Controlled Substance Prescriptions & Good Faith Dispensing Policy

The pharmacist **must** use the elements of Good Faith Dispensing in conjunction with state and federal controlled substance laws when filling **all** prescriptions.

Controlled substances may only be dispensed to patients who have a prescription for a valid medical purpose issued by a practitioner acting in the usual course of professional practice. A **corresponding responsibility** rests with the pharmacist to ensure that controlled substance prescriptions are issued for a legitimate medical purpose by an individual practitioner in the usual course of professional practice.

Any pharmacist who fails to meet his/her "corresponding responsibility" obligation when dispensing a prescription for a controlled substance, or does not follow the validation procedures outlined below, is subject to disciplinary action up to and including termination of employment.

Prescription Validation Procedures for Good Faith Dispensing of Controlled Substances

Follow these procedures to validate a controlled substance prescription:

1. ***Patient ID***: Ask for government issued identification. If the pharmacist does not have an established relationship with the patient, verify and document the patient's identity including name and address on the prescription hard copy or scan the ID into Intercom Plus as an "additional image". If your state has more stringent identification requirements, follow those guidelines.

2. ***Prescriber***: Confirm that the prescriber has authority to prescribe controlled substances by verifying the validity of the prescriber's information including the DEA number and state license number.

3. ***Prescription Drug Monitoring Program (PDMP)***: If available in your state, use the PDMP to obtain additional information to help determine the validity and confirm the appropriateness of the prescription. (See link to state specific websites under Additional Resources section below.)

4. ***Data/DUR Review***: Review the patient's profile to resolve and document any associated DURs appropriately.

5. ***Evaluate the Elements of Good Faith Dispensing:*** Contact the prescriber for verification or to clarify the elements of good faith dispensing for the prescription. If the prescriber cannot be reached, do not dispense the prescription. Even if the prescriber verifies that the prescription is valid, it is the pharmacist's responsibility to confirm that the elements of good faith dispensing are satisfied prior to dispensing.

   The following are examples that should alert a pharmacist to questionable circumstances. This list is not intended to be all inclusive. A 'yes' answer to any of the questions below does not necessarily equate to a refusal to fill. A 'yes' answer means that the pharmacist has a responsibility to follow up with either the patient and/or prescriber for additional information to satisfy the good faith requirements. Pharmacists shall use their professional judgment when determining if the elements of good faith are present prior to dispensing controlled substance prescriptions.

Usual Course of Professional Practice:
• Is the controlled substance prescription written outside the usual course of the prescriber's professional practice or specialization, also known as their scope of practice? For example: a pediatrician prescribing pain medications for an adult, or a pain clinic doctor prescribing the same medication regimen for all of his patients. • Are there unusual geographical distances between the patient, pharmacist and/or prescriber that cannot be reasonably explained? • Is there a lack of a consistent prescriber/patient relationship? • Does the prescription appear to be issued pursuant to an online diagnosis questionnaire? For example, does the prescriber only list a website on the prescription which indicates that he/she has no physical office address where patients can be examined?

Trends for Prescribers and Patients:
Is there a noticeable trend in controlled substance prescribing by one prescriber or for a large number of patients such as: • Unusual dosages, directions, or quantities beyond those normally prescribed? • Dosages or directions that conflict with approved labeling? • Frequent combination prescriptions for known drug "cocktails" such as a benzodiazepine, opioid and carisoprodol? • Increased frequency of prescriptions for the same or similar controlled substances?

Prescribers:

Is the prescriber:

- Unwilling to provide the reason for prescribing the controlled substance in order for the pharmacist to confirm that it is for a legitimate medical purpose?
- Unwilling to partner with the pharmacist and provide necessary documentation such as diagnosis, previous therapies, expected length of therapy, etc?
- Always difficult to reach and/or only willing to communicate through office staff?
- Abusive or threatening?

Does the prescriber:

- Consistently write prescriptions for controlled substances for the same patient or for several different patients?
- Frequently authorize early refills without explanation or documentation?

Does the prescriber's practice:

- Operate as a "cash only" business and not accept government or 3rd party insurance payment?
- Have a different phone number on the prescription than found using the "prescriber inquiry" function in Intercom Plus?

