



From Compliance to Growth: Scaling Your Compounding Business with Success

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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.

Pharmacist and Technician Learning Objectives

1. Review key regulatory policies and advocacy updates, including concerns with patient access to Compounded Bioidentical Hormone Therapy (cBHT), the compounding of animal drugs Guidance for Industry (GFI #256), insanitary conditions overreach, any future compounding Memorandum of Understanding (MOU), adverse event reporting, and more.
2. Identify opportunities to improve regulatory compliance through delegation of designated person responsibilities.
3. Review metrics used for scaling determinations in a compounding pharmacy practice pertaining to lab utilization, staffing and profit margins.
4. Explore aspects of marketing plans for compounding pharmacy practices including the use of relationship building, patient and provider education, and the development of niche markets.

Agenda – Perennial Advocacy

- Compounding of Animal Drugs, Final GFI #256
- Memorandum of Understanding (MOU)
- Drug Shortages
- Adverse Event Reporting
- Insanitary Conditions
- Patient Access to Compounded Bioidentical Hormone Therapy (cBHT)
- Process of PCAC Meetings

Agenda – Recent Advocacy

- Demonstrably Difficult to Compound Proposed Rule
- FDA's Draft Report, Removing Notice and Comment Period
- USP Related Advocacy
- Compounding In the States

Agenda – Business Considerations

- Scaling Considerations
- Designated Person
- Meeting Patient Expectations
- Gaining Market Share

Perennial Advocacy

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



Memorandum of Understanding (MOU)

- Oct. 2020 – FDA issues standard MOU
- Oct 2022 – FDA delays implementation
- Ongoing concerns
 - Conflict with state laws
 - Patient access for states that do not sign
 - Distribute vs. dispense

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0800 (expires 10/31/2023).

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate¹ and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.² This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

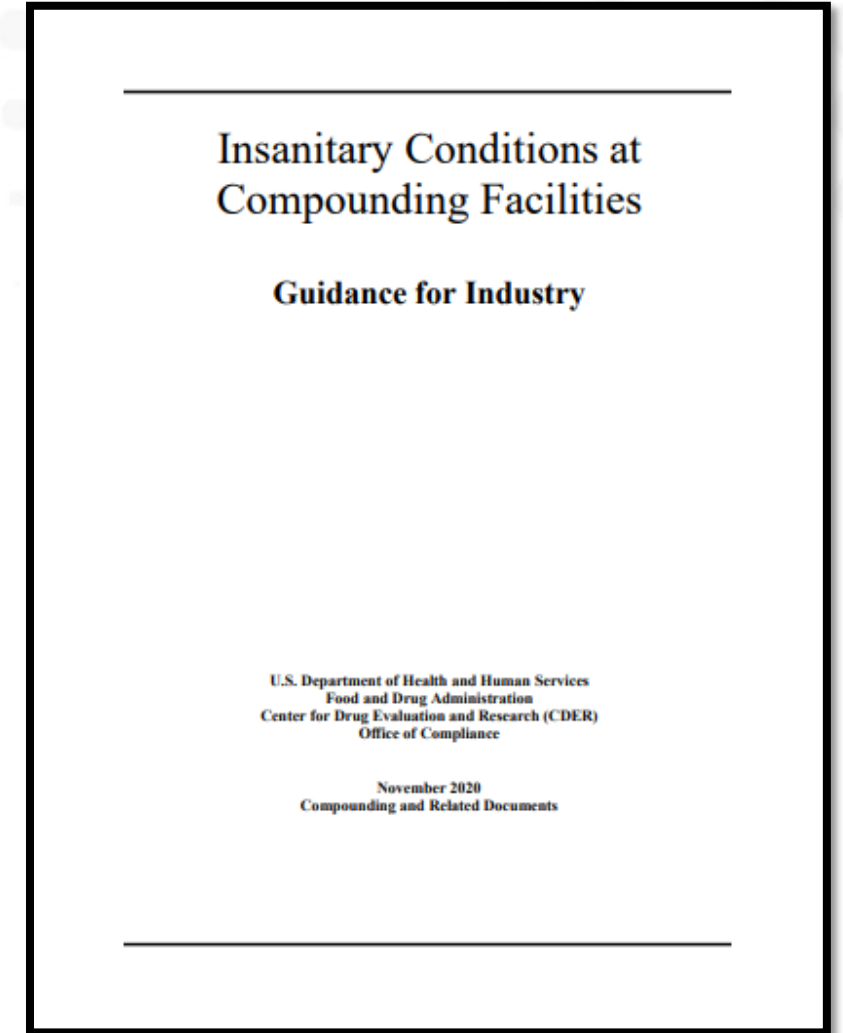
1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

