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**From:** Hilker, Heidi [heidi.hilker@walgreens.com]  
**Sent:** 9/17/2015 9:32:35 AM  
**To:** Daugherty, Patricia [patricia.daugherty@walgreens.com]; Bratton, Edward [edward.bratton@walgreens.com]  
**Subject:** RE: Question about opioid dispensing policy  
**Attachments:** good\_faith\_dispensing.pdf; td\_gfd\_policy.pdf; td\_gfd\_checklist.pdf

I reviewed the policies for both the GFD and TDGFD and also reviewed the TDGFD checklist. I looked at the FAQs as well.

Thank you  
Heidi

Heidi Hilker PharmD.  
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**From:** Daugherty, Patricia  
**Sent:** Thursday, September 17, 2015 9:03 AM  
**To:** Hilker, Heidi; Bratton, Edward; Stahmann, Eric  
**Subject:** RE: Question about opioid dispensing policy

Hi Heidi,  
Can you please send me the content you reviewed on Storenet so I can see what you are referring to? Is it our GFD policy or TDGFD Policy you were looking it?  
Feel free to give me a call anytime so we can discuss.  
Thanks  
Patty

**Patricia Daugherty PharmD**  
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**From:** Hilker, Heidi  
**Sent:** Thursday, September 17, 2015 8:43 AM  
**To:** Bratton, Edward; Daugherty, Patricia; Stahmann, Eric  
**Subject:** Question about opioid dispensing policy

PLAINTIFFS TRIAL  
EXHIBIT  
**P-15037\_00001**

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P-15037 \_ 00001

Hi team,

I have worked with Eric and Ed in previous roles I have had at Walgreens. I am now working in the clinical office and much of my role is focused on supporting the business and operations teams with clinically related needs, such as content accuracy reviews, literature reviews, etc. I was asked by my vice president (Karen Babos) to look into how Walgreens may be able to impact the 3 new PQA opioid related measures. I knew that we had some policies in place regarding opioid dispensing that may address these measures. I have reviewed the content on storenet and I had a couple questions about how we are evaluating the execution of the procedures and what areas you feel need to be enhanced or updated. Please let me know if you are able to share information with me and I will set up a time for us to talk. Also, let me know if all three of you should be in this meeting or if there are others to include.

**Thank you**

**Heidi**

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## 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. **Identification:** If the pharmacist does not have an established relationship with the patient, ask for government issued identification and verify and document the identity of the patient or the person dropping off the prescription on the patient's behalf, including name and address on the prescription hard copy or scan and print a copy of the ID utilizing the manual fax process and attach it to the hard copy.  
  
→ **NOTE: If your state prohibits the scanning and copying of an ID, follow your state's regulations.**
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.
  - StoreNet > Rx Ops > Pharmacy Policy and Procedures > Rx Integrity > DEA > DEA License Number Validation
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.
  - StoreNet > 3rd Party > Third Party Reference > State Specific Information > All States
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's clinical staff for verification or to clarify the elements of good faith dispensing for the prescription. If the prescriber's clinical staff cannot be reached, do not dispense the prescription. Even if the prescriber's clinical staff 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.

→ **NOTE: For Hospice and Oncology Patients Only:**

If you are unable to reach the prescriber's clinical staff, the pharmacist may fill the prescription without verification provided the elements of Good Faith Dispensing are met.

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's clinical staff 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 3<sup>rd</sup> 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's clinical staff 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., 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. **Reporting Regulations (state specific):** If your state has additional regulations for refused prescriptions, such as reporting to local law enforcement or documenting the refusal on the hard copy, follow your state's regulations.

## **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

\*\*Reporting Regulations - only if required by your state

\*\*\*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.

→ **NOTE:** Pharmacists in WE stores are allowed to perform virtual product review for all controlled substances.

