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How Your Pharmacy (503A) Should Navigate Relationships with 503B Outsourcing Facilities

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

Speaker

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Founder

ATRIUM24

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Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist and Technician Learning Objectives

1. Review the legality of 503B facilities selling to 503A facilities.
2. Discuss the FDA draft guidance from 2023 and how it is interpreted by pharmacies, boards of pharmacies, and states.
3. Outline best practices for evaluating potential 503B facilities to partner with.
4. Summarize operational concerns for purchasing from 503B outsourcing facilities and strategies to mitigate these concerns.

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First, What is a 503A Pharmacy?

Patient-Specific:

- Compounds medications only with a prescription for an individual patient.

State-Regulated:

- Primarily regulated by state pharmacy boards.

Exempt from cGMP:

- Does not follow FDA's manufacturing requirements for large-scale producers but must follow USP standards (<795>, <797>, <800>).

No Mass Manufacturing:

- Cannot compound for mass distribution or sell drugs in bulk.

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Am I 503A, even if I don’t compound?

- Yes, a **standard retail pharmacy** is still considered a **503A pharmacy** even if it does **not engage in compounding**.
- The term "503A" refers to a section of the **Federal Food, Drug, and Cosmetic Act (FDCA)**, which distinguishes between traditional compounding pharmacies (503A) and outsourcing facilities (503B).
- A pharmacy classified under section 503A is typically one that compounds medications for individual patients based on a valid prescription. However, even if a pharmacy does not engage in compounding, it can still be classified as a 503A.

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What is a 503B: FDA Registered Outsourcing Facility?

- **No Patient-Specific Prescriptions Required:**
  - Can compound medications in bulk and distribute them for office use or stock in healthcare settings.
- **FDA-Regulated:**
  - Subject to FDA oversight
  - Must comply with cGMP regulations.
- **Mass Production:**
  - Allowed to compound large quantities of medications and distribute them across state lines.
- **Office Use Compounding:**
  - Supplies compounded drugs to healthcare facilities for use without patient-specific prescriptions.
- **Higher Regulatory Standards:**
  - Must follow stricter safety, quality, and manufacturing standards than 503A pharmacies, including cGMP.

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The Comparison

503A Pharmacies

- Registered with the State Board of Pharmacy
- Registered as Pharmacies
- Follow USP guideline
- Patient Specific Dispensing Required
- Limited to Smaller Batch Sizes

503B Pharmacies

- Registered with the FDA
- Registered as Manufacturers
- Follow cGMP Guidelines
- Patient Specific Dispensing Not Required
- Larger Batch Sizes permitted

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Legality: 503B to 503A

Historically, 503B's have sold to hospitals and clinics

In June 2023, an FDA Guidance explicitly clarified that a 503B MAY sell to a 503A for the first time

- An FDA Draft Guidance is standard industry practice

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FDA Draft Guidance

Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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FDA Prohibition on 503B Wholesaling

- **June 2023 – FDA Draft Guidance**
  - Discusses the *prohibition on wholesaling* under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
  - In simpler terms, it outlines restrictions on how drugs made by 503B *outsourcing facilities* can be distributed.
  - Within the document, it lists "Activities **Not** Prohibited by the Wholesaling Provision".
    - Section e (line 329) reads: An outsourcing facility distributes a drug it compounded to a **state-licensed pharmacy**, federal facility, or licensed physician, **which subsequently dispenses the drug pursuant to a prescription.**
    - This allows 503Bs to sell to 503A Pharmacies!

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FDA Prohibition on 503B Wholesaling

Exceptions: The drugs can still be:

- Administered to patients in hospitals or clinics.
- Dispensed by pharmacies if there's a valid prescription.

Purpose:

- These rules exist to make sure that compounded drugs are only used for patients who really need them, to protect the drug approval process, and to prevent unsafe or ineffective drugs from being widely distributed.

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A 503B outsourcing facility is allowed to manufacture/compound:

- **Sterile drugs**, including drugs that may not be readily available in FDA-approved form.
- **Bulk compounded drugs** under CGMP (Current Good Manufacturing Practice) standards.
- **Drugs intended for use in hospitals, clinics, or pharmacies**, either for direct administration to patients or for dispensing with a prescription.
- **Drugs on the FDA's drug shortage list**, ensuring critical medications are available during shortages.

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What would a 503A buy from a 503B?

- GLP-1's:
  - Semaglutide
  - Tirzepatide
  - Retatrutide
    - Potentially coming soon
- TriMix
- Sterile Eye Drops
- Veterinary Compounds
- and more!