¹ For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.
² As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

1

Other Advocacy Issues

- **Drug Shortages**
 - 503A pharmacies as tertiary suppliers
 - HR 167: *Patient Access to Urgent-Use Pharmacy Compounding Act*
- **Adverse Event Reporting**
- **Insanitary conditions**
 - Guidance did not address NCPA concerns



Patient Access to cBHT

- 2020 NASEM Report
- September 2020 NCPA, APC and NASPA letter to FDA
- April 2022 meta-analysis in *Menopause* journal
- August 2022 advocacy effort generates nearly 2,000 physician signatures



Process of PCAC Meetings

October 29, 2024 Meeting

Result:

- Voted against adding four substances to the 503A bulks list of substances that can be used for compounding: L-theanine, ibutamoren mesylate, ipamorelin, and kisspeptin-10.
- Voted unanimously to add hydroxyprogesterone caproate to the FDA list of withdrawn drugs that should not be compounded

Asks:

Speakers should have at least:

- Four calendar weeks from the release of the FDA packet to the due date for nominating themselves.
- Two calendar weeks between the due date for nominating speakers and the due date for submitting slides.

Remote or in person participation allowed

Recent Advocacy

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.

FDA's Draft Report, Removing Notice and Comment Period

Issued request for comment on if FDA can issue:

- “Level 1 guidance” for immediate implementation without prior comment
- “Level 2 guidance”: public comment upon implementation

NCPA concerns

- No proper notice and comment period, could implicate compounding

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2023-N-5653]

**Food and Drug Administration's Draft
Report and Plan on Best Practices for
Guidance; Availability**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice of availability, request
for comments.

USP Related Advocacy



May 2024 comments to USP expert committees

- NCPA ask: USP should clarify that an expert should be a current compounding pharmacist with at least ten years recent and relevant compounding experience in a 503(A) pharmacy.

April 2024 joint NCPA/APC letter to FDA and boards of pharmacy

- Problem: delays in stability test results from analytical labs, from increased volume from new USP requirements
- Comments to FDA and boards:
 - Alerted them of backlogs
 - Recognized the importance of testing
 - Stated implications of backlogs to compounders and patients

Advocacy in the States

- NCPA endorsement of Arkansas HB 1801 that would allow pharmacies to purchase compounded drugs from outsourcing facilities (March 2025)
- NCPA endorsement of New York S. 3236/A.678 allowing pharmacy technicians to compound (March 2025)
- NCPA opposition to Massachusetts levying an assessment on pharmacy proposed in its Fiscal Year 2026 budget

Other Regulatory Issues

Recent FDA Guidance/Alerts

- Compounding discretion for tirzepatide and semaglutide end dates:
 - 503A tirzepatide: Feb 2025
 - 503B tirzepatide: Mar 2025
 - 503A semaglutide: April 2025
 - 503B semaglutide: May 2025
- Guidance for 503A and 503B compounding (Jan 2025)
- Reminder to use ingredients suitable for sterile compounding (Oct 2024)
- Warning for dosing errors with compounded semaglutide injectibles (July 2024)
- Alert of compounded drugs containing sulfites (June 2024)