### 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.



Revised 2/21/2014  
Revised 8/01/2013  
Revised 6/11/2012  
Revised 11/08/2011  
Revised 7/17/2011  
Revised 6/20/2011  
Revised 3/28/2007  
Revised 2/7/2007

## Target Drug Good Faith Dispensing Policy

Walgreens requires ALL pharmacists and pharmacy team members to adhere to the Controlled Substance Prescriptions and Good Faith Dispensing Policy and procedures. Additionally, for certain controlled substances, Walgreens requires ALL pharmacists and pharmacy team members to also adhere to the Target Drug Good Faith Dispensing (TD GFD) Policy and procedures outlined below. This TD GFD Policy is intended to be a supplemental policy which will aid pharmacists in determining if the prescription has been written for a legitimate medical purpose. This policy is not a replacement for professional judgment and should not in any way replace sound decisions that pharmacists are required to make while filling prescriptions.

Walgreens is taking a strict stance on compliance with these requirements. Failure to comply will result in disciplinary action up to and including termination of employment.

## Procedures

When dispensing prescriptions for Target Drugs, you are responsible for utilizing the Target Drug Good Faith Dispensing Checklist (TD GFD Checklist) and procedures outlined below. The following drugs are considered Target Drugs:

- ALL Oxycodone (single ingredient tablets/capsules)
- ALL Hydromorphone (single ingredient tablets)
- ALL Methadone (single ingredient tablets)
- Other (optional - district specific)

The TD GFD Checklist will be used to identify the key points of the validation procedures and to create a standardized process that all pharmacists must use to determine whether a Target Drug should be dispensed. Validation criteria will include, but not be limited to, identifying the patient and utilizing a state's Prescription Drug Monitoring Program (PDMP) if available.

→ **NOTE: Both pharmacists and pharmacy technicians will be reviewing sections of the checklist to ensure that all of the elements of TD GFD are met.**

## Prescription Validation Procedures for Target Drugs

The TD GFD Checklist will be used to do the following:

- a. Identify the key points of the validation process
- b. Create a standardized process that all pharmacists shall use to determine if a Target Drug should be dispensed
- c. Validate by both pharmacists and technicians that the elements of TD GFD are met

## Drop Off

1. Identify Target Drug
2. Begin TD GFD Checklist procedures

3. Review patient comments in IC+ prior to processing any prescriptions for Target Drugs to determine if another Walgreens location has already completed the TD GFD Checklist and refused to dispense the prescription.
  - i. Patient comment example: "Oxycodone Rx dated MM-DD-YY Dr Smith failed GFD on MM-DD-YY, Store #0123, RPh Initials"

→ **NOTE: Ensure that the most recent TD GFD comment is visible.**

4. Inform the patient that it may take additional time to process the prescription. If the patient is unknown to the pharmacy staff, obtain patient's government issued photo identification, scan and print a copy of the ID to attach to the hard copy utilizing the manual fax process. If someone other than the patient is dropping off the prescription, scan and print a copy of the ID and attach it to the hard copy.

→ **NOTE: ID is optional for Hospice, Oncology, and bedside delivery patients, unless it is required by state regulations.**

→ **NOTE: If your state prohibits the scanning and copying of an ID, follow your state's regulations.**

5. Determine if the patient is new to Walgreens. Note: Caution must be used when dispensing a Target Drug to patients with no IC+ history.
6. Scan the prescription.
7. Verify the geographical proximity. The patient and/or prescriber must have an address within the reasonable geographic location of the pharmacy or the distance must be reasonably explained.
  - i. Valid examples may include: patient lives in a rural area, patient is seeing a specialist, etc. The pharmacist must feel comfortable that the explanation is reasonable and may confirm with the patient or prescriber as needed.
8. Once all of these steps are complete, the prescription should be passed to the pharmacist in a red "waiting bin" to complete the validation process.

## **Target Drug Good Faith Dispensing and Validation Procedures**

### **Pharmacist Validation**

1. Review documentation and TD GFD Checklist from the technician and review patient comments for additional GFD-centered documentation, potentially from other locations where patient attempted to fill.
2. Discuss any concerns with the patient/caregiver in the store or via phone. The patient/caregiver can provide information to clarify and resolve any concerns, questions, or red flags related to the prescription. Document the conversation in the notes section of the checklist.
3. Verify if the prescription is being filled on time and not early.
4. Check the Target Drug prescription for unusual dosage, directions, or decoy. A "decoy" is a non-controlled drug written with a Target Drug or other cocktail prescription (combination of an opioid, Xanax and Soma) for a product (e.g., ibuprofen, HCTZ, lisinopril) which the patient states he/she does not need.
5. Check central profile for the following:
  - a. Multiple prescribers and payment type (cash) trends,
  - b. Fill history for current medication as well as other Target Drugs, and

