

**CPA** 



**Growth. Performance. Success.**

**2024 ANNUAL CONVENTION**



# Regulations and Relationships: How to Build A Compounding Business You Can Scale

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**NCPA 2024 Annual Convention and Expo**

Columbus, Ohio

# Speaker



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Flatirons Family Pharmacy

# Disclosure Statement

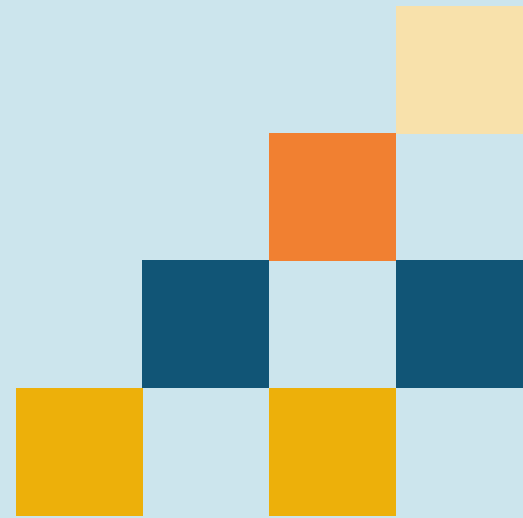
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# Pharmacist and Technician Learning Objectives

1. Review the latest regulatory policies and advocacy efforts related to compounding
2. Outline key financial considerations for evaluating a compounding business plan.
3. Discuss business-building strategies for scaling compounding operations.
4. Describe opportunities for advanced staff roles and responsibilities in compounding pharmacies





# Regulation Updates

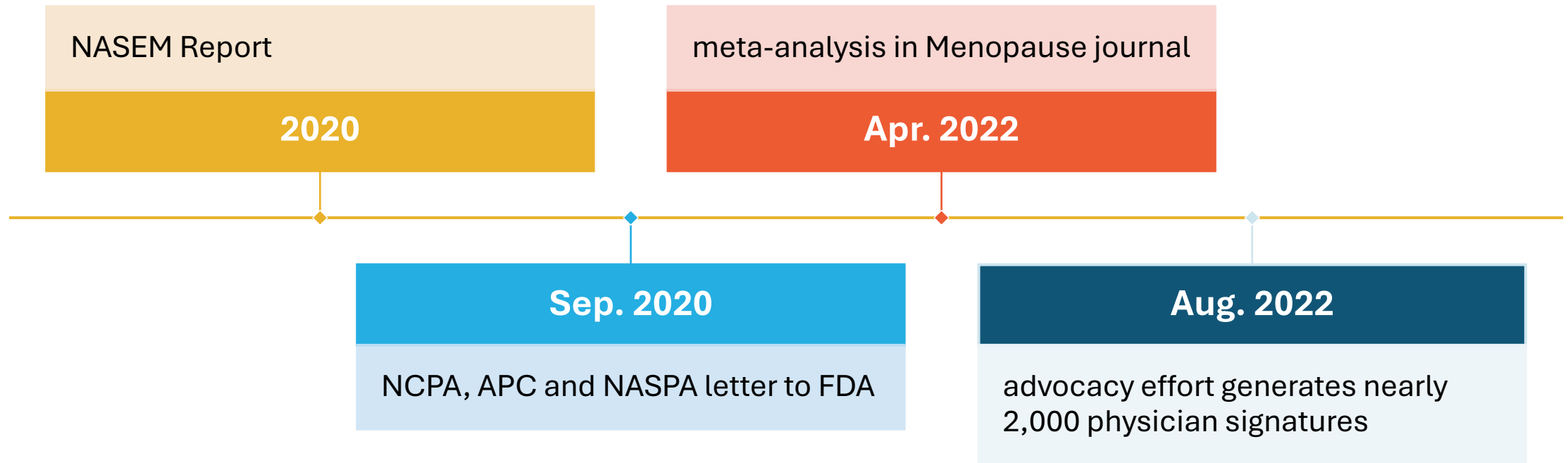
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# Compounding of Animal Drugs

- FINAL GFI #256  
FDA's Final Guidance (August 2022)
- Delayed enforcement to April 2023
- FDA responds to concerns (Feb. 2023)
- VCPR
- Don't dispense to vet who didn't write script
- Documentation of medical rationale
- FDA's FAQs on GFI #256 (March 2023)
- Office stock
- Examples of “clinical difference”
- Adverse event reporting

# Patient Access to cBHT





# Demonstrably Difficult to Compound Proposed Rule

- *Proposed Rule: March 2024*
- **NCPA comments: June 2024**
- Insufficient notice and comment period
- List lacks evidence
- FDA can't add "categories" to 503A DDC list

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 216**

**[Docket No. FDA-2023-N-0061]**

**RIN 0910-AI31**

**Drug Products or Categories of Drug  
Products That Present Demonstrable  
Difficulties for Compounding Under  
Sections 503A or 503B of the Federal  
Food, Drug, and Cosmetic Act**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Proposed rule.