DEA: Anticipatory Compounding For Controls Not Allowed

- A DEA-registered pharmacy may compound a controlled substance without obtaining a separate DEA-registration as a manufacturer, if said compounding is pursuant to a valid patient specific prescription. 21 U.S.C. § 802(15).
- The pharmacy may only dispense a controlled substance to the ultimate user or a member of the ultimate user's household. 21 U.S.C. § 802(10).
- Delivering a compounded controlled substance to anyone other than the ultimate user or member of the ultimate user's household is distributing and not dispensing, and such activity is outside the scope of a DEA-registered retail pharmacy. 21 U.S.C. § 802(11); 21 C.F.R. § 1301.13(e)(1).



Scaling Successfully

1. How will I get more market share?
2. How will I successfully meet patient expectations for turnaround time and level of service?
3. How will I ensure that I am meeting/exceeding quality and regulatory standards?



Reverse, Reverse

- ✓ How will I ensure that I am meeting/exceeding quality and regulatory standards?
- ✓ How will I successfully meet patient expectations for turnaround time and level of service?
- ✓ How will I get more market share?



Quality/Regulatory

Scaling Considerations



Planning for Quality



- Designated Person(s)
 - One person or a DP team?
 - Assignments
 - Documentation review
- SOPs
 - When was your last update?
 - Are they being followed?
- Investigations/CAPA
 - Can you detect errors?
 - Are you collecting data and is this data being evaluated?

