#### **Designated Agent Training Packet**

You are about to become a Designated Agent for your employer. This is a very big responsibility. Once you are officially authorized, you will be able to call in prescriptions and fax prescriptions to the pharmacy on behalf of the Registered Agent (Dentist who is prescribing the medication.)

This training and following Authorization does not allow you to prescribe, dispense or determine medical necessity. Please read the following for the exact scope of your duties as a Designated Agent. Your employer may have more restrictive policies in place to further direct your duties, They may not have less restrictive policies in place.

Read the following pages and identify your role as a Designated Agent. Complete the quiz at the end of this training packet. You may keep this packet and refer to it if you have any questions. You may also reference The Designated Agents Tracking Log for more information.

## Who Is an Agent of an Individual Practitioner for the Purpose of Communicating a Prescription for a Controlled Substance

**Definition of a Designated Agent:** A "designated agent" is "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser or prescriber. A Designated Agent must be officially authorized to act on the behalf of the Registered Agent (who is the dentist who can prescribe controlled substances). Just saying, "You are a Designated Agent is not enough. You must complete this training and agree to follow the rules and regulations that pertain to your duties as a Designated Agent.

# Acts That a Designated Agent May Take in Connection With Controlled Substance Prescriptions

- 1. As an authorized agent of an individual practitioner, you may prepare a written prescription for the signature of the practitioner, as long as the practitioner, in the course of regular professional practice, has determined that there is a legitimate medical purpose for the prescription and has dictated to you the required elements of the prescription. (see next page for Elements of a Prescription)
- 2. You may telephone the pharmacy and convey a Schedule III-V controlled Substance when a DEA-registered individual practitioner has made a valid oral prescription by conveying all the required prescription information to you.
- 3. You may fax to the pharmacy a practitioner-signed prescription for a Schedule III-V controlled Substance as long as the prescription contains all of the elements of a valid prescription.

#### Medical Determination of Need for a Controlled Substance Prescription Cannot Be Delegated

DEA regulations state: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his

professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

This very clearly means the practitioner must determine that a prescription for a controlled substance is for a legitimate medical purpose. This determination is the sole responsibility of the practitioner and may not be delegated.

Simply stated: You may not determine who gets a prescription and why. You do not have the training or the authority to provide medical necessity.

## The Elements of a Valid Prescription Must be Specified by the Practitioner and Cannot be Delegated

Controlled substance prescriptions are orders for medication to be dispensed to an ultimate user and are required to contain specific information including:

- a) Patient name \* must be a patient of record
- b) Patient address
- c) Drug name
- d) Drug strength
- e) Quantity prescribed
- f) Directions for use
- g) Name, address and DEA number of the issuing practitioner

Additionally, all prescriptions for controlled substances must be dated as of, and signed on, the day they are issued.

**Paper prescriptions** must be manually signed by the issuing practitioner in the same manner that the practitioner would sign a check or other legal document.

**Electronic prescriptions** for controlled substances must be signed in accordance with DEA regulations, which can be found at http://www.deadiversion.usdoj.gov/21cfr/cfr/2111cfrt.htm.



The DEA makes it very clear: The authorized agent does not have the authority to make medical determinations. Only the Registered Practitioner can determine medical

As an authorized agent, you may prepare a controlled substance prescription only based on the instructions of the prescribing practitioner as to the required elements of a valid prescription and then provide the prescription to the practitioner to review.

You do not have the authority to make medical determinations. The practitioner must personally sign the prescription, whether manually or electronically. The prescribing practitioner cannot delegate his or her signature authority to you!

#### Communication of a Valid Prescription for a Schedule III, IV, or V Controlled Substance May be Delegated to an Authorized Agent

A pharmacy may legally dispense Schedule III, IV and V controlled substances to a patient with a "written or oral prescription." The DEA regulations further specify that a pharmacist may dispense a Schedule III, IV, or V controlled substance pursuant to "either a paper prescription signed by a practitioner [or] a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy,

You as an authorized agent may transmit such a practitioner- signed paper prescription via facsimile or phone to the pharmacy on behalf of the practitioner.

