Alliance for Pharmacy Compounding

Compounding the Joy of Living®

Recommended Best Practices for Clinic Direct Billing (Office Pay) for Patient-Specific Compounded Medications by Compounding Pharmacies

April 1, 2024

The Alliance for Pharmacy Compounding represents compounding professionals, as well as prescribers, patients, and other stakeholders. We have developed this 'Best Practices' guidance regarding billing of patient-specific compounded medications directly to a provider's office to assist compounding pharmacies in complying with federal and state laws. Not all states allow clinic direct billing by pharmacies, so pharmacists should perform due diligence, including understanding state and federal law, before engaging in this practice.

The brief is not specific to a particular state's laws or particular drugs, nor is it intended to be an exhaustive statement on clinic direct billing. It should not be relied upon as advice. Pharmacies should seek legal counsel on the matter before initiating clinic direct billing for patient-specific compounded medications.

What is it?

Direct clinic billing – also known as "office pay" – refers to a traditional 503A compounding pharmacy billing a provider or clinic directly for *dispensing* a *patient-specific* prescription written by a prescriber for a compounded medication. The pharmacy is paid by the prescriber or clinic for that prescription, then the prescriber or clinic bills the patient directly for the exact cost of the drug.

The prescribed compounded medication may be delivered to the clinic or to the patient by the pharmacy and is intended only for that specific patient's use. The medication is then administered to the patient in the prescriber's office or sent home with the patient (in this circumstance, the provider acts as a "pick-up location" for the drug. Not all states allow this practice.)

503A pharmacies may also act as a supplier, in limited circumstances*, of commercially available medications to a provider's office. These commercially available medications should be supplied in their original container/packaging and are not required to have a prescription, unlike a compounded medication which must only be dispensed upon receipt of a valid prescription.

When is clinic direct billing appropriate or necessary?

Physicians or other prescribers may have patient-specific prescriptions billed to the clinic for a variety of reasons. Some examples include:

- Patient does not have a permanent address (unhoused, lack of transportation to a pharmacy, visiting or traveling from out-of-state or -country)

- Office procedure requires a preparation that is not appropriate for at-home administration by patient and must be administered in the prescriber's office as a part of treatment.
- Drug is administered as a part of a research clinical trial.
- Prescriber deems it appropriate for in-office training and observation of first dose before sending patient home with the drug.
- Clinic acts as a "pick up location" for the patient for convenience reasons.
- Compounded preparation is intended to be a "continuation of care" after an in-office or in-hospital procedure and wouldn't be appropriate for the patient to use otherwise.

What clinic direct billing is not

Federal law forbids traditional 503A pharmacies from dispensing a drug without a patient-specific prescription. Therefore, clinic direct billing should not be confused with the *distribution* of drugs by 503B outsourcing facilities to hospitals and clinics for "office administration" – also known as "office use" – to patients *without a prescription*. Compounded office-use drugs – say, a compounded numbing agent to be applied before a minor surgical procedure or an injectable ketamine preparation for anesthesia due to a shortage of the commercial product in the marketplace – are prepared by 503B outsourcing facilities in bulk and are billed and shipped to a provider's office for administration in the office. 503B outsourcing facilities are allowed in federal law to distribute drugs without a patient-specific prescription. The products sourced from a 503B facility will not be delivered with a label containing the patient's name. Office-use medications typically would not be billed by the clinic to a particular patient as a separate line item. The prescriber may include the cost of the drug in the overall visit/procedure costs for the patient.

In short, direct clinic billing of patient-specific prescriptions is known as "office pay." When conducted properly, it is a necessary and legitimate practice. This should not be confused with distributions of drugs without a prescription by 503B outsourcing facilities, known as "office use."

Best Practices

The following best practices are intended to assist pharmacies in that aim of properly conducting direct office billing for prescribers and clinics that deem it appropriate.