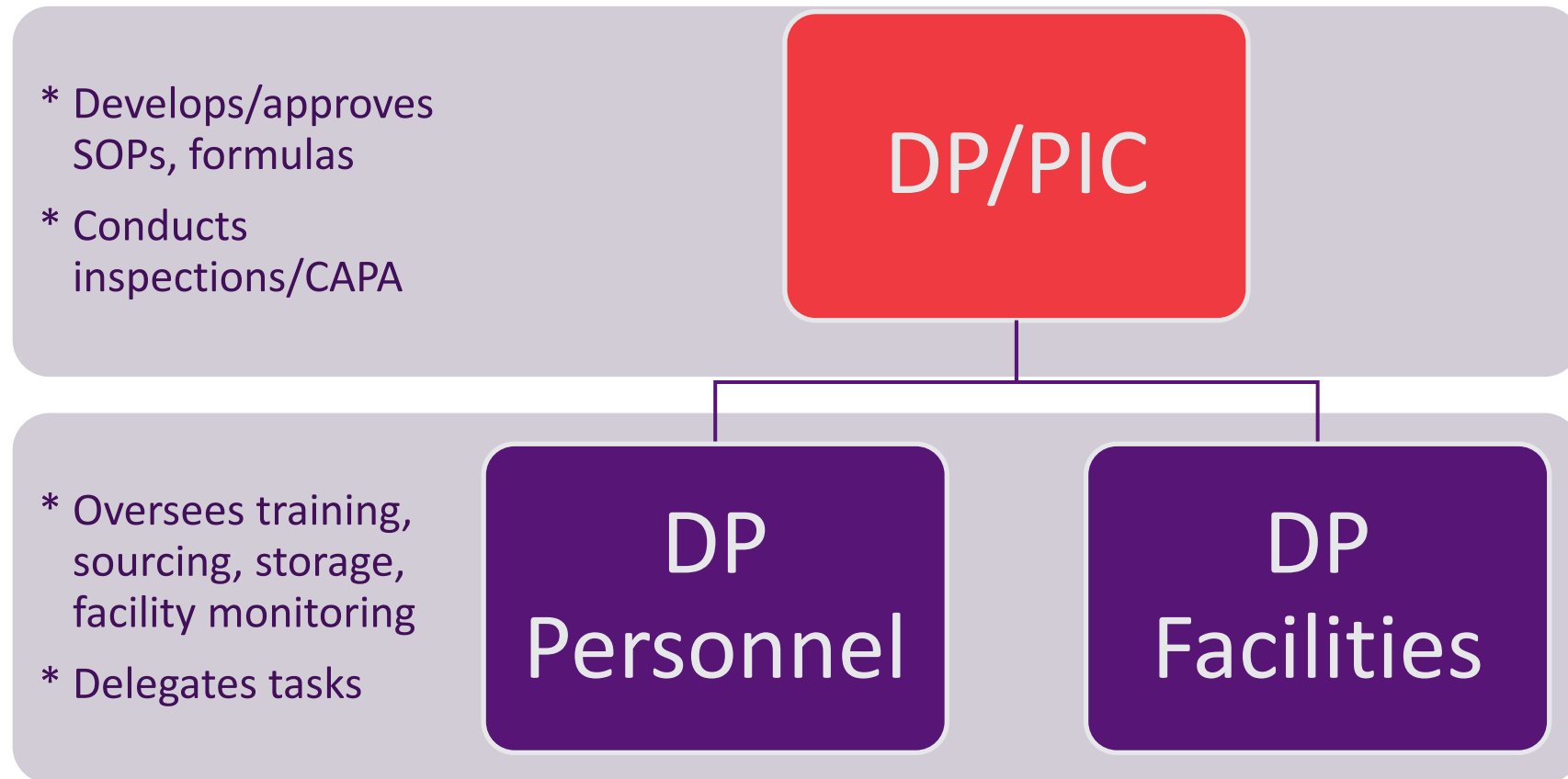
DP Responsibilities

Nonsterile Compounding

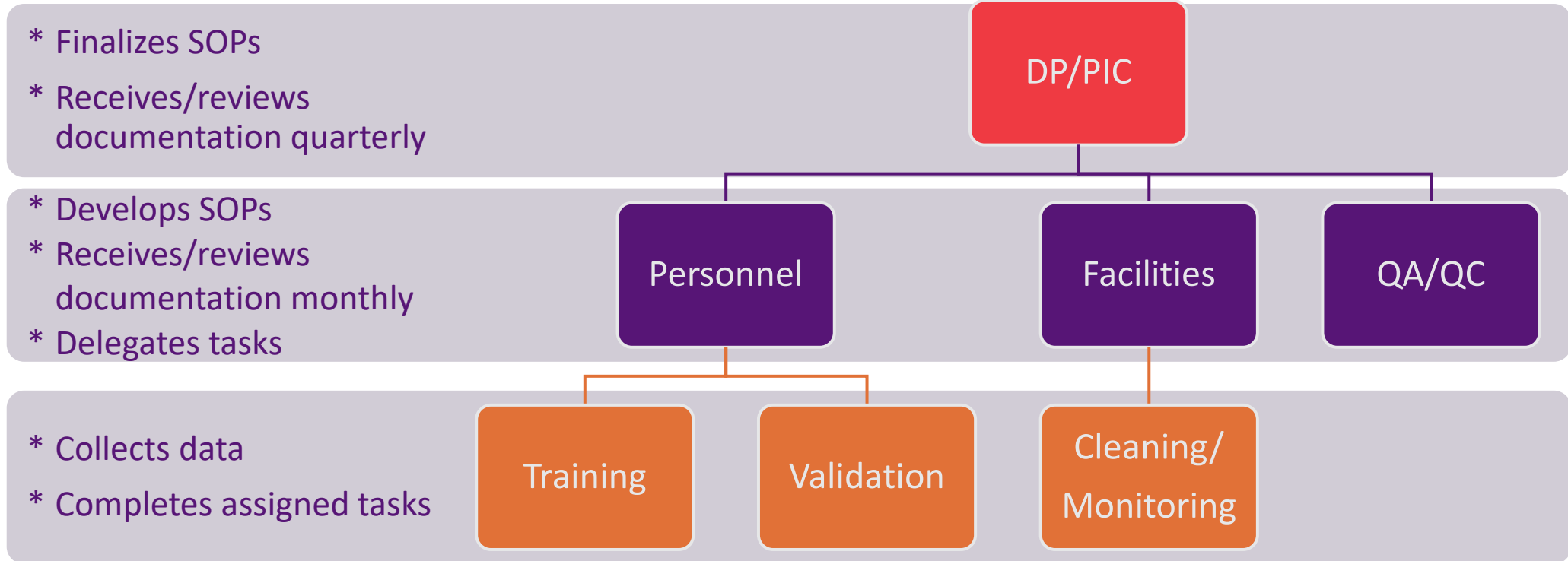


- Overseeing a training program to ensure competency of personnel
- Selecting components
- Monitoring/observing compounding activities and taking immediate corrective action
- Ensuring that SOPs are fully implemented
- Establishing, monitoring and documenting procedures for handling/storing

DP Team Examples



DP Team Examples



Your Turn

Overseeing a Training Program

- _____
- _____

Selecting Components

- _____
- _____

Monitoring/Observing Compounding Activities

- _____
- _____

Ensuring SOPs Are Fully Implemented

- _____
- _____

Handling/Storage

- _____
- _____



SOPs That Scale

- Mock inspection / gap analysis
- Analyze existing processes
- Automate where possible
- Divide and conquer



QA/QC/Investigations/CAPA



Inspectors experience your pharmacy through your documentation



This is how you provide confidence that you can self-regulate



It's not as difficult as you might think



Investigations

- You receive complaints/adverse event reports from patients regularly
- You already handle these
- You may or may not document them



Incident/accident reporting and follow-up			
Reporting an incident <input type="checkbox"/> accident <input type="checkbox"/>			
General Information			
Date and time of incident/accident:		Reported by:	
Name of patient affected, if applicable:		Full address:	
		Phone number:	
Pharmacy personnel involved:			
Information about incident/accident			
(Summary of the situation and consequences)			
