Message

From: Svihra, Ed [ed.svihra@walgreens.com]
Sent: 3/23/2013 8:35:01 AM
To: Lemmons, Doug [doug.lemmons@walgreens.com]; Couffer, Gordon [gordon.couffer@walgreens.com]; Jones, John [john.jones@walgreens.com]; Womersley, Mike [mike.womersley@walgreens.com]
CC: Amos, Ken [ken.amos@walgreens.com]; Ranick, Marcie [marcie.ranick@walgreens.com]; Jonkman, Scott [scott.jonkman@walgreens.com]
Subject: National Target Drug Good Faith Dispensing (TD GFD) Documents
Attachments: National TD GFD Policy Final.pdf; ATT00001.htm; National TD GFD Checklist Final.pdf; ATT00002.htm; National TD GFD FAQ Final.pdf; ATT00003.htm; National Prescriber TD GFD Letter.pdf; ATT00004.htm; Clinical Pain Management Document.pdf; ATT00005.htm; image001.gif; ATT00006.htm; National TD GFD Power Point Final.pptx; ATT00007.htm

Flag: Follow up

Doug, Gordon, John and Mike,

Here are the advance copies of the National TD GFD documents. MLPDs and DLPMs will receive this information in April to coincide with the conference calls scheduled for each division.

Thanks,

Ed

Begin forwarded message:

From: "Dymon, Christopher" <christopher.dymon@walgreens.com>
To: "Mourad, Maher" <maher.mourad@walgreens.com>, "Holmes, Dana" <dana.holmes@walgreens.com>, "Gamble, Greg" <greg.gamble@walgreens.com>, "Cook, Matt" <matt.cook@walgreens.com>, "Freeman, Michael" <michael.j.freeman@walgreens.com>, "Stacey, Brett" <brett.stacey@walgreens.com>, "Roch, Liz" <liz.roch@walgreens.com>, "Thoss, Sue" <sue.thoss@walgreens.com>, "Provost, Kristie" <kristie.provost@walgreens.com>, "Svihra, Ed" <ed.svihra@walgreens.com>, "Gates, Rick" <rick.gates@walgreens.com>, "Murray, Denman" <denman.murray@walgreens.com>, "Pinon, Dwayne" <dwayne.pinon@walgreens.com>, "Graham, Jim" <jim.graham@walgreens.com>, "Zagami, Patty" <patty.zagami@walgreens.com>, "Madarasz, Anika" <anika.madarasz@walgreens.com>, "Vickhammer, Steve" <steve.vickhammer@walgreens.com>, "Mills, Troy" <troy.mills@walgreens.com>, "Wooley, Mark" <mark.wooley@walgreens.com>, "Gibson, Ellen" <ellen.gibson@walgreens.com>, "Daugherty, Patricia" <patricia.daugherty@walgreens.com>, "Stahmann, Eric" <eric.stahmann@walgreens.com>, "Dymon, Christopher" <christopher.dymon@walgreens.com>, "Bratton, Edward" <edward.bratton@walgreens.com>, "Swords, Rex" <rex.swords@walgreens.com>, "Lovejoy, David" <david.lovejoy@walgreens.com>, "Hansen, Suzanne" <suzanne.hansen@walgreens.com>, "Trotz, Sherrise" <sherrise.trotz@walgreens.com>, "Tisdell, Lorinda" <lorinda.tisdell@walgreens.com>, "Platts, Debbie" <deborah.platts@walgreens.com>, "Bhana, Sanjay" <sanjay.bhana@walgreens.com>, "Polster, Tasha" <tasha.polster@walgreens.com>, "Umbleby, Mike" <mike.umbleby@walgreens.com>, "Creek, Cheryl" <cheryl.creek@walgreens.com>, "Dughri, Darem" <darem.dughri@walgreens.com>, "Kennedy, Darren" <darren.kennedy@walgreens.com>
Subject: National Target Drug Good Faith Dispensing (TD GFD) Documents

Redacted – Attorney Client Privileged

PLAINTIFF TRIAL EXHIBIT
P-20789_00001

Be Well,
Chris

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[cid:image001.gif@01CDEDAF.AEF27F40]

National Target Drug Good Faith Dispensing Policy

Walgreens requires ALL pharmacists and pharmacy team members to adhere to the Controlled Substance Prescriptions & Good Faith Dispensing Policy and procedures.<link to GFD> 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) <link to 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, utilizing a state's Prescription Drug Monitoring Program (PDMP) if available, and verifying the prescription with the prescriber.