Patients:

Does the patient:

- Consistently request early refills?
- Exhibit 'drug seeking' type behaviors?
- Selectively fill only controlled substance prescriptions?
- Request to pay by cash or by using a cash discount card (in a possible attempt to circumvent third party billing restrictions)?
- Have controlled substance prescriptions from several different prescribers?

- Is the patient unable to provide a valid reason for taking the controlled substance (i.e. a valid diagnosis or legitimate medical purpose)?
- Is the patient or patient's agent unable to present a valid ID?
- Do multiple patients drop off prescriptions around the same time for the same medication from the same prescriber?
- Is the individual picking up controlled substance prescriptions on behalf of multiple patients? Do these individuals reside at different addresses or have no apparent relationship to each other?

Prescriptions:

Does the prescription:

- Appear to be altered or forged?
- Contain misspellings?
- Contain atypical abbreviations or none at all?
- Have an unusual presentation – prescriber's handwriting is too legible, is written in different color inks, different handwriting, or with erasure marks?

6. ***Document***: It is imperative that pharmacists document all efforts used to validate good faith dispensing.
   - Prescriber information: If the prescriber confirms the validity of the prescription, document the date, name of the individual spoken to and any other pertinent information such as diagnosis, previous therapy, length of treatment, etc. on the prescription hard copy and/or annotate the image.
   - Patient information: If the patient provides an ID or other pertinent information such as medical history, health conditions, allergies, previous therapy, etc., scan any images into Intercom Plus as an "additional image", annotate the image, and/or document the information on the prescription hard copy. Update the information in the patient profile or in comments as appropriate.
   - Elements of Good Faith: Document any information pertaining to the elements of good faith on the prescription hard copy and/or annotate the image.

7. ***Pharmacist Action*:** After reviewing the elements of good faith and following the validation procedures, the pharmacist must use his or her professional judgment to determine how to proceed:

   - ***Dispense***: If the prescription is valid and meets the elements of Good Faith, process and dispense the prescription as usual.

   - ***Not Valid to Dispense***: If the prescriber indicates that the prescription is not valid, document the prescription with the following: "Rx not valid per prescriber" and do not dispense.

   - ***Refusal to Dispense***: If the prescriber informs the pharmacist that a prescription for a controlled substance is valid, but the pharmacist determines that the elements of good faith dispensing are not present, the pharmacist has a responsibility to refuse to dispense.

NOTES:
• **If you are unable to satisfy the elements of good faith, inform the patient that you are unable to fill the prescription. Do not provide inaccurate information to the patient such as misrepresenting that you are out of stock or stating that the prescriber is under investigation. Any prescription for which the pharmacist is not satisfied that the elements of good faith are met can be refused based on the pharmacist's discretion.**
• **Dispensing a prescription that the pharmacist knows is fraudulent is a violation of state and federal law. If asked by law enforcement to dispense a fraudulent prescription, do NOT dispense and inform law enforcement that this is a violation of state and federal law. Knowingly dispensing a prescription with anything other than what is written on the prescription (i.e., candy, OTC medication, etc.) is a violation of company policy. Violation of state and federal law and/or company policy will result in disciplinary action, up to and including termination of employment.**

