

503B: The Better Choice for Practices

As a 503B, we take pride in meeting the highest standards for manufacturing, quality, and compliance. Unlike traditional 503A compounding pharmacies, 503B facilities are regularly inspected by the FDA and can produce large batches to support office-based dispensing. At SKNV, we're committed to delivering reliable and consistent medications providers can trust.

503B vs 503A

	503B Outsourcing Facilities	503A Traditional Compounding Pharmacies
QUALITY ASSURANCE	<ul style="list-style-type: none"> • Subject to periodic FDA inspections • Quality Department must be in place • Every manufacturing process must be validated • Must conduct extensive testing to release drug batches • Operates within State Boards of Pharmacy regulations 	<ul style="list-style-type: none"> • Operates within State Boards of Pharmacy regulations
CREATION	<ul style="list-style-type: none"> • Created as a result of the 2013 Drug Quality and Security Act (DQSA) to provide safe and effective compounded drugs for individuals and Rx distribution at a larger scale 	<ul style="list-style-type: none"> • 503A was enacted in 1997 and revised in 2013 by the DQSA to carve out “traditional” pharmacy compounding for individuals from FDA oversight
PRESCRIPTION REQUIREMENTS	<ul style="list-style-type: none"> • Does not require patient specific prescriptions • Can be manufactured in large batches for office inventory 	<ul style="list-style-type: none"> • Must have a patient specific prescription • CANNOT provide office inventory
LICENSURE	<ul style="list-style-type: none"> • Registered with the FDA • Regulated by the State Boards of Pharmacy 	<ul style="list-style-type: none"> • NOT registered with the FDA • Regulated by the State Boards of Pharmacy
REGULATORY COMPLIANCE	<ul style="list-style-type: none"> • Complies with Current Good Manufacturing Practices (CGMP) to ensure quality of drug products • Complies with State Boards of Pharmacy regulations • Required to report drugs compounded and associated adverse events to the FDA. 	<ul style="list-style-type: none"> • Complies with State Boards of Pharmacy regulations • Not required to report drugs compounded or associated adverse events to the FDA under the 503A section in regulatory and compliance.



The SKNV VIP System

At SKNV, we own every stage of the prescription journey, from manufacturing to delivery to practice support, all within one connected system.

This allows us to simplify care, eliminate unnecessary barriers, and strengthen the provider-patient relationship at every touchpoint.

Every Provider is a VIP

SKNV puts providers back at the center of the care.

- ✔ Prescribe customized dermatology medications produced in a US FDA-registered 503B facility.
- ✔ Reduce reliance on third parties: no insurance hurdles, substitutions, or delays.
- ✔ Provide medications directly from your office or through direct-to-patient delivery.
- ✔ Rely on transparent sourcing and consistent manufacturing standards

Every Patient is a VIP

The experience doesn't stop at the prescription.

- ✔ Simple access to prescribed medication.
- ✔ Clear, straightforward pricing.
- ✔ Fewer steps between consultation and treatment.
- ✔ Convenient access through in-office dispensing or home delivery.
- ✔ Ongoing support that leaves patient feel informed and cared for.

Every Prescription is a VIP

Each prescription is treated with the attention it deserves.

- ✔ Manufactured under current Good Manufacturing Practices.
- ✔ Designed for consistency, stability, quality, and scalability.
- ✔ Built to support provider-direct dispensing and office inventory.
- ✔ Managed within one fully connected system.

The SKNV VIP Experience

A simpler system.

A stronger provider-patient connection.

A better way to deliver prescription dermatology.

The standard for prescription dermatology.

Our Connected System

Driven by Technology