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 Checklist and refused to dispense the prescription.

i. Patient comment example: "Oxycodone, Dr Smith failed GFD on 10-16-2012 Store #0123, RPh NFP"

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. 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.
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 prescribing physician 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. Verify if the prescription is being filled on time and not early.
3. Check 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.
3. 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.
4. Verify and review the ID that is attached to the prescription.
5. Review DUR history for the patient (use system generated DURs, third party DURs, and clinical knowledge).
6. 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 to the hard copy. The PDMP report must be removed if releasing the hard copy to law enforcement, DEA agents, or 3rd Party Auditors.

Prescriber Validation

1. If in your professional judgment a call to the prescriber is warranted, contact the prescriber to validate the prescription (last step on checklist) and document in the notes section of the checklist. Pharmacists are expected to use their professional judgment when ensuring the prescription is written for a legitimate medical reason. Validation can include, but not be limited to, taking the following actions:
    a. Determine if the prescriber is issuing the prescription within his/her scope of practice.
    b. Obtain a diagnosis and document on the checklist. If the prescription is not appropriate for the diagnosis, discuss with the prescriber whether dispensing is appropriate.
    c. Determine if the therapeutic regimen is within the standard of care.
    d. Discuss expected length of treatment.
    e. Obtain date of last physical and pain assessment.
    f. Discuss use of alternative prescription medications for pain control.
    g. Discuss coordination with other clinicians involved in patient care.

    For Hospice and Oncology patients only:
    If you are unable to reach the prescriber, the pharmacist may fill the prescription without verification by the prescriber provided the elements of Good Faith Dispensing are met.

National Target Drug Good Faith Dispensing Checklist (Link)

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 checklist,
2. The PDMP report, Note: remove PDMP before releasing hard copy to external people such as law enforcement, DEA agents, or 3rd party auditors, etc.
3. Printed image of the ID of the person dropping off the prescription,
4. If the prescription is not being picked up by the patient, printed image of the ID of the person picking up the prescription, and
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, Dr Smith failed GFD on 10-16-2012 Store #0123 RPh NFP "

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. Notify the DEA of refusal to fill via fax (LINK) or, if in Florida, via the Florida Webform. Document the date and time DEA was faxed on the copy of the refused prescription.
4. 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.
5. Do NOT deface the original prescription; all documentation should be noted on the TD GFD checklist.

Pick-Up

The following must occur at pick-up:

1. Request government issued photo identification from person picking up the prescription. **NOTE: If someone other than the patient is picking up the prescription, scan and print a copy of the ID and attach it to the prescription hard copy.**
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.

National 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 determine if the prescription can be filled. Attach checklist to hard copy of Rx.

	Yes	No	Mandatory Checklist Requirements; Must be Yes to fill prescription.	RPh/Tech Initials
1	☐	☐	Valid government photo ID copied and attached to hard copy. For eRx, attach copy at pick-up.	
2	☐	☐	No GFD refusal for this particular presciption in patient comments on IC+ profile.	
3	☐	☐	If available in your state, PDMP has been reviewed, printed and attached to hard copy.	
			Additional Checklist Requirements; every "no" is a red flag. Use your professional judgment to assess the prescription.	
4	☐	☐	Patient has received this prescription from Walgreens before.	
5	☐	☐	This prescription is from the same prescriber for the same medication as the previous fill.	
6	☐	☐	Patient and/or prescriber address is within geographical proximity to pharmacy; variances can be explained.	
7	☐	☐	Prescription is being filled on time.	
8	☐	☐	3rd Party Insurance is billed (cash or a cash discount card is a red flag).	
9	☐	☐	Quantity is 120 units or less; or 60 units or less if paid by cash or cash discount card.	
10	☐	☐	Patient has been on this same medication strength and dose for less than 6 months.	

If in your professional judgement a call to the prescriber is warranted, review step 11.
If no call is required, complete this form with your signature.

11	☐	☐	**Call to Prescriber** To begin the conversation with the prescriber, verify/confirm any number of the following points (*document in notes section*). *Prescription is written within prescriber's scope of practice *Diagnosis *Therapeutic regimen is within standard of care *Expected length of treatment *Date of last physical and pain assessment *Use of alternative/lesser prescription medications for pain control *Coordination with other clinicians involved in patient care **For Hospice and Oncology patients only:** If unable to reach the prescriber, RPh may fill the Rx without verification by the prescriber provided the elements of Good Faith Dispensing are met.

I attest that I have used the Good Faith Dispensing Checklist validation procedures and my professional judgement to review this prescription and I have:

☐ Dispensed: Product review Pharmacist signature _____

☐ Refused: Pharmacist signature _____

(RPh must fax a copy of the refused Rx Hard Copy to DEA. FL use webform)

Notes:

PATIENT INTERNAL TALKING POINTS

What if a patient questions me?

There are legitimate reasons why customers might need these products. Remember, most prescriptions for these medications will be for legitimate medical conditions and not used for diversion. Please apologize for the delay and help the patient understand why we have to comply with the verification procedures.