# Draft Guidance: Prohibition on Wholesaling Under Section 503B

- FDA's interpretation of the FD&C Act: a drug compounded by an outsourcing facility may be eligible for exemptions in 503B where the drug is distributed...**to a State-licensed pharmacy... [NCPA emphasis]**
- Concerns for future of 503A compounding and patient access

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## 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.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Dominic Markwordt, 301-796-3100.

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)

June 2023  
Compounding and Related Documents

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# Setting Up for Success



# Assessing Potential for Success

**Market Research:**  
You must know your  
local and multi state  
competition

Who is your target  
customer, and can  
they support  
sustained business  
growth?

What will be your  
specialty?

# Setting Up For Success



Compliance with FDA and State Regulations for compounding



**Compliance with USP <795>** for non-sterile compounding and **USP <797>** for sterile compounding and follow **USP <800>** for handling hazardous drugs.



Just because your state doesn't enforce USP 800 doesn't mean you shouldn't follow it



You will need clean rooms, laminar airflow hoods, autoclaves, and specialized equipment like mortar and pestles, balances, molds, etc.



# Know Your Numbers

Annual Operating Cost – different for every location

Revenue Goals- if you don't set goals how can you reach them?

Profit Margins- rule used to be 85% GP Margin pre USP  
800

Annual/Bi Annual Price Increases

With 50-100 compounds a day revenue can range from  
\$50,000-\$100,000

# If You Build It.....

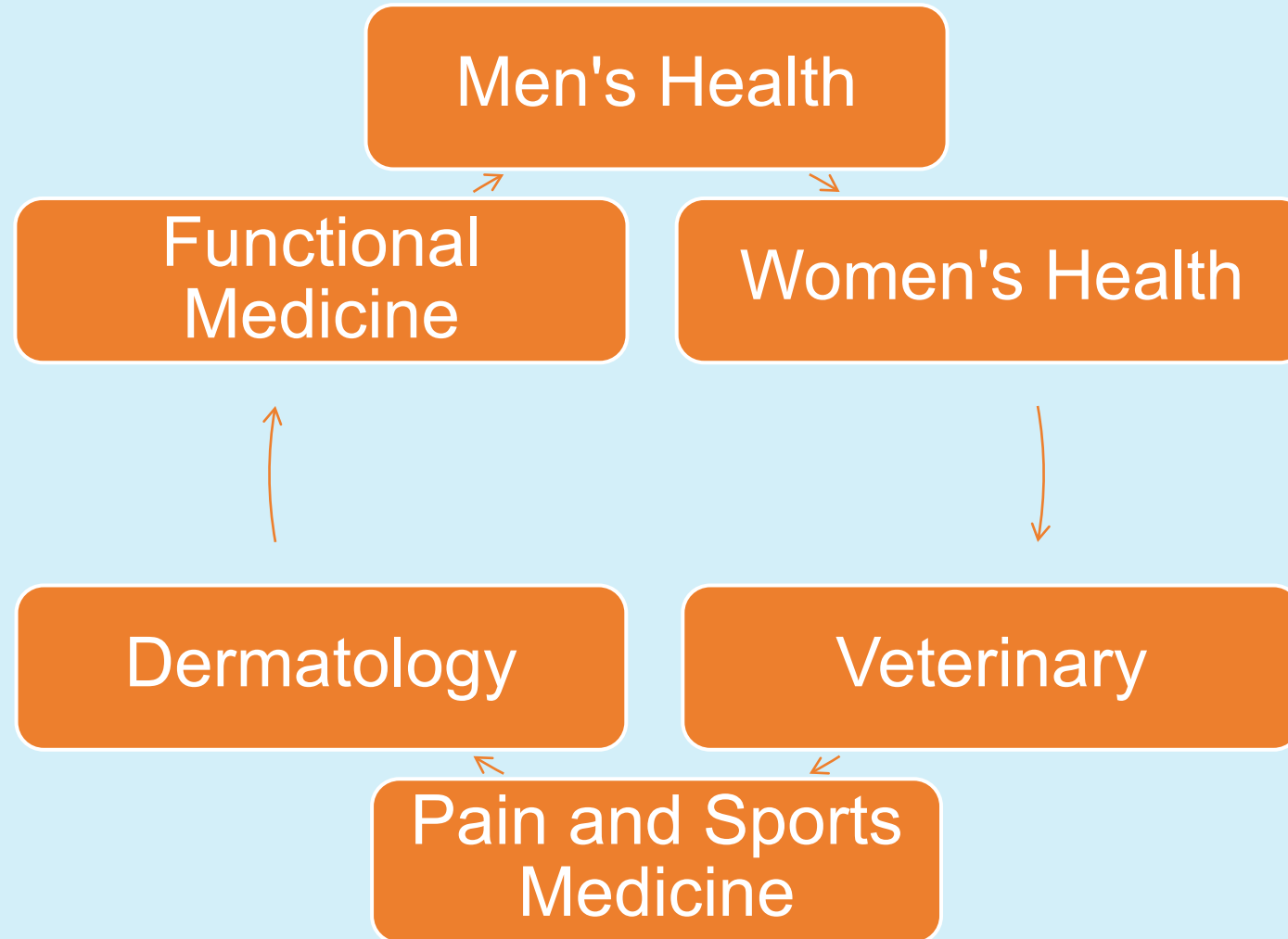


# What Can Your Market Support?

- Will you bill insurance or be cash only?
- If you plan to bill insurance, what accreditation will you get and how will you recoup the financial investment you made?
- Will you offer sterile compounding or just nonsterile?
- Will you ship or deliver in addition to pick up?
- Can your demographic support compound pricing that keeps your compounding lab operating at or near a 90% gross profit?



# Niche Market Opportunities



# Marketing and Growth Strategies

## Branding

- What sets you apart from others
- What about your branding will make them remember you
- Remember your employees represent your brand

## Online Presence

- SEO and website
- Social Media
- Mobile Friendly
- Prescriber Portal Option