Disclosed to the patient concerned: <input type="checkbox"/>			
Name of pharmacist responsible for follow-up:			
Analysis of causes			
Causes:	Options for corrections or changes:	Corrections or changes chosen:	
Action plan			
Actions	Responsible	Deadline	✓
Monitoring			
Verifications	Responsible		✓
Closing the file			
Pharmacist responsible for follow-up:		Date file closed:	

Meeting Patient Expectations

Scaling Considerations



Logistics of Scaling Up



Workspaces



Level 1

- 6 ft/person
- 1 person



Level 2

- 6 ft/person
- Plus processing



Level 3


- 6 ft/person
- Order entry
- Filling
- Shipping


Staff

- Generally – 1 pharmacist, 3 technicians, 1 support person per 50 compounds
- Payroll is likely 35-40% of operating expenses



Equipment

 Use your investing dollars wisely – not every flashy piece of equipment will help your practice

 Does it save time?

 Does it save money?

 Does it open new revenue streams or enhance existing streams?

 Does it improve quality?

Inventory



Utilize predictive software programs or usage reports to order smarter



Buy in bulk ONLY when it makes sense



If you are pursuing a niche market, have the inventory on hand ahead of time



100%

Traditional Community Pharmacy

Revenue (Sales)	100%
- COGS	80%
Gross Profit	20%
- Payroll Expenses	13%
- Occupancy Expenses	1%
- Operational Expenses	3%
Net Profit	3%



- 80%

Gross Profit 20%



Net Profit 3%



- 17%



100%

Compounding Pharmacy

Revenue (Sales)	100%
- COGS	25%
Gross Profit	75%
- Payroll Expenses	35%
- Occupancy Expenses	6%
- Operational Expenses	14%
Net Profit	20%