What to say to the Patient:

- "I'm sorry, but Walgreens is working hard to ensure our patients get the medications they need, but also that we do everything we can to help reduce the abuse of controlled pain medications. As a result, we have to take a bit more time with each prescription."

- "I apologize for the inconvenience, but the time we take to review each prescription is a necessary to ensure we are meeting our commitment for the safe dispensing of medications to our patients."

What if I refuse to fill the prescription, what do I say to the patient?

- "Walgreens is working hard to ensure the safe dispensing of controlled pain medications. Based on my clinical review and professional judgment, this prescription does not meet the requirements Walgreens has put in place for dispensing these medications. Therefore, we cannot fill this prescription in good faith at this or any Walgreens. I apologize for any inconvenience."

What if the patient says they will take it to the Walgreens down the street?

- "Due to the requirements put forth by Walgreens (as stated above) this prescription cannot be filled at this or any Walgreens location. I apologize for any inconvenience."

What if the patient wants a copy of our policy and procedures around Good Faith Dispensing?

- You cannot give a patient a copy of our policy and procedures around Good Faith Dispensing.

Team Members - if you need help handling an upset customer, call a member of management.

PATIENT EXTERNAL TALKING POINTS (PATIENT FACING)

Why is Walgreens doing this?

We want to ensure that our patients continue to have access to the medications they need and are serious about our role in reducing abuse of controlled substances.

How will this affect my prescriptions?
We have a new verification process and we will work through some of the steps quickly as possible. As a result of this process, it may take longer to fill certain pain medications.

What if I cannot wait for my prescription?
We understand that there may be unique circumstances and will do our best to accommodate you. Please speak to one of our pharmacy team members and we will contact you when your prescription is ready.

Will it take longer than 24 hours?
Our goal is to complete this additional verification process within 24 hours, however, if we are unable to reach the physician, it may take longer. We appreciate your patience and understanding.

Why do you need my ID?
We require a government issued photo identification prior to dispensing certain controlled substance medications in order to confirm the identity of the person dropping off and/or picking up your prescription.

PRESCRIBER TALKING POINTS

What can the pharmacist say to the prescriber?
"Walgreens is working hard to ensure the safe dispensing of controlled pain medications. Based on my clinical review and professional judgment, this prescription does not meet the requirements we have put in place for dispensing these medications. Therefore, I cannot fill this prescription in good faith."

How will this affect my patients?
Due to the additional steps required for our verification process, we are asking that patients allow additional processing time in order to fill their prescriptions for the following single ingredient medications: Methadone, Oxycontin, Hydromorphone and Other (optional - selected by the district).

What are the additional verification steps?
The pharmacist may be calling your practice to verify:

- Prescription is written within your scope of practice
- Diagnosis code
- Therapeutic regimen is within standard of care
- Expected length of treatment
- Date of last physical and pain assessment
- Use of alternative/less potent prescription medications for pain control
- Coordination with other clinicians involved in patient care

What is the reasoning behind the additional verification process?
Our intent is to partner with you to ensure that patients receive their appropriate therapy and that the necessary documentation is captured to satisfy DEA regulations. This process is designed to protect both you and the pharmacist.

What if the prescriber, or their office staff, refuse to give me the information needed in order for me to verify the prescription is being prescribed in good faith because they say due to HIPAA, they cannot give me this information?
The Privacy Rule allows those doctors, nurses, hospitals, laboratory technicians, and other health care providers that are covered entities to use or disclose protected health information, such as X-rays, laboratory and pathology reports, diagnoses, and other medical information for treatment purposes without the patient's authorization. This includes sharing the information to consult with other providers, including providers who are not covered entities, to treat a different patient, or to refer the patient. See 45 CFR 164.506

Is Walgreens the only retail pharmacy doing this?
Every retail pharmacy is required to comply with DEA regulations; however Walgreens has taken a more proactive role to ensure the health and safety of our patients.

Will Walgreens report me to the DEA?
Walgreens is required to notify the DEA of a refusal to fill a controlled substance prescription if our pharmacist determines that the prescription was forged, altered or issued for other than a legitimate medical purpose.

How many prescriptions will be affected by this process?
Our pharmacists refuse any controlled substance prescription that does not meet our good faith dispensing guidelines.

What if the prescriber wants a copy of our policy and procedures around Good Faith Dispensing?
You cannot give a prescriber a copy of our policy and procedures around Good Faith Dispensing. You can offer to fax the prescriber communication letter which discusses Good Faith Dispensing.

GENERAL INTERNAL TALKING POINTS

Is it just plain oxycodone or is it any formulation with oxycodone (e.g. Percocet)? Single entity Oxycodone only. Not Percodan or Percocet for example.

Does a "failed GFD" mean that we can never fill for that patient again?
No, just for that specific prescription (written by that doctor on that date).