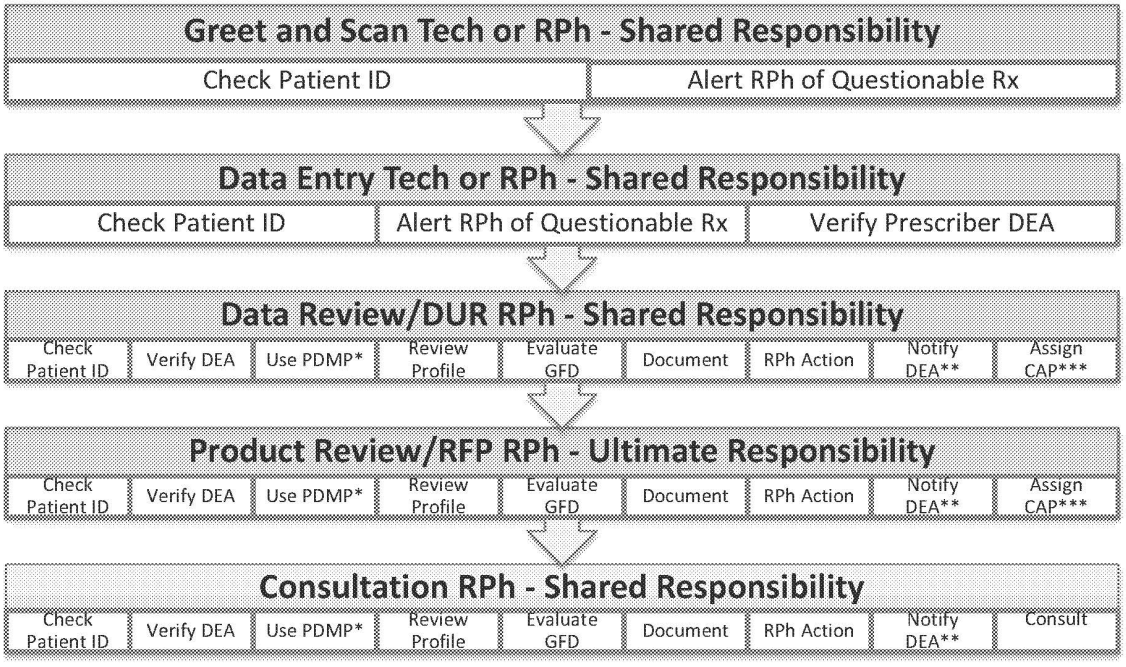
8. ***Notify DEA***: The local DEA office must be notified of refusals to fill if such refusal is based on a determination that the prescription was forged, altered, issued outside of the usual course of professional practice, or does not meet the elements of good faith. If a pharmacist refuses to dispense a controlled substance, a copy of the prescription must be faxed to the local DEA office within **two business days** of a pharmacist's refusal to fill.
    - Use the DEA Fax template.
    - Follow the proper procedures on tracking disclosure of patient "protected health information" located on StoreNet: RxOps > Pharmacy Policy and Procedures: Privacy/HIPAA > PHI Disclosure Webform Guidelines.
    - Print a photo copy or image of the prescription and place in a California folder marked fraudulent/denied prescriptions. File with the other hard copy prescription records for future reference along with any additional documentation.
    - Contact local law enforcement if required by your state. A copy of the prescription may be given to local law enforcement upon verbal request.

Roles and Responsibilities

Everyone in the pharmacy has a role in ensuring that the elements of Good Faith Dispensing are met. While all pharmacists and technicians have an obligation to assist with validation of Good Faith Dispensing requirements during the dispensing process, the **Product Review/RFP (Retail Fill Process) Pharmacist** has the ***ultimate responsibility*** for ensuring that the elements of Good Faith are present.

During the Product Review/RFP process, the pharmacist is attesting not only that the product is correct but also that Good Faith Dispensing guidelines have been validated and documented appropriately. The goal is that all elements of Good Faith Dispensing have been validated before getting to the Product Review/RFP Pharmacist. The Product Review/RFP Pharmacist should then be able to confirm the elements of Good Faith Dispensing have been met and continue with the dispensing process.

Summary of Good Faith Dispensing (GFD) Procedures by Role and Responsibility:



*Use PDMP –if available in your state

**Notify DEA –if forged, altered, or refusing to fill based on good faith requirements

***Assign CAP/Patient Chart Consult –if patient consultation is deemed appropriate

Note: In POWER stores, only a pharmacist should perform the RFP process for CII controlled substances. Technicians should not perform RFP on CIIs and must pass to a pharmacist to complete the RFP process.

Office-Use Prescriptions

Prescriptions must be issued for a specific patient. Prescriptions written for "office use" are not valid.

Emergency Schedule II Dispensing

Notify your district pharmacy supervisor if a prescriber fails to provide a hard copy for an emergency Schedule II telephone prescription within the legally required time period. The pharmacy supervisor will evaluate the situation and then contact the appropriate regulatory agencies, if necessary.

Additional Resources:

1. DEA Diversion Website
    - Local DEA office
    - Pharmacist Guide to Preventing Fraud
    - Pharmacist Responsibility to recognizing drug abuse
2. DEA Fax template Link
3. State Specific Identification Procedures
4. Prescription Drug Monitoring Program (PDMP) Websites (state specific)
5. Controlled Substance Action Plan for Stores

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