- c. Unusual drug therapy combinations or decoys.
6. Verify and review the ID that is attached to the prescription.
7. Review DUR history for the patient (use system generated DURs, third party DURs, and clinical knowledge).
8. If available in the state, the pharmacist must access the Prescription Drug Monitoring Program (PDMP), review, print, and attach to prescription hard copy. If the prescription is refused as a result of PDMP review, see Refusal Procedures.

→ **NOTE: Do not give the patient a copy of the PDMP report. Staple the PDMP report to the hard copy. The PDMP report must be removed if releasing the hard copy to law enforcement, DEA agents, or 3<sup>rd</sup> Party Auditors.**

→ **NOTE: If your state prohibits the printing of a PDMP report, follow your state's regulations.**

9. After product review, the pharmacist can create a MSC exception from the Work Queue on the prescription to remind the pharmacy staff to ask for a government issued photo ID if the patient or person picking up the prescription is unknown to the pharmacy staff.
  - i. MSC comment example: "Check Patient ID, RPh Initials"

### **Prescriber Validation**

1. If in your professional judgment a call to the prescriber's clinical staff is warranted, contact the prescriber's office to validate the prescription and document in the notes section of the checklist. Pharmacists are expected to use their professional judgment when ensuring that the prescription is written for a legitimate medical reason. You should contact a prescriber's office if, through other validation procedures, you are unable to resolve red flags related to the prescription. Since the purpose of calling a prescriber's office is to try to resolve the issues causing you to question the legitimacy of a prescription, you should tailor your conversation accordingly. Validation may include, but not be limited to, taking the following actions:
  - Verification that the patient is under the care of the prescriber on the prescription.
  - Verification that the patient has, in fact, been prescribed chronic opioids.
  - Obtaining information to support a patient travelling a long distance to have an opioid prescription filled.
  - Obtaining a clinical diagnosis to support a prescription for chronic opioid use.
2. If the prescriber's clinical staff is unable to provide the information necessary to validate a prescription, speak with the prescriber about the remaining issues causing you to question the prescription.

→ **NOTE: Routine calls to the prescriber to validate prescriptions are unnecessary and are not required under this policy.**

### **For Hospice and Oncology patients only:**

If you are unable to reach the prescriber's clinical staff, the pharmacist may fill the prescription without verification provided the elements of Good Faith Dispensing are met.

### **Target Drug Good Faith Dispensing Checklist**

The pharmacist shall complete the TD GFD Checklist, ensuring that each line item is initialed by either a pharmacist or technician, regardless of whether the prescription is refused or dispensed. The checklist is intended to bring consistency across all Walgreen locations and to help the pharmacist determine if extra measures need to be taken to ensure that the prescription was written for a legitimate medical need.

#### **If the Prescription is Dispensed**

If after reviewing the information on the TD GFD Checklist the pharmacist determines that the prescription meets TD GFD requirements and will be dispensed, the pharmacist must attach the following items to the prescription hardcopy:

1. The TD GFD Checklist
2. The PDMP report, Note: remove PDMP before releasing hard copy to anyone, including law enforcement, DEA agents, or 3<sup>rd</sup> party auditors.
3. Printed image of the ID of the person dropping off the prescription
4. If the prescription is being picked up by someone unknown to the pharmacy staff, printed image of the ID of the person picking up the prescription
5. Any other relevant information

#### **If the Prescription is Refused**

If the pharmacist determines that the prescription does not meet TD GFD requirements, the pharmacist must complete the following tasks:

1. Immediately add a comment in "Patient Comments" in the following format:  
"Oxycodone Rx dated MM-DD-YY Dr Smith failed GFD on MM-DD-YY, Store #0123, RPh Initials"
2. Print an image of the prescription and give the original prescription hardcopy back to the patient, informing him/her that the prescription cannot be filled at any Walgreens because it does not meet the elements of Good Faith Dispensing.
3. File a copy of the refused prescription and all documentation, including the completed checklist, PDMP report, printed image of ID, and any other relevant documentation in refusal folder.
4. Do NOT deface the original prescription; all documentation should be noted on the TD GFD Checklist.

