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# Unlock New Opportunities with High-Quality GLP-1 Inhibitors from a 503b Outsourcing Facility

Semaglutide and Tirzepatide Opportunities

Buddy King | Dakota Health | Sept 2024

Presentation Topic: Semaglutide Opportunities Session  
Title: Pharmacy Practice Updates and Trends

# Buddy King, President

“Your Healthcare Partner”

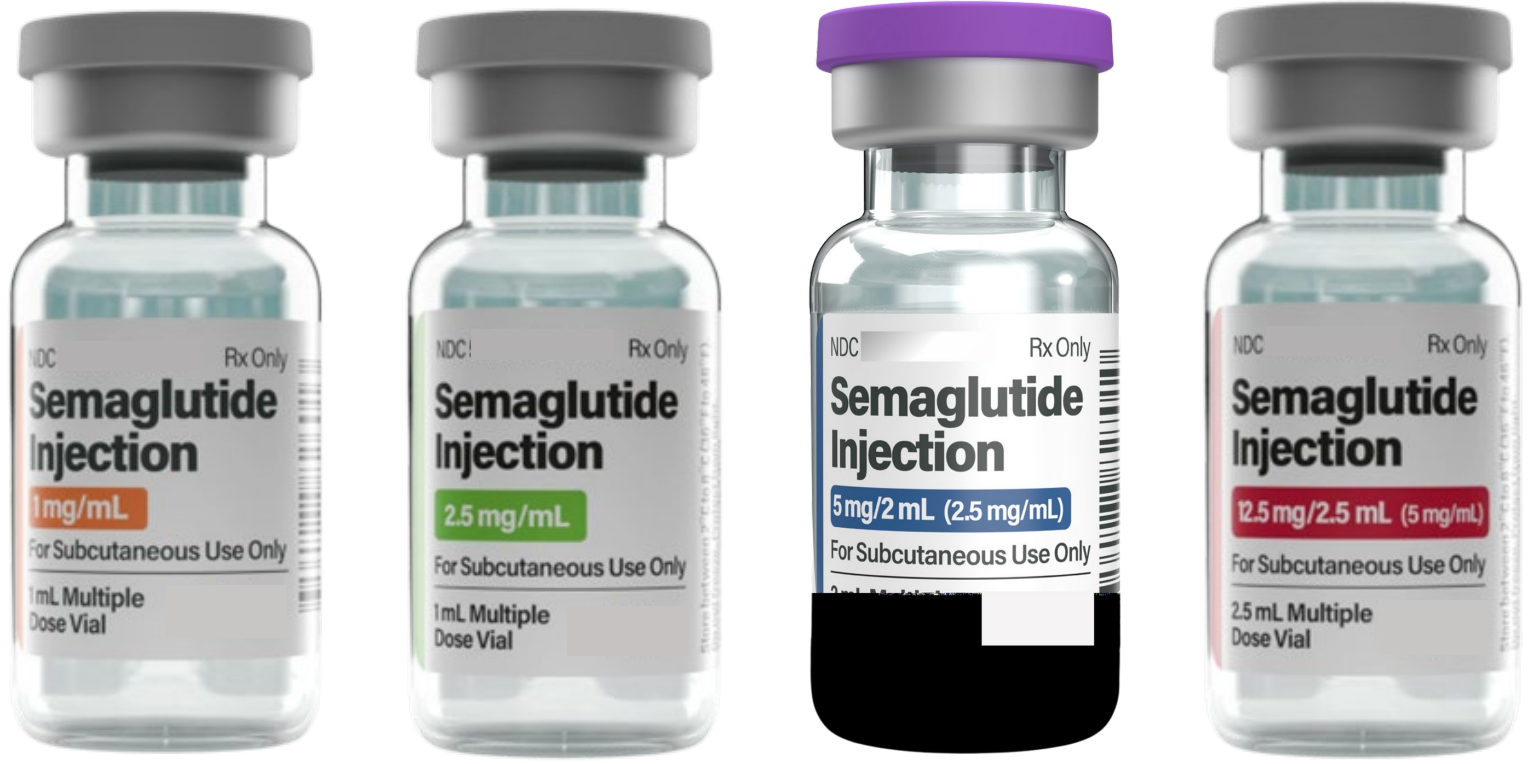
- 30+ years of experience in the pharmaceutical industry
  - Branded and Generic prescription pharmaceuticals
  - Marketing
  - Wholesale
  - Retail pharmacy
  - Business development

Dakoda Health is dedicated to **supporting independent pharmacies** and physicians with innovative, high-quality products and services that can help you grow your business and better serve your patients. Our offerings include a premium line of nutraceutical supplements, a robust telemedicine platform, and cutting-edge weight management solutions featuring GLP-1 medications like **Semaglutide and Tirzepatide**. These products are clinically proven to support weight loss and management, meeting the increasing demand for effective, modern health solutions.

