

Covers 503A compounding pharmacies and 503B outsourcing facilities preparing sterile and non-sterile compounded drugs, including hormone, weight-loss, and veterinary compounding. Retail pharmacies use CWCO-SUP-PHARMACY; home infusion CWCO-SUP-INFUSION. Complete with ACORD 125 and 126. Attach state licenses, the latest board or FDA inspection, and USP 797 certification reports.

1 APPLICANT / BUSINESS INFORMATION

LEGAL BUSINESS NAME	DBA	FEIN	YEARS IN BUSINESS
PHARMACY ADDRESS	CITY / STATE / ZIP	WEBSITE	

Facility type:
☐ 503A pharmacy ☐ 503B outsourcing facility ☐ Both

PRIMARY CONTACT / PHARMACIST-IN-CHARGE	PHONE	EMAIL

STATE PHARMACY LICENSE NO(S). / STATES SHIPPED TO	PCAB ACCREDITATION / FDA REGISTRATION

2 OPERATIONS

PRODUCT CATEGORY	% OF REVENUE

Categories: sterile injectables; ophthalmics; IV admixtures; hormone replacement; weight-loss (GLP-1); dermatology / pain creams; capsules / troches; pediatric; veterinary; hazardous drugs (chemo).

Customers (check all):

- ☐ Patients (prescription)
 ☐ Physician office use
 ☐ Hospitals / surgery centers
 ☐ Med spas / wellness clinics
 ☐ Veterinarians
☐ Other pharmacies

Volume:

Prescriptions per month	Sterile preparations per month	Pharmacists	Technicians	States shipped to
% shipped out of state				

3 EXPOSURE & RISK QUESTIONS — STERILITY, POTENCY & QUALITY

Contaminated steroid injections from a Massachusetts compounder killed at least 64 people and sickened about 750 in 2012, leading to a \$200 million settlement.

3-1 Are clean rooms and hoods certified every six months to USP 797? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-2 Is environmental monitoring (air and surface sampling) done on a written schedule? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-3 Are sterile preparations tested for sterility and endotoxins before release? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-4 Are any bulk ingredients sourced from non-FDA-registered or research-grade suppliers? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-5 Are potency tests done by an outside lab on a set schedule? ☐ Yes ☐ No
 IF YES, EXPLAIN

3-6 Has the pharmacy recalled any product in the last 5 years? ☐ Yes ☐ No
IF YES, EXPLAIN

3-7 Has the FDA or a state board issued a Form 483, warning letter, or disciplinary action? ☐ Yes ☐ No
IF YES, EXPLAIN

4 EXPOSURE & RISK QUESTIONS — PRODUCTS, BILLING & HAZARDOUS DRUGS

Two Florida compounders paid at least \$7.4 million in 2023 over allegations they added a costly ingredient to pain creams to raise reimbursement.

4-1 Does the pharmacy compound GLP-1 or other weight-loss drugs? ☐ Yes ☐ No
IF YES, EXPLAIN

4-2 Does the pharmacy compound copies of commercially available drugs? ☐ Yes ☐ No
IF YES, EXPLAIN

4-3 Does the pharmacy sell to med spas, clinics, or prescribers for office use? ☐ Yes ☐ No
IF YES, EXPLAIN

4-4 Are hazardous drugs handled in separate rooms that meet USP 800? ☐ Yes ☐ No
IF YES, EXPLAIN

4-5 Does the pharmacy pay marketers or sales reps commissions on prescriptions? ☐ Yes ☐ No
IF YES, EXPLAIN

4-6 Does the pharmacy bill Medicare, Medicaid, or TRICARE for compounded drugs? ☐ Yes ☐ No
IF YES, EXPLAIN

4-7 Has a patient reported a serious adverse event from a compounded product? ☐ Yes ☐ No
IF YES, EXPLAIN

5 PAYROLL, SALES & REVENUE

TOTAL ANNUAL PAYROLL (\$, ILLUSTRATIVE)	NUMBER OF EMPLOYEES	CONTRACT SALES REPS
ANNUAL REVENUE (\$, ILLUSTRATIVE)	STERILE COMPOUNDING REVENUE (\$)	GOVERNMENT PAYER REVENUE (\$)

6 PRIOR INSURANCE & LOSS HISTORY

Attach currently-valued loss runs for the last 5 years.

CURRENT PHARMACIST / PRODUCTS CARRIER	LIMIT / DEDUCTIBLE	RETROACTIVE DATE

6-1 Has any carrier declined, cancelled, or non-renewed coverage for this business in the last 5 years? ☐ Yes ☐ No
IF YES, EXPLAIN

6-2 Has a dispensing error, contamination, or injury claim been made against the pharmacy? ☐ Yes ☐ No
IF YES, EXPLAIN

DATE OF CLAIM	DESCRIPTION	TOTAL INCURRED (\$, ILLUSTRATIVE)	OPEN / CLOSED

6-3 Is the applicant aware of any incident, complaint, or circumstance not yet resulting in a claim that could reasonably give rise to one? ☐ Yes ☐ No
IF YES, EXPLAIN

7 RISK MANAGEMENT

7-1

Is every compounded preparation made from a written master formulation record?

☐ Yes ☐ No

IF YES, EXPLAIN

7-2

Are compounding staff tested for aseptic technique (media fill) at least every six months?

☐ Yes ☐ No

IF YES, EXPLAIN

7-3

Is there a written recall plan with lot tracking to every patient and prescriber?

☐ Yes ☐ No

IF YES, EXPLAIN

8 SIGNATURE & FRAUD WARNING

The undersigned declares that the statements and answers given in this supplemental are true, complete and correct to the best of their knowledge, and that no material fact has been withheld or misstated. The applicant agrees that this supplemental, together with all ACORD applications and attachments, forms the basis of any submission to insurers and may be relied upon by them. Signing this supplemental does not bind coverage. This supplemental is an intake document prepared by Cory Washington & Co. LLC to support carrier submission; it does not itself provide coverage.

FRAUD NOTICE: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information, or conceals for the purpose of misleading information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. (State-specific fraud warnings apply; see state amendatory notice.)

APPLICANT / AUTHORIZED SIGNATURE (TYPE FULL NAME)	TITLE	DATE
PRODUCER — CORY WASHINGTON & CO. LLC	PRODUCER SIGNATURE (TYPE FULL NAME)	DATE