## Building Relationships

- Gold standard for growth and stability
- Grassroots sales
- Educate your patients and providers
- What information are you leaving behind



What Does  
Your Logo  
Say About  
You?



# Do Your Marketing Materials Stand Out?



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WITH EXCELLENT  
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# Will Your Marketing Materials Bring them Back to You?

## PET COMPOUNDING

Customized dosing and formulations for each animal needs



Buprenorphine Suspension

Cisapride Suspension

Doxycycline Suspension

Gabapentin Suspension

Metronidazole Suspension

Prednisolone/ Suspension

Ursodiol Suspension

Methimazole TD Suspension

Fluoxetine TD Suspension

Budesonide Capsules

Chlorambucil Capsules

DES Capsules

Gabapentin Capsules

Methimazole TD Cream

Piroxicam Capsules

Prednisolone/ TD Cream

Fluoxetine TD Creams

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- Chicken
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- Bacon
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- Marshmallow

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### PEDIATRIC RX ORDER FORM: COMPOUNDS

PATIENT NAME: \_\_\_\_\_ DOB: \_\_\_\_\_ PHONE: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_  
 ALLERGIES: \_\_\_\_\_  
 Please complete the above demographics or send in a face sheet.

#### REFLUX

- Lansoprazole  3mg/mL  6mg/mL Suspension (QTY # \_\_\_\_)  
 SIG: Take \_\_\_\_\_ mL by mouth once daily 30 minutes before a meal.  
 Omeprazole 5mg/mL Suspension (QTY # \_\_\_\_)  
 SIG: Take \_\_\_\_\_ mL by mouth once daily 30 minutes before a meal.  
 Famotidine 40 mg/5 mL Suspension (QTY# \_\_\_\_)  
 SIG: Take \_\_\_\_\_ mL by mouth once daily.  
 SIG: Take \_\_\_\_\_ mL by mouth twice daily.

#### PAIN/FEVER

- Acetaminophen  125mg  250mg Troches (QTY #30)  
 SIG: Dissolve 1 troche sublingually or between cheek and gum every 4-6 hours as needed.  
 Acetaminophen  160mg  240mg Lollipops (QTY #12)  
 SIG: Suck on and dissolve 1 lollipop by mouth every 4-6 hours as needed.  
 Acetaminophen  150mg  300mg Suppositories (QTY #30)  
 SIG: Insert 1 suppository rectally every 4-6 hours as needed.  
 Ibuprofen  100mg  200mg Troches (QTY #30)  
 SIG: Dissolve 1 troche sublingually or between cheek and gum every 4-6 hours as needed.  
 Ibuprofen  100mg  200mg Lollipops (QTY #12)  
 SIG: Suck on and dissolve 1 lollipop by mouth every 6-8 hours as needed.  
 Ibuprofen  100mg  200mg Suppositories (QTY #30)  
 SIG: Insert 1 suppository rectally every 6-8 hours as needed.