Partnering with Dakota Health provides independent pharmacies with a significant **opportunity to expand their product portfolio and attract new patients by offering in-demand weight management therapies**. Our GLP-1 products, Tirzepatide & Semaglutide, are priced competitively, allowing pharmacies to pass on savings to patients while boosting their profit margins

Our telemedicine platform offers another growth opportunity, **enabling pharmacies to offer virtual consultations** and prescription management services. This platform allows you to extend your reach beyond the local community and provide more convenient, personalized care.

Dakoda Health is committed to building **strong partnerships with independent pharmacies** and physicians, providing you with the tools and resources needed to thrive in today's competitive healthcare environment. By partnering with us, you not only expand your service offerings but also position your business for profitable sustainable growth in a rapidly evolving market.



# SEMAGLUTIDE INJECTION – 3 STRENGTHS



# TIRZEPATIDE INJECTION – 3 STRENGTHS

# Overview

## Overview of Semaglutide & Tirzepatide

- **Guaranteed Inventory**
- **Guaranteed FDA approved API** (Active Pharmaceutical Ingredient)
- **Multiple strengths and vial sizes available**
- **Made by an FDA-approved manufacturer, NOT** from a compounding pharmacy
- No salts or additional peptides added
- UPS Next Day Air; 2-Day Shipping
- Eight-month BUD (Shelf Life)
- Registered NDC number (non-billing)
- Bulk orders for clinic/pharmacy use can be shipped to your facility in over 23 states

# Why GLP-1 Inhibitors Matter

- Semaglutide and Tirzepatide: Critical therapies for weight management and type 2 diabetes
- High demand for these medications in the healthcare landscape
- Opportunity for independent pharmacies to provide these life-changing treatments



# The Compounding Dilemma for Retail Pharmacies

- Traditional compounders can't supply compounded medications to retail pharmacies
- Limited options to meet patient needs for GLP-1 inhibitors
- Potential missed revenue and patient care opportunities





# What is a 503b Outsourcing Facilities?

A **503B outsourcing facility** is a specialized compounding pharmacy that is regulated by the U.S. Food and Drug Administration (FDA) under Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA). These facilities differ from traditional compounding pharmacies (regulated under Section 503A) and are designed to meet specific needs in healthcare settings. Here's a breakdown of their key characteristics:



# Key Features of a 503b Outsourcing Facilities

## Key Features of a 503B Outsourcing Facility:

### 1. Bulk Compounding Without Patient-Specific Prescriptions:

503B outsourcing facilities are allowed to compound large batches of sterile and non-sterile drugs without needing a prescription for a specific patient. This is a key distinction from traditional compounding pharmacies (503A), which typically require patient-specific prescriptions.

### 2. FDA Registration and Regulation:

These facilities must register with the FDA and comply with FDA's **Current Good Manufacturing Practices (CGMPs)**, which are stringent quality standards that also apply to large pharmaceutical manufacturers. This means 503B facilities are subject to routine FDA inspections and must meet high safety and quality standards.

### 3. Sterile Compounding:

Most 503B outsourcing facilities focus on sterile compounding, such as preparing injectable drugs, intravenous (IV) solutions, and other products that must be free from contamination.

### 4. Hospitals and Healthcare Providers:

Hospitals, clinics, and healthcare providers often use 503B outsourcing facilities to obtain large volumes of compounded drugs, especially when commercially manufactured drugs are unavailable, or when specialized doses and formulations are required.

### 5. Exemptions from Certain FDA Requirements:

While 503B facilities must comply with CGMPs, they are exempt from certain parts of the FDA's premarket approval process (which applies to standard pharmaceutical manufacturers). However, their products are not considered FDA-approved even though they are regulated.

### 6. Track and Trace (Drug Supply Chain Security Act - DSCSA):

503B facilities must comply with the Drug Supply Chain Security Act (DSCSA), which requires them to follow certain protocols to track and trace the medications they compound through the supply chain to ensure their safety.

