

IbnSina_Compounded_Medication_Disclosure_eSign.pdf

Agreement (read only)

IbnSina Compounded Medication Disclosure and Patient
Acknowledgment
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Compounded Medication Disclosure

As part of care provided through IbnSina, a licensed healthcare provider may prescribe a compounded medication when, in the provider's clinical judgment, a patient has an individualized clinical need that may not be adequately met by an available commercially manufactured medication or available dosage/formulation.

Compounded medications are prepared by independent licensed pharmacies by combining, mixing, altering, or otherwise preparing ingredients pursuant to a valid prescription for an individual patient. IbnSina does not compound, manufacture, store, dispense, or ship medications.

FDA Status and Important Differences

The patient has been specifically informed and understands that compounded medications are not FDA-approved products. The U.S. Food and Drug Administration does not review or approve compounded medications for safety, effectiveness, quality, manufacturing consistency, or labeling before they are dispensed in the same manner as FDA-approved drug products.

Compounded medications may differ from FDA-approved commercially available medications in formulation, concentration, strength, inactive ingredients, appearance, stability, and other characteristics. Compounded medications may carry known and unknown risks, including side effects, adverse reactions, dosing variability, contamination, reduced potency, excessive potency, or other medication-related risks.

Discussion of FDA-Approved and Other Alternatives

The patient confirms that the prescribing provider discussed reasonable treatment alternatives, including FDA-approved commercially available medications when clinically appropriate and available, as well as the option not to proceed with compounded medication therapy.

After discussion of the alternatives, potential benefits, limitations, and risks, the patient and prescribing provider elected to proceed with a compounded medication because the provider determined that an individualized dose, strength, formulation, or treatment approach was clinically appropriate for the patient's specific needs. The purpose of using a compounded medication is to allow individualized therapy; no representation or guarantee is made that a compounded medication will provide superior results or "maximum benefit" compared with an FDA-approved product.

Pharmacy Standards and Independence

If a compounded medication is prescribed, it will be prepared and dispensed by an independent U.S.-based licensed compounding pharmacy that is expected to operate in accordance with applicable federal and state pharmacy laws, licensure requirements, and compounding standards applicable to that pharmacy and prescription.

IbnSina may work with pharmacies selected based on licensing, regulatory status, operational standards, and ability to provide the prescribed formulation. However, IbnSina does not manufacture the medication and does not independently guarantee the pharmacy's compounding process, sterility, potency, quality, shipping, or

regulatory compliance. Questions regarding preparation, ingredients, testing, dispensing, storage, or shipping should be directed to the dispensing pharmacy.

Clinical Decision-Making and Patient-Specific Dosing

The decision to prescribe any medication, including a compounded medication, is made by the treating licensed healthcare provider based on the patient's medical history, reported symptoms, prior treatment, current medications, allergies, contraindications, treatment goals, and the provider's independent clinical judgment.

The patient understands that individualized or non-commercially available doses may be prescribed when clinically appropriate. The patient should use the medication only as prescribed and should not change the dose, frequency, or method of administration without direction from the prescribing provider.

Risks, Side Effects, and Follow-Up

The patient has had an opportunity to discuss expected benefits, material risks, common and potentially serious side effects, contraindications, precautions, and appropriate follow-up for the prescribed therapy. The patient agrees to provide accurate and complete medical information and to promptly report significant side effects, new medical conditions, pregnancy, medication changes, allergic reactions, or other concerns.

No specific clinical outcome, amount of weight loss, or other treatment result is promised or guaranteed.

Patient Acknowledgment and Consent

By signing below, the patient acknowledges and confirms that:

- I understand that the medication prescribed to me may be a compounded medication and is not FDA-approved.
- I understand that the FDA does not review or approve compounded medications for safety, effectiveness, or quality before dispensing in the same manner as FDA-approved products.
- I have been informed of reasonable alternatives, including FDA-approved commercially available treatment options when clinically appropriate and available, and I have had the opportunity to ask questions.
- I understand why a compounded medication and/or individualized dose or formulation is being considered for my specific clinical needs.
- I understand that compounded medications may have risks that are similar to, different from, or not as well characterized as FDA-approved medications.
- I understand that the prescribing decision is based on the licensed provider's independent clinical judgment and my individual circumstances.
- I understand that the dispensing pharmacy is an independent licensed pharmacy and that IbnSina does not manufacture, compound, store, dispense, or ship my medication.
- I voluntarily consent to treatment with the prescribed compounded medication after discussion of the above information and alternatives.
- I understand that I may ask questions at any time and may decline or discontinue treatment after discussing appropriate medical considerations with my healthcare provider

☐ I hereby agree to the document above.

Name*

First Name:

Last Name:

Signature*

(This will require your client's signature)

Date*