The pharmacy has the right and authority to inquire into the legitimacy of the prescription. Keep in mind, the practitioner remains responsible for ensuring that the prescription conforms to the law and regulations, and they can call and verify your credentials at any time.

# Generally, a Valid Schedule II Controlled Substance Prescription May Not be Communicated by Facsimile or Phone

Because Schedule II controlled substances have the highest potential for abuse and the greatest likelihood of dependence among the pharmaceutical controlled substances, the controls on Schedule II drugs are the most restrictive.

The law requires that a Schedule II controlled substance be dispensed by a pharmacy only with a written prescription, **except in emergency situations**, and prohibits Schedule II prescriptions from being refilled. So, in most cases, a pharmacist must receive the original, manually signed paper prescription or an electronic prescription prior to dispensing a Schedule II controlled substance.



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## Emergency Oral Communication of a Valid Schedule II Controlled Substance Prescription May Not be Delegated to an Authorized Agent

In case of an emergency when Schedule II controlled substances are needed without a written prescription, you many NOT call that prescription in to the pharmacy. Emergency oral prescription for Schedule II controlled substances must come from the prescribing dentist only.

If the prescribing individual practitioner is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner and/or other good faith efforts to ensure the practitioner's identity. Because the more specific requirement that the emergency Schedule II oral authorization must be from a registered individual practitioner supersedes the general rule that an employee or agent of the individual practitioner may communicate prescriptions to a pharmacist, the prescribing individual practitioner must personally communicate the emergency oral prescription to the pharmacist.

A Designated Agent may not call in an oral prescription for a Schedule II controlled substance on behalf of a practitioner even in an emergency circumstance.

#### **Commonly Prescribed Schedule II Drugs:**

These are some of the most common Schedule II drugs. You do not have the authority to call or fax these prescriptions in to a pharmacy.

- o Codeine,
- o Morphine,
- o Fentanvl.
- Oxycodone HCL,
- o Hydrocodone,
- o Bitartrate Hydromorphone,
- o Oxymorphone,
- Meperidine

#### It's Time for a Quiz!

Complete the Quiz and present it to your supervisor.

Emplo	oyee Name:
Date: _	TOOTUCOD
Super	visor Signature:
Quiz S	core:
1.	A "" is "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser or prescriber.
2.	Who determines the medical need for the prescription?
3.	Identify the missing elements of the properly written prescription:  a) b) Patient address c) d) Drug strength e) Quantity prescribed f) g) Name, address and DEA number of the issuing practitioner
4.	True or False: Paper prescriptions must be manually signed by the issuing practitioner in the same manner that the practitioner would sign a check or other legal document.
5.	Which Schedule Drugs prescriptions can you call in or fax to a pharmacy? Schedule,
6.	List 3 commonly prescribed Schedule II drugs:
7	When are you as a Designated Agent permitted to call or fax a Schedule II prescription in to

the pharmacy?

#### Designated Agent Quiz Answer Key:

- 1. A "**Designated Agent**" is "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser or prescriber.
- 2. Who determines the medical need for the prescription? The Dentist or Prescribing Dentist
- 3. Identify the missing elements of the properly written prescription:
  - a) Patient Name
  - b) Patient address
  - c) **Drug Name**
  - d) Drug strength
  - e) Quantity prescribed
  - f) Directions for Use
  - g) Name, address and DEA number of the issuing practitioner
- 4. **True** or False: Paper prescriptions must be manually signed by the issuing practitioner in the same manner that the practitioner would sign a check or other legal document.
- 5. Which Schedule Drugs prescriptions can you call in or fax to a pharmacy? Schedule III, IV, V
- 6. List 3 commonly prescribed Schedule II drugs: **Any 3 of these drugs: Codeine, Morphine, Fentanyl, Oxycodone HCL, Hydrocodone, Hydromorphone, , Meperidine,**
- 7. When are you as a Designated Agent permitted to call or fax a Schedule II prescription in to the pharmacy? **Never. Only schedule III, IV and V controlled substances.**