1. Before a 503A pharmacy agrees to bill a compounded patient-specific prescription to a provider's office, it should obtain a signed physician/prescriber attestation. The prescriber should attest that:
    a. The compounded medication is only for use by the patient to whom it was prescribed and dispensed.
    b. No portion of the drug will be administered or dispensed to anyone other than the individual patient to whom it was prescribed. Any excess in the container that is not intended to be sent home with the patient will be discarded.

    c. In accordance with federal and state laws and regulations, the prescriber will not "upcharge" for the compounded medication and will only collect from the patient the fee the clinic was billed by the pharmacy for the medication.
        i. This in no way prohibits a prescriber from charging a patient for consultative, diagnostic, administrative, or other services billed as part of the care they provide the patient.
2. Make a reasonable effort to verify that the prescription is for an individual patient.
    a. Determine that a legitimate patient-prescriber relationship exists.
    b. Assure that the dispensing quantity is consistent with what the patient could reasonably use or be administered in the calculated days-supply.
    c. If multiple dose injectable vial sizes are larger than a patient should be administered in a 28-day period (multiple-dose vials should be labeled to be discarded 28 days after puncture), vial should be clearly labeled that it is for the indicated patient *only*.
3. Adhere to all applicable laws and regulations, both federal and state.
    a. Know in detail the federal, state, and DEA controlled substance laws and regulations your pharmacy is required to comply with – both in the state in which your pharmacy is located and in the state to which you will be shipping the medication.
        i. For controlled substances, understand DEA's constructive transfer rules and if/how constructive transfer applies to the drug for which you are direct billing.
        ii. Familiarize yourself with requirements about child-resistant packaging requirements and signature-on-delivery for controlled medications. These vary state to state.
    b. Though the pharmacy may bill a compounded controlled substance drug to a provider's office, it nevertheless must be delivered directly to the patient or a patient's agent Exceptions to this MAY be made by DEA as seen in this letter.**
    c. The prescriber or a member of their staff cannot be an agent for the patient.
4. Veterinary clinic billing considerations
    a. Office-stock compounding from bulk drug substances for Nonfood-Producing Animals is only allowed for items on the FDA's list of Bulk Drug Substances for Compounding Office Stock Drugs for use in Nonfood-Producing Animals
    b. Constructive transfer rules governing controlled substances *may* not apply to animals "living" at the prescriber's facility (i.e., zoos).
    c. Occasionally, an entire group or flock of animals are considered one animal in terms of prescription requirements if they can be thought of as a unit. The pharmacy must be able to perform DUR and treat all of them as one (a herd of deer that are around the same age, for example).
5. Marketing
    a. Ensure that you, your team, and the prescriber know not to make claims that a compounded drug can cure or treat a health condition or that compounded drugs are "safe" or "effective." ("Safe" and "effective" have legal definitions in federal law and may not be used with regard to compounded medications.)

b. Some compounding pharmacy owners recommend occasionally spot-checking prescribers' or clinics' social media/website to verify they are not making claims about compounds you prepared or posting pictures of your preparation online.
c. Compounded medications are not and should never be marketed as "generic" medications by a pharmacy or a prescriber that may be administering compounded medications in their office. Compounded drugs are not the same as generic drugs.

6. Know your prescriber and their limitations
    a. Many prescribers have questions about administration of compounded preparations. Be wary of making specific recommendations without written evidence, but instead:
        i. Recommend training courses or webinars.
        ii. Inform them anecdotally about how other prescribers you work with have chosen to administer the drug.
    b. Only dispense medications within a prescriber's scope of practice and within their skill level in prescribing and administering.
    c. Direct providers to attend trainings for CME when they are contemplating offering compounded medications that have specialized administration considerations, including but not limited to:
        i. Numbing creams
        ii. Chemical Peels
        iii. Wart Removing Compounds
        iv. IV therapy
        ~~v.~~ Internal numbing treatments before PRP injections

** Some states require a 503A pharmacy to register as a wholesaler in order to supply* commercial *medications to a provider for office use or impose limits on the volume of distribution of commercial drugs they can perform as a percentage of their total sales. Some wholesalers do not allow or only allow under limited circumstances resale of their commercial medications. Consult an attorney before engaging in this practice.*

*** The document linked from DEA on constructive transfer (sending a single dose of a controlled substance to the prescriber's office) from 2016 is the current thinking and opinion of DEA and does not carry the weight of law. Consult an attorney before engaging in this practice.*

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 500 compounding small businesses – including compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

In traditional compounding, pharmacists create a customized medication, most often from pure ingredients, for an individual patient pursuant to a prescription. Pharmacists' ability to compound medications from pure ingredients is authorized in federal law and for good reason: Manufactured drugs

don't come in strengths and dosage forms that are right for everyone, and prescribers need to be able to prescribe customized medications when, in their judgment, a manufactured drug is not the best course of therapy for a human or animal patient.

Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.