Gross
Profit 75%



- 25%



Net
Profit 20%



- 55%

INCOME STATEMENT	Average 36 Compounding Pharmacies	Top 25%
TOTAL REVENUE	\$ 3,363,949.46	\$ 4,643,781.02
TOTAL COGS	\$ 921,256.28	\$ 1,106,993.83
COGS PERCENT OF SALES	27.39%	23.84%
GROSS PROFIT DOLLARS	\$ 2,442,693.18	\$ 3,536,787.19
GROSS PROFIT PERCENT OF SALES	72.61%	76.16%
Merchant Fees	\$ 87,450.62	\$ 109,871.14
PERCENT OF SALES	2.60%	2.37%
TOTAL POSTAGE & DELIVERY EXPENSES	\$ 156,314.05	\$ 189,582.45
PERCENT OF SALES	4.65%	4.08%
TOTAL MARKETING / SALES EXPENSES	\$ 99,499.90	\$ 93,085.91
PERCENT OF SALES	2.96%	2.00%
TOTAL PAYROLL EXPENSE	\$ 1,225,085.75	\$ 1,500,810.85
PERCENT OF SALES	36.42%	32.32%
TOTAL OCCUPANCY EXPENSE	\$ 175,163.46	\$ 180,117.98
PERCENT OF SALES	5.21%	3.88%
TOTAL OPERATIONAL EXPENSE	\$ 243,338.72	\$ 218,535.01
PERCENT OF SALES	7.23%	4.71%
EARNINGS BEFORE INTEREST, TAXES, DEPRECIATION, AMORTIZATION (EBITDA)	\$ 455,840.69	\$ 1,244,783.86
EBITDA PERCENT OF SALES	13.55%	26.81%

Gaining Market Share

Scaling Considerations



Gaining Market Share

- This is the easiest part of the equation
- Old-school marketing still works
- New tricks — AI



what is the best way to market a compounding pharmacy

Marketing a **compounding pharmacy** effectively requires a combination of traditional trust-building techniques and modern digital marketing. Since compounding is specialized and highly regulated, success hinges on education, relationships, and credibility. Here's a strategic approach:



1. Define Your Niche and USP (Unique Selling Proposition)

- Are you focused on hormone replacement therapy (HRT), veterinary meds, pediatrics, dermatology, pain management, etc.?
- Highlight what sets you apart: sterile compounding? Quick turnaround? Pharmacist consultation?

2. Build Medical Provider Relationships

- **Physician Outreach:** Visit local doctors, dentists, vets, and specialists with brochures and sample prescriptions (if permitted).
- **Lunch-and-Learns:** Host educational sessions on how your compounds can support patient outcomes.
- **Referral Incentives:** Offer value-added services like prior authorization support or fast turnaround to increase provider loyalty (without violating kickback laws).





3. Build a Credible Online Presence

- **Professional Website:** Include services, therapeutic areas, pharmacist bios, testimonials, and educational resources.
- **SEO Optimization:** Target keywords like “compounding pharmacy near me,” “bioidentical hormone therapy [city],” or “custom pet medications.”
- **Google My Business Profile:** Helps with local search visibility.

4. Leverage Social Media (Educational > Promotional)

- Share:
 - Patient-friendly explainer videos about compounding.
 - Behind-the-scenes of your cleanroom or lab (non-confidential).
 - Answers to common questions about HRT, topical pain gels, etc.
- Focus on platforms your audience uses—usually Facebook, Instagram, and LinkedIn (for provider targeting).

5. Content Marketing & Email

- Blog about:
 - “Why compounding can help where commercial meds fail”
 - “Compounded medications for pets: A guide for pet parents”
 - Collect emails for newsletters with updates, promotions, and patient education.
-

6. Emphasize Trust, Safety & Compliance

- Highlight accreditations (e.g., PCAB, USP 800 compliance).
 - Feature staff credentials and pharmacist availability.
 - Share testimonials or success stories (with HIPAA compliance).
-

7. Offer Exceptional Customer Service

- Make it easy to transfer prescriptions.
- Provide text/email alerts for prescription readiness.
- Encourage satisfied patients to leave Google reviews.