When a 2nd store sees a comment "failed GFD" do they have to refax the DEA?
No.

If the rx is just too soon to fill but would pass on all other points, do we refuse the rx and document in the comment field or just give the rx back and tell the patient to bring back on a certain day?
The rx too early to fill alone may not be considered a true refusal. If you determine this is not a true refusal, comments are not needed in the patient profile and you will not need to notify the DEA. You can give the patient an opportunity to come back and fill when it's not too soon to fill.

If I am in a state that has access to PDMP and can't access the PDMP site to look up the patient, then I can't fill the Rx until I review the PDPMP correct?
Yes that is correct. You can hand the prescription back to the patient if they do not want to wait.

In the case where there is a refusal, can we scan the completed TDGFD checklist into that patient's file under patient images rather than just comments?
Unfortunately, we do not have the memory storage space to scan these into IC+ across the entire chain. Please use the patient comments. Ensure the most recent TDGFD comments are showing, remove older comments, and abbreviate if needed.

Is it ok to fill a prescription if I know there is a pain contract on file for the patient/clinic?
A pain contract does not necessarily make it ok to fill the prescription. Follow the TDGFD checklist and review any red flags. The DEA has made is clear that we have to know our patients and their prescribers. In order for us to do our due diligence, we must use our professional judgment for each prescription we review and determine whether we can fill the prescription in good faith.

If someone brings in an Rx from a known cash only clinic do we still need to complete the checklist?
Document on the TDGFD checklist cash clinic and send refusal of rx to DEA.

What do we do if we call the prescriber or their staff does not respond in 24 hours (72 hours if on a weekend) to our inquiry? If the patient does not want to wait and asks for the hard copy back, would we treat it like a refusal and complete the DEA web-form and put the comment in the patient's profile?
If the prescriber hasn't called back and the patient wants their rx back, it is okay to give the rx back to the patient to take to another pharmacy. No documentation in the patient comments is necessary.

What if the prescriber calls back and refuses to provide any information?
If this doesn't meet the pharmacist need for due diligence to verify GFD, do not fill the prescription. This prescription should be faxed (in FL use webform) as a refusal to the DEA and patient comments must be entered in IC+ to document the refusal. The response to the patient can be, "Walgreens is working hard to ensure the safe dispensing of controlled pain medications. Unfortunately, *your prescriber is not able to give us the information we need in order to for me to verify the requirements that we have put into place when dispensing this medication.* Therefore, we cannot fill this prescription in good faith at this or any Walgreens. I apologize for any inconvenience."

What type of physician outreach will we be doing to educate our prescribers on the new policy?
Legal has approved a prescriber communication letter that will be sent out to prescribers via fax.

Regarding Bedside Delivery programs, patients in the hospital do not always have their government issued ID with them, are we still going to require this from these patients?
No, just document that the patient was in an institution and it was a bedside delivery.

Are Hospice prescriptions considered exempt from the new procedures?
The TDGFD checklist is still required for each target prescription. Please document the ID of the driver/delivery service, or the person picking up the prescription instead.

What if the DEA or local law enforcement wants the pharmacy to fill a fraudulent prescription as part of a DEA investigation or sting on a prescriber?
Do not fill a fraudulent prescription. Inform your Pharmacy Supervisor and District Loss Prevention supervisor before assisting the DEA or local law enforcement with any investigations.

How will prescriber communication work for Power or Central fills stores?
If the prescribers are coming through the prescriber IVR and select 4 for returning call, those will go direct to the store. The majority of call backs should be going that route or leaving a message on store voicemail. However, if the prescriber selects 2 for "new prescription," they would come to our pharmacists. We have trained our pharmacist on the TD GFD so they are aware of the drugs involved and have been instructed to transfer to the store any specific

questions or communications involving these drugs. One of the observations from our staff is the scripts are not always scanned and residing in the work queue for us to key off of. So that may pose a challenge if a prescriber's office is calling back and does not refer to the drug name they are providing the diagnosis for or validating they issued the script. If the prescriber's office does reference the target drug, then the call should be transferred to the store immediately by our pharmacists. If there are general questions pertaining to TD GFD and why the prescribers' office is being called, we try to handle those calls in line with the pharmacist talking points to avoid sending those calls to the store.

Dear Valued Prescriber,

Walgreens wants to ensure that our patients continue to have access to the medications they need while fulfilling our role in reducing the potential abuse of controlled substances. Our intent is to partner with you to ensure that patients receive their appropriate therapy and that the necessary information to confirm the appropriateness of the prescription is documented to satisfy DEA requirements. This process is designed to protect both you and the pharmacist.