→ **NOTE: If your state has additional regulations for refused prescriptions, follow your state's regulations.**

### **Pick Up**

The following must occur at pick up:

1. Request government issued photo identification from the person picking up the prescription.

→ **NOTE: If the person is known to the pharmacy staff, there is no need to obtain the ID at pick up. Check the Work Queue and remove the MSC exception (if applicable).**

→ **NOTE: If the person is unknown to the pharmacy staff, check the Work Queue and remove the MSC exception (if applicable), scan and print a copy of the ID, and attach it to the prescription hard copy.**

→ **NOTE: If your state has additional regulations for prescription pick up, follow your state's regulations.**

2. Ensure that the checklist requirements have been met.

**It is imperative that pharmacists document all efforts used to validate Good Faith Dispensing. Failure to do so will result in disciplinary action up to and including termination.**

Revised 9/23/2013  
Revised 4/15/2013  
Revised 4/5/2013  
Revised 3/27/2013  
Original 11/26/2012

Target Drug Good Faith Dispensing Checklist			
Patient Name:		Rx #:	Date:
Please select drug & provide strength (tablets/capsules only):			
Oxycodone_____ Hydromorphone_____ Methadone_____ Other (optional - district specific)_____			
Check boxes that apply to assist you in determining if the prescription should be filled. Attach checklist to hard copy of Rx.			
	Yes	No	Mandatory Checklist Requirements; Must be Yes to fill prescription.
1	<input type="checkbox"/>	<input type="checkbox"/>	Valid government photo ID copied and attached to hard copy of Rx. For eRx, attach copy at pick-up. ID is optional for Hospice, Oncology, bedside delivery, and patients <u>known</u> to the pharmacy staff, unless it is required by state regulations.
2	<input type="checkbox"/>	<input type="checkbox"/>	No prior GFD refusal for <u>this</u> prescription in patient comments in IC+ profile.
3	<input type="checkbox"/>	<input type="checkbox"/>	If available in your state, PDMP has been reviewed, printed and attached to hard copy of Rx.
Through a conversation with the patient/caregiver in the store or via phone, resolve any concerns, questions, or red flags (examples below) that are related to the prescription. Document in notes section.			
			Additional Checklist Requirements; every "no" is a red flag. Use your professional judgment to assess the prescription for potential abuse, misuse, or diversion.
4	<input type="checkbox"/>	<input type="checkbox"/>	Patient has received this prescription from Walgreens before.
5	<input type="checkbox"/>	<input type="checkbox"/>	This prescription is from the same prescriber for the same medication as the previous fill.
6	<input type="checkbox"/>	<input type="checkbox"/>	Patient and/or prescriber address is within geographical proximity to pharmacy; any variances can be reasonably explained.
7	<input type="checkbox"/>	<input type="checkbox"/>	Prescription is being filled on time. If your state regulates early refills of controlled substance prescriptions, follow your state's regulations.
8	<input type="checkbox"/>	<input type="checkbox"/>	3rd Party Insurance is billed (cash or a cash discount card is a red flag).
9	<input type="checkbox"/>	<input type="checkbox"/>	Chronic prescription use can be explained and is supported by documentation (ICD 9/10 codes or diagnosis consistent with chronic pain condition).
10	<input type="checkbox"/>	<input type="checkbox"/>	Patient does not appear intoxicated or under the influence of illicit drugs.
If in your professional judgment a call to the prescriber's clinical staff is warranted, document conversation in notes section. If no call is required, complete this form with your signature. (For Hospice and Oncology patients only: if unable to reach the prescriber's clinical staff, RPh may fill the prescription without verification provided the elements of Good Faith Dispensing are met.)			
			Notes:
I attest that I have used the Target Drug Good Faith Dispensing Checklist validation procedures and my professional judgment to review this prescription and I have:			
<input type="checkbox"/>	Dispensed:	Product review Pharmacist signature _____	
<input type="checkbox"/>	Refused:	Pharmacist signature _____	
(RPh must make a copy of the Rx for the refusal file folder)			

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