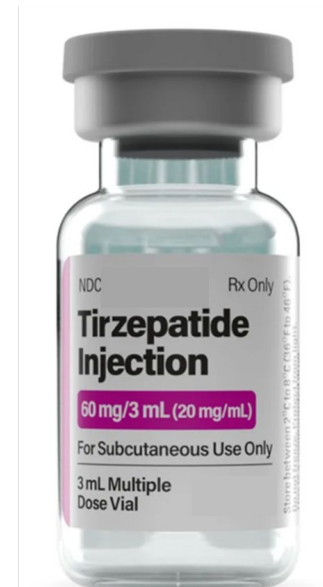
# Benefits of 503b Outsourcing Facilities

## **Benefits of 503B Outsourcing Facilities:**

- **Increased Safety:** Since they follow CGMPs and are subject to FDA inspections, the medications from 503B facilities generally have higher quality and safety standards compared to traditional compounding pharmacies.
- **No Need for Patient-Specific Prescriptions:** Healthcare institutions can order bulk compounded drugs without needing individual patient prescriptions, making 503B facilities essential for hospitals.
- **Sterility Assurance:** For hospitals and providers needing sterile medications, 503B facilities offer a reliable source of high-quality products.

# The 503b Outsourcing Advantage

- Provides access to Semaglutide and Tirzepatide for Retail Pharmacies
- FDA CGMP-compliant production
- High-quality assurance with every batch



# Empowering Patients with Affordable GLP-1 Inhibitors

- Offering GLP-1 inhibitors at a lower cost than traditional options
- Patients can now afford life-changing treatments
- Building loyalty and trust through affordable, high-quality care



# Unmatched Quality and Safety Standards

- FDA CGMP compliance ensures consistent quality, potency, and safety
- Rigorous testing for sterility and potency on every batch
- Reliable, consistent supply of medications



# Ensuring Consistent Supply to Meet Demand

- Large-scale production ensures a steady supply
- No disruption even in periods of high demand
- Always available to meet your patients' needs



# FDA Oversight for Maximum Compliance

- 503b Outsourcing Facilities are directly regulated by the FDA
- Ensures safety and protection for your pharmacy and patients



# A New Revenue Stream

- Tap into the growing demand for GLP-1 inhibitors
- Provide high-quality medications at affordable prices
- Increase your pharmacy's profitability while enhancing patient care

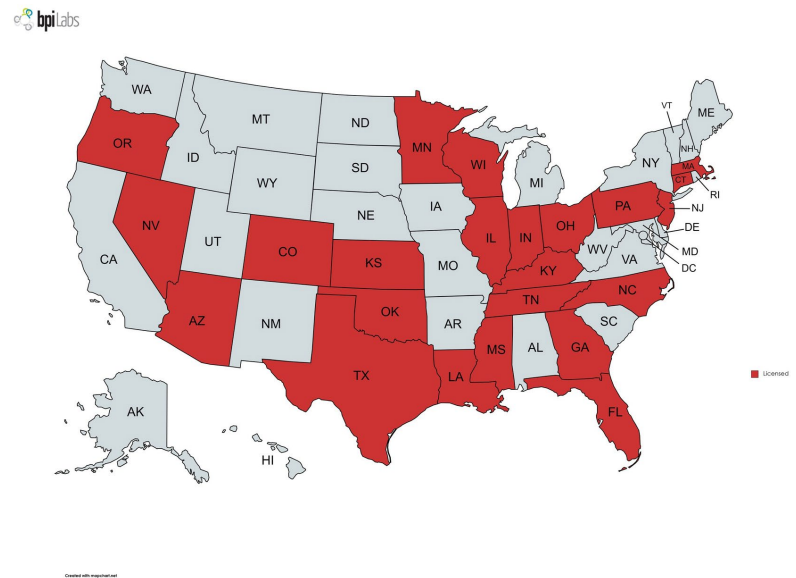


# Opportunity Across the U.S.

Bulk order shipping to the following states:

- Arizona (AZ)
- Colorado (CO)
- Connecticut (CT)
- Florida (FL)
- Georgia (GA)
- Illinois (IL)
- Indiana (IN)
- Kansas (KS)
- Kentucky (KY)
- Louisiana (LA)
- Massachusetts (MA)
- Mississippi (MS)
- Nevada (NV)
- New Jersey (NJ)
- North Carolina (NC)
- Ohio (OH)
- Oklahoma (OK)
- Oregon (OR)
- Pennsylvania (PA)
- South Carolina (SC)
- Tennessee (TN)
- Texas (TX)
- Wisconsin (WI)

**Available in all Red States**



Thank You.