According to Title 21 of the Code of Federal Regulations, section 1306.04, pharmacists are required by the DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose. The regulation states the following:

> 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)** and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Our pharmacists are required to take additional steps when verifying certain prescriptions for controlled substances. This verification process may, at times, require the pharmacist to contact you for additional information necessary to fill the prescription. While the information requested may vary, potential questions could include information about the diagnosis, ICD-9 code, expected length of therapy and previous medications/therapies tried and failed. Privacy laws allow you to share this information with another healthcare professional who is providing care to the patient.

We realize that this process may generate questions and concerns from both you and the patient and we will do our best to respond in a professional and courteous manner. We recognize that sharing appropriate information with our pharmacists may require additional time from you or your office staff and we want to thank you in advance for partnering with us to provide the best care to our patients.

Be well,

Your Walgreens Pharmacist

Walgreens

Clinical Office
Clinical Affairs
Walgreen Co.
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Deerfield, IL 60084

Title: Management of Acute and Chronic Pain	**Effective/Approved Date**
Clinical Affairs Vice President: David Lorber, MD	**Revision Date:**

Table of Contents

The information contained in this deliverable represents a focused review of a small sample of studies rather than an extensive review of all existing studies on a topic. Thus, this information is intended for internal staff but should not be generalized as a standard of care for all patients or clinical settings nor should this be released to the public or press until the embargo release. If you have further questions or additional research needs on this topic, please contact the Clinical Affairs Department.

October 15, 2012
From The Clinical Affairs Department

Evidence Based Medicine-Clinical Framework
Management of Acute and Chronic Pain

Purpose of Document

This document's purpose is to provide a clinical framework related to the management of chronic and acute pain by providing reference materials to Walgreens business units and clinical staff. The document is also intended to facilitate clinical program development following evidence based guidelines.
This document should be used as a reference for:

- *Evidence based medicine guideline support of clinical program development*
- *Suggested educational materials to be shared with patients*
- *Suggested education of healthcare providers*

It should not be used as:

- *A substitute for detailed business unit processes or as an alternative to instructions from a prescriber*

Clinical Affairs Contact:

David B Lorber, MD

Background Information

Duarte defines acute pain as temporarily related to injury and that resolves during the appropriate healing period. It often responds to treatment with analgesic medications and treatment of the precipitating cause. Characteristics may include the following:

- Duration is short lived - less than 3 months;
- Pain of varying intensity, initially severe then subsiding as healing takes place;
- Nervous system is usually intact;
- Reasons for pain can be pinpointed - pain is caused by trauma, surgery, acute medical conditions or a physiological process;
- Responds well to conventional analgesia - opioids, local anesthetics, etc;

Chronic pain is defined as persistent pain, which can be either continuous or recurrent and is of sufficient duration and intensity to adversely affect a patient's well-being, level of function, and quality of life.

The ultimate goal of chronic pain treatment is to improve patient function through the development of long-term self-management skills including fitness and a healthy lifestyle in the face of persistent pain.

Medications should not be the sole focus of treatment in managing pain and should be used when needed to meet overall goals of therapy in conjunction with other treatment modalities. In addition, it is important to remember that careful selection and close monitoring of all non-malignant pain patients on chronic opioids is necessary to assess the effectiveness and watch for signs of misuse or drug seeking behaviors

Other goals of treatment include:

- Improve the assessment and continuous reassessment of patients with chronic pain diagnosis
- Improved and effective use of non-opioid medications in treatment of patients with chronic pain

- Improved and effective use of opioid medications in the treatment of patients with chronic pain

Clinical Management of the Patient with Acute or Chronic Pain

- Patients presenting with acute or chronic pain should have an adequate pain assessment that includes documentation of pain location, intensity, quality, onset, and duration, how pain is manifested, what provides relief, what makes it worse.
- Patient self-report is the "most reliable indicator of the existence and intensity of pain" (National Institutes of Health) and is a key component of chronic pain assessment. Tools to assess chronic pain should:
    - Be appropriate to the person regardless of age, race, creed, socioeconomic status and psychological or emotional background
    - Be used early in the process of patient evaluation
- In the evaluation of the patient with chronic pain, it is essential to perform a good general history and physical examination of the patient. In addition, certain areas deserve specific attention.
    - Identification of the onset and progression of initial problem may help to focus management plan appropriately.
    - Prior medical treatment and use of medications with response is helpful
    - Some inquiry of sleep and diet is also helpful.
- It is essential also to elicit any history of depression or other psychopathology that may affect the perception of pain
    - Past or current physical, sexual, or emotional abuse
    - A history of chemical dependency, including alcohol is of interest in this patient population.