7. Offer Exceptional Customer Service

- Make it easy to transfer prescriptions.
- Provide text/email alerts for prescription readiness.
- Encourage satisfied patients to leave Google reviews.



Would you like a sample marketing plan or flyer copy tailored to a specific niche (like hormone therapy or veterinary meds)?





yes

Great! To make this really useful, please answer a few quick questions:

1. **What is your compounding pharmacy's niche or main focus?** (e.g., HRT, pain management, veterinary, dermatology, pediatrics)
2. **What city or region are you targeting?**
3. **Do you want a digital-focused plan, print materials like flyers, or both?**
4. **Any unique selling points (USPs)** your pharmacy has (e.g., fast turnaround, PCAB-accredited, sterile compounding, pharmacist consultations)?

Once I have that info, I can create a customized marketing plan and sample flyer copy for you.





4. Email Lead Funnel

Goal: Educate and nurture potential patients into customers

Steps:

- Offer a free e-guide: "The Beginner's Guide to Bioidentical HRT"
- Collect emails via quiz results or guide download
- Automate 5-part email drip campaign:
 - Email 1: Welcome + your story
 - Email 2: Signs you may need HRT
 - Email 3: Why compounding matters
 - Email 4: What to expect with BHRT
 - Email 5: How to get started (with pharmacist call-to-action)

Custom-Compounded Bioidentical HRT in North Alabama

Struggling with fatigue, mood swings, hot flashes, or low libido? You're not alone — and you don't have to settle for one-size-fits-all medications.

At [Pharmacy Name], we specialize in **personalized hormone therapy** tailored to your body's needs.

Led by a pharmacist **board-certified in Anti-Aging Medicine** and **PCAB-accredited**, we ensure the highest standards of safety, accuracy, and care.

📍 Serving North Alabama | 🚀 Estrogen | Progesterone | Testosterone | DHEA | More

- ✅ Physician collaboration
- ✅ Custom dosages and delivery forms
- ✅ Fast turnaround + pharmacist consultation

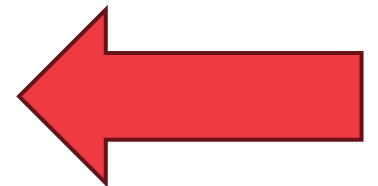
Take our FREE Hormone Imbalance Quiz

👉 [yourpharmacy.com/hrt-quiz]

Or speak with our expert pharmacist today.

📞 Call: [Phone Number] | 🌐 [Website URL] | 💬 DM us anytime

Would you like me to create that **5-part email funnel** or a **sample social media content calendar** as the next step?





5-Part Email Funnel – Bioidentical HRT



Email 1: Welcome & Your Story

Subject Line: Welcome – Your Journey to Hormone Balance Starts Here

Preview Text: Learn how personalized hormone therapy can help you feel like yourself again.

Body:

Hi [First Name],

Thank you for joining our community focused on restoring balance and vitality through **bioidentical hormone therapy (BHRT)**.

I'm [Your Name], a board-certified pharmacist in Anti-Aging Medicine and founder of [Pharmacy Name], a **PCAB-accredited compounding pharmacy** in North Alabama.

We specialize in creating custom HRT solutions — because your hormones, symptoms, and needs are unique.

Over the next few emails, I'll help you understand what BHRT is, how it works, and whether it might be right for you.

Stay tuned — and if you ever have a question, just reply to this email.

To your health,

[Your Name]

[Contact info]

[Website link]



I'm not sure where this rabbit hole ends...

Would you like me to now create a **30-day social media content calendar** for Facebook & Instagram focused on HRT education and trust-building?



AI Activity — Let's Pretend

- Open ChatGPT on your phone or laptop
- Type in the following prompt, filling in the blanks with your niche or a niche you are interested in:
- “Pretend I am a _____ and you are a compounding pharmacist. Send me a marketing script.”





Questions?

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