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Vetting a 503B

1. **FDA Registration & Compliance, Inspection History**
2. **State Licensing**
3. **cGMP Adherence: Quality Assurance**
    1. Third Party Validation Testing
    2. API from FDA Registered supplier
4. **Compliance with Prohibition on Wholesaling**
    1. CanNOT buy from brokers, MUST buy from the 503B Directly
    2. May use a GPO for contract pricing, but still order must be direct

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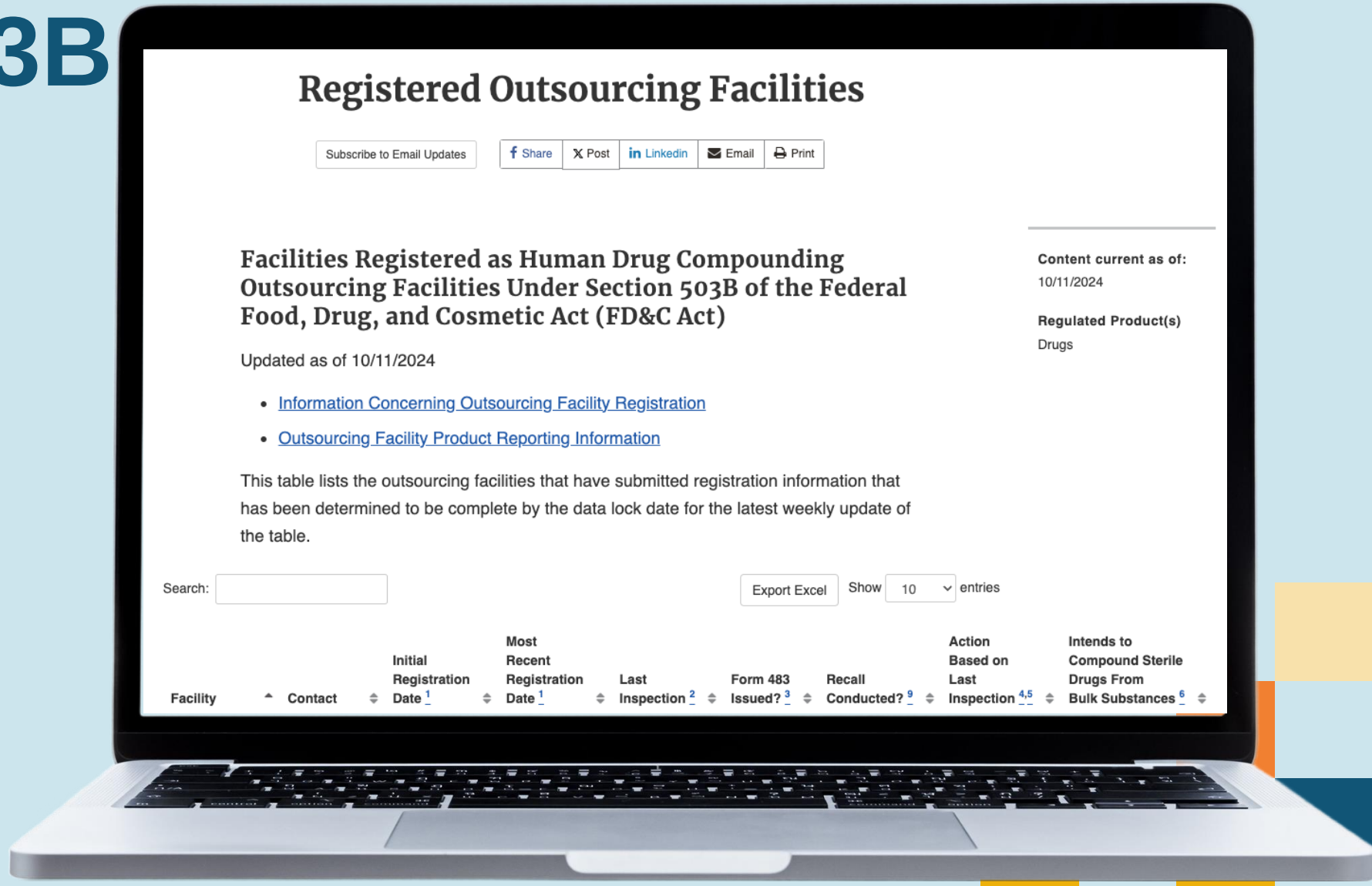
Vetting a 503B: FDA Compliance

Look them up!

- https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities
- 82 Registered Outsourcing Facilities (as of Oct 14, 2024)
- Only a handful report that they're making the shortage GLP's: semaglutide & tirzepatide
    - https://dps.fda.gov/outsourcingfacility

Vetting a 503B FDA Compliance



https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

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Vetting a 503B: FDA Compliance

Last inspection?

Some facilities have not yet been inspected

Form 483 Issued?

Issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

Recall Conducted?

Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both.

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Vetting a 503B: FDA Compliance

Action Based on Last Inspection

- “Open” means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.

- FMD-145 - Release of the Establishment Inspection Report (EIR)

Vetting a 503B: FDA Compliance

Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]
3/10/2014	10/19/2023	5/29/2024	Yes	No	Open[7]

Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]
10/29/2020	12/5/2023	10/27/2022	Yes	No	FMD-145 Letter Issued 3/30/2023

Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]
10/23/2019	11/30/2023	10/10/2024	Yes	No	Open

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Potential Operational Concerns

- Check 503B's active state license
- Verify cold chain management (if applicable)
- Review adverse event reporting protocols
- Confirm recall procedures
- Inspect facility cleanliness and quality standards
- Confirm liability insurance and indemnification
- Ensure responsive customer service
- Review product offerings and customization options
- While quality and compliance are paramount, pricing should be competitive
- Assess reliability of supply chain and delivery

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Questions?

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