#### MOUTH/THROAT PAIN

- Tetracaine 0.5% Lollipops (QTY #6)  
 SIG: Suck on lollipop for 10-15 seconds then stop every 2-3 hours as needed.

#### ACNE

- Clindamycin 1%, Benzoyl Peroxide 5%, Niacinamide 5% Topical Cream (QTY #60g)  
 SIG: Apply to the affected area twice daily.  
 Clindamycin 1%, Tretinoin 0.025% Topical Cream (QTY #30g)  
 SIG: Apply to the affected area at bedtime.

#### NAUSEA

- Ondansetron 2mg/mL Suspension (QTY # \_\_\_\_)  
 SIG: Take \_\_\_\_\_ mL by mouth every 8 hours as needed.  
 Ondansetron 4mg Lollipops (QTY #12)  
 SIG: Suck on and dissolve 1 lollipop by mouth every 8 hours as needed.  
 Ondansetron 4mg Suppositories (QTY #12)  
 SIG: Insert 1 suppository rectally every 8 hours as needed.

#### ANTIBIOTICS

- Metronidazole 50mg/mL Suspension (QTY # \_\_\_\_)  
 SIG: Take \_\_\_\_\_ mL by mouth every 8 hours.  
 Sulfamethoxazole 800mg, Trimethoprim 160mg/15mL Suspension (QTY # \_\_\_\_)  
 SIG: Take \_\_\_\_\_ mL by mouth every 8 hours.  
 SIG: Take \_\_\_\_\_ mL by mouth every 12 hours.

#### ATOPIC DERMATITIS

- Zinc 0.2%, Clobetasol Propionate 0.05%, Cyanocobalamin 0.07% Cream (QTY #60g)  
 SIG: Apply to affected area twice daily for up to 2 weeks.  
 Azelastine 0.1%, Clobetasol Propionate 0.05% Gel (QTY #60g)  
 SIG: Apply to affected area twice daily for up to 2 weeks.

#### DIAPER RASH

- Cholestyramine 5%, Mupirocin 0.5%, Miconazole Nitrate 0.5% Topical Ointment (QTY #30g)  
 SIG: Apply to the affected area 2-3 times daily for up to 7 days.  
 Cholestyramine 5%, Zinc Oxide 5% Topical Cream (QTY #30g)  
 SIG: Apply to the affected area 2-3 times daily for up to 7 days.

#### TOPICAL ANTIFUNGAL/ANTIBIOTIC/STEROID

- Hydrocortisone 2%, Clotrimazole 2% Cream (QTY #30g)  
 SIG: Apply to the affected area twice daily for \_\_\_\_\_ weeks.  
 Betamethasone Valerate 0.05%, Miconazole Nitrate 2%, Mupirocin 1% Ointment (QTY #30g)  
 SIG: Apply to the affected area twice daily for \_\_\_\_\_ weeks.

#### WARTS

- Salicylic Acid 15%, Cimetidine 5% Gel (QTY #15g)  
 SIG: Apply to the affected area twice daily.

PRESCRIBER NAME: \_\_\_\_\_ NPI: \_\_\_\_\_ DEA: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_

# It's a Business of RELATIONSHIPS





# Expanded Staff Roles

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# Sales vs Marketing

## Know the Difference



# Marketing

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Focus: Creating awareness, generating interest, and building a brand presence.



**Goal:** To attract potential customers by communicating the value of a product or service and driving them towards purchasing decisions.



**Activities:** Market research, branding, advertising, content creation, digital marketing (social media, SEO), public relations, and lead generation.

# Sales



**Focus:** Closing deals and converting leads into customers.



**Goal:** To directly engage with prospects, address their needs, and persuade them to purchase a product or service.



**Activities:** Direct selling, relationship-building, negotiating, handling objections, and account management.

# Who is the FACE of Your Company?



Is it the owner?



Is someone out doing sales?



Is it what you put on Social Media?



Is it your Pharmacy or Ops Manager?



# Is Someone Actively Building Relationships?

Sales  
Representative

Pharmacy  
Manager

Owner



# It Doesn't Happen Overnight



Questions?



# Contact Information

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