Major Recommendations Related to the Use of Chronic Opioid Therapy (COT) for the Treatment of Chronic Pain (NonCancer Related)

- Clinicians may consider a trial of COT as an option if chronic noncancer pain (CNCP) is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms.
- Clinicians may consider using a written COT management plan to document patient and clinician responsibilities and expectations and assist in patient education
- Clinicians and patients should regard initial treatment with opioids as a therapeutic trial to determine whether COT is appropriate.
- Opioid selection, initial dosing, and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms

Monitoring

- Clinicians should reassess patients on COT periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and functional level, progress toward achieving therapeutic goals, any noted adverse events, and adherence to prescribed therapies.
- In patients on COT who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan.

- In patients on COT not at high risk and not known to have engaged in aberrant drug-related behaviors, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care.

High-Risk Patients

- Clinicians may consider COT for patients with CNCP and history of drug abuse, psychiatric issues, or serious aberrant drug-related behaviors only if they are able to implement more frequent and stringent monitoring parameters. In such situations, clinicians should strongly consider consultation with a mental health or addiction specialist.
- Clinicians should evaluate patients engaging in aberrant drug-related behaviors for appropriateness of COT, referral for assistance in management, or discontinuation of COT

Dose Escalations, High-Dose Opioid Therapy, Opioid Rotation, and Indications for Discontinuation of Therapy

- When patients request repeated dose escalations in COT, clinicians should evaluate potential causes and reassess benefits relative to harms
- In patients currently utilizing longer term COT, clinicians should evaluate for unique opioid-related adverse effects, changes in health status, and adherence to the COT treatment plan on an ongoing basis, and consider more frequent follow-up visits
- Clinicians should taper or wean patients off of COT who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress toward meeting therapeutic goals, or experience severe adverse effects

Identifying a Medical Home and When to Obtain Consultation

- Patients on COT should identify a clinician who accepts primary responsibility for their overall medical care. This clinician may or may not prescribe COT, but should coordinate consultation and communication among all clinicians involved in the patient's care

Opioids in Pregnancy

- Clinicians should counsel women of childbearing potential about the risks and benefits of COT during pregnancy and after delivery. Clinicians should encourage minimal or no use of COT during pregnancy, unless potential benefits outweigh risks. If COT is used during pregnancy, clinicians should be prepared to anticipate and manage risks to the patient and newborn.

Potential Harms

Opioids may cause adverse effects such as:

- Constipation
- Nausea and vomiting
- Sedated or clouded mentation
- Hormone deficiencies (with chronic or sustained use of opioids)
- Pruritus and myoclonus

Methadone

Few trials have evaluated benefits and harms of methadone for CNCP. In addition, a number of epidemiologic studies suggest an increased rate of methadone associated deaths in the United States. QT interval prolongation and cardiac arrhythmias may occur in patients on methadone, particularly at higher doses, or with concomitant use of drugs that interact with methadone or that themselves prolong QT

interval.

Clinicians who prescribe methadone should be familiar with its clinical pharmacology and associated risks. Methadone has a very long and highly variable half-life, which necessitates careful titration to avoid delayed adverse events, such as overdose.

There is a greater risk of impairment when starting opioid therapy, when increasing doses, and when taking other drugs or substances that may have central nervous effects, including alcohol.

The VIGIL SYSTEM

The VIGIL system involves the following five components: verification, identification, generalization, interpretation, and legalization. These five components are designed to help pharmacists classify patients by risk, as follows:

Verification: Is this a responsible opioid user?

- Talk with the patient.
- Avoid filling Schedule II (CII) opioid or hydrocodone/acetaminophen prescriptions for the first time without verifying the prescription with the prescriber.
- Find out the legitimate medical purpose for the medication.
- Provide a partial supply if unable to verify the prescription.

Identification: Do I know for sure who this person is?

- Require a government-issued photo ID or a reasonable substitute for anyone, including any family member, picking up CII or other narcotic prescriptions.
- Photocopy the ID or write down the information.

Generalization: Do we agree on mutual responsibilities and expectations?

- Use statements with patients such as, "I am your pharmacist and I agree to promptly and respectfully provide medications and services if certain rules are met."
- These rules may include the patient agreeing to keep all controlled substances under lock and key, not sharing the medications with anyone, agreeing to only using one pharmacy to fill controlled substances, and agreeing that the prescriber may be contacted if refills are too early or if emergency supplies are needed when there is no real emergency.

Interpretation: Do I now feel comfortable allowing this person to have controlled substances?

- Use a brief questionnaire available online such as the Opioid Risk Tool or Screener or Opioid Assessment for Patients in Pain to predict misuse or abuse by patients.
- Obtain family or friend participation and feedback regarding success of therapy based on patient functioning.

Legalization: How can I stay squeaky clean in meeting my legal requirements?

- Follow all state and federal laws for controlled substances with no exceptions.
- Conduct medication histories and provide education for all chronic pain patients.
- Document everything you have done.

