
- Capsules

Don't all pharmacies compound drugs?

Most chain / grocery retail pharmacies have basic compounding for a small selection of drugs , IM/IV medications are not prepared)

- Flavoring is added to liquid medications
- Oral therapies are prepared by adding sterile water to the drug

Some independent retail pharmacies promote themselves as “compounding pharmacies”

- Actively practice compounding to differentiate themselves from chain or grocery drugstores ; typically produce topical creams, ointments, solutions

What other pharmacies compound?

Hospitals, specialty pharmacies and home infusion companies are capable of advanced compounding

- This typically involves formulating IM/IV drug therapy
- It requires specific training, proper equipment, a sterile pharmacy workspace and specialized handling / storage of medications before, during and after preparation

There are also larger, “institutional” compounding pharmacies known as “503Bs” ...

How are larger “503Bs ” different?

Their customers may not have the equipment, sterile workspaces or enough pharmacy staff to produce larger quantities of compounded therapies

- These entities are referred to / defined as “outsourcing facilities” which “are at one geographic location or address engaged in compounding of sterile drugs and have elected to register as an outsourcing facility which complies with all of the requirements of section 503B of the Federal Food, Drug and Cosmetic Act”

How do 503Bs fit into the marketplace?

They produce higher volumes of more advanced compounded medications shipped to various healthcare provider entities including:

- Home Infusion Companies
- Long Term Care Facilities
- Hospitals / Clinics / Surgical Centers
- Psychiatric Care Facilities
- Prison Infirmaries

What products do 503Bs produce?

The products / services they provide typically focus on medications aligned with:

- IV bags
- Prefilled syringes
- Other delivery formats for automated, manual or gravity therapy delivery setups

How many larger compounding or 503B pharmacies are there?

There are many national, regional and locally-based institutional compounding pharmacies, some of the larger ones are:

- Cantrell Drug Company
- Central Admixture Pharmacy Service Inc./CAPS
- CuraScript
- Omnicare
- PharMEDium / AmerisourceBergen
- Wedgewood Pharmacy

What other details are important?

Some government and industry stakeholders think the FDA should more assertively regulate 503B pharmacies and others that actively practice large scale compounding

There is ongoing debate as to whether they should be more closely classified as pharmacies or manufacturers

There are significant issues when they do not:

- Closely follow safe, sterile pharmacy practice which impacts quality and patient care
- Abide by local, state or federal clinical commerce laws

What is Compounding's outlook?

Compounding is an ongoing part of standard pharmacy practice and plays an important role across the healthcare industry

Individualized patient care and a wider array of treatment options continues to drive demand for compounded medications

Health and safety are integral to quality patient care; clinician and regulatory involvement will continue to assess and improve the performance of compounding pharmacies

Thank you for viewing my presentation. I am a Healthcare Marketer seeking a new opportunity...

My background is:

- **Healthcare Marketing (pharma, device and programs)**
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