Evaluating the risk

Pharmacists can use VIGIL as a guide for counseling pain patients. For low-risk patients, verifying an ID may be acceptable. For those who are medium risk, limiting the quantity dispensed and/or implementing a medication use agreement with the patient may be reasonable. More labor-intensive interventions may be needed for patients who fall in the high-risk category, such as requesting the prescriber to forward patient records to the pharmacy for review. Most importantly, pharmacists should use their common sense and best judgment when dispensing controlled substances to help reduce abuse, noted Brushwood.

Tanzi, M VIGIL helps pharmacists screen controlled substances" American Pharmacists Association
http://www.pharmacist.com/node/50295 Accessed 10/14/2012

Appendix

References for Recommended Guidelines

Institute for Clinical Systems Improvement (ICSI). Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2011 Nov. 112

Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, Donovan MI, Fishbain DA, Foley KM, Fudin J, Gilson AM, Kelter A, Mauskop A, O'Connor PG, Passik SD, Pasternak GW, Portenoy RK, Rich BA, Roberts RG, Todd KH, Miaskowski C, American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009 Feb;10(2):113-30.

Management of Opioid Therapy for Chronic Pain Working Group. VA/DoD clinical practice guideline for management of opioid therapy for chronic pain. Washington (DC): Department of Veterans Affairs, Department of Defense; 2010 May

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction. Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to reduce abuse of opioid drugs. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests as required by state law, is strongly advised.

U.S. Food and Drug Administration Oxycontin Medication Guide. July 2012.

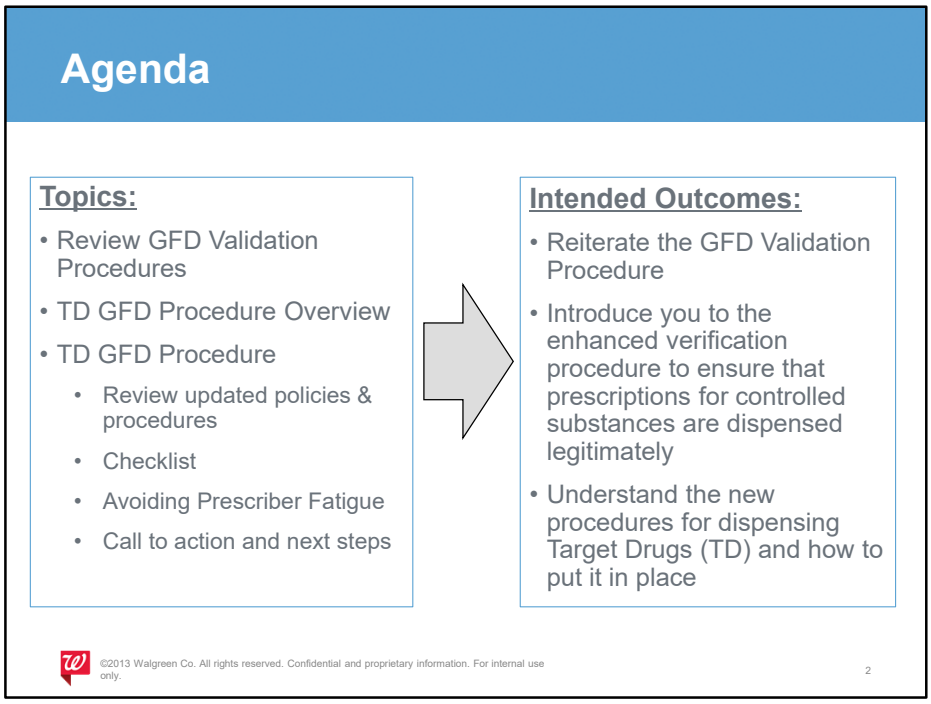
Every day I help people **get, stay and live well.**

Target Drug (TD)
Good Faith Dispensing (GFD)

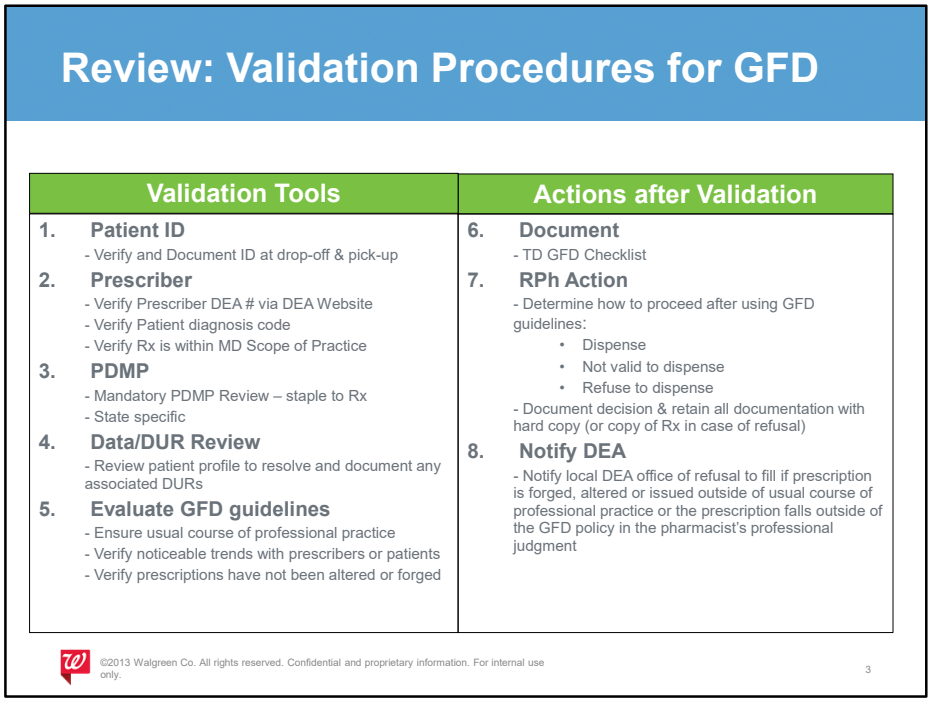
Insert EPD Name

April 2013

Walgreens
AT THE CORNER OF HAPPY & HEALTHY™



We'll start with a quick review of the GFD policy and then go into the new Target Drug GFD.



Let's review the updated validation procedures contained in the Good Faith Dispensing Policy.

The first 5 steps describe how pharmacy team members are able to determine the validity of a prescription. The last 3 are actions that should be completed after the initial validation steps. Every situation will not be the same. In some circumstances, you will use all GFD tools, however in other situations you may only need to use a few. We expect our pharmacists to use their professional judgment when dispensing controls and document accordingly.

Key Points to Highlight:

. 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. It is not enough to only verify if a prescription is fraudulent.

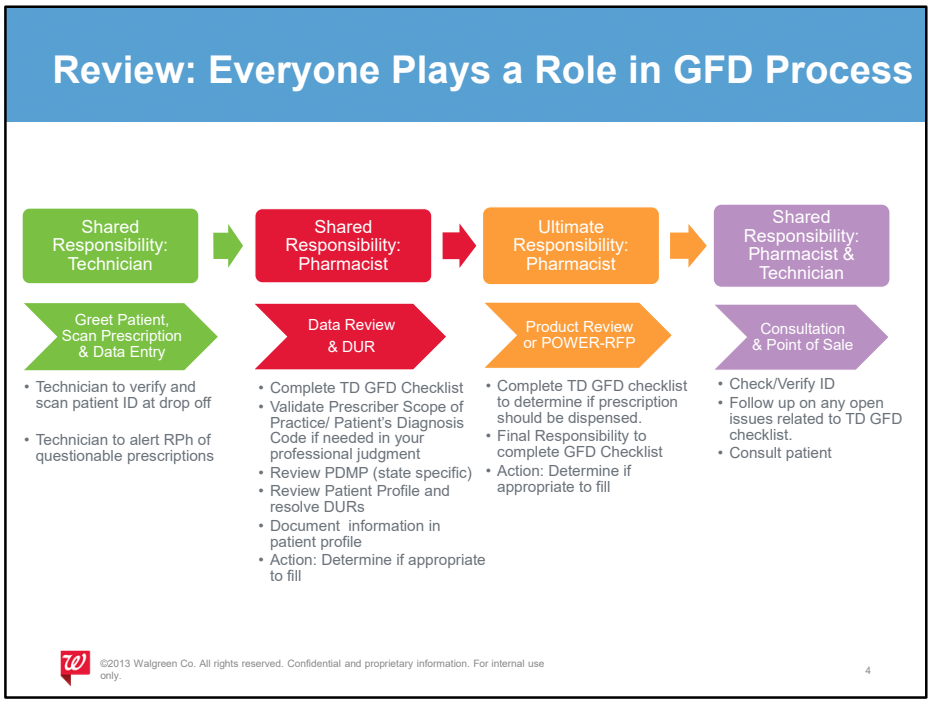
In the policy, there are examples that should alert a pharmacist to questionable circumstances. Such as:

- Is the rx written outside the prescriber's scope of practice? For example, a pediatrician writing a controlled substance for an adult
- Does the prescriber frequently write for unusual quantities or directions?

This list is not intended to be all inclusive. A 'yes' answer to any of the questions listed 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.

Please emphasize: The prescription must be valid and meet the elements of Good Faith for the prescription to be dispensed or the pharmacist should refuse to fill. Proper documentation is required. The local DEA office must be faxed within two business days for any refusals to fill. (Point 6, 7 and 8).

It is important that store leadership supports our pharmacists who make appropriate good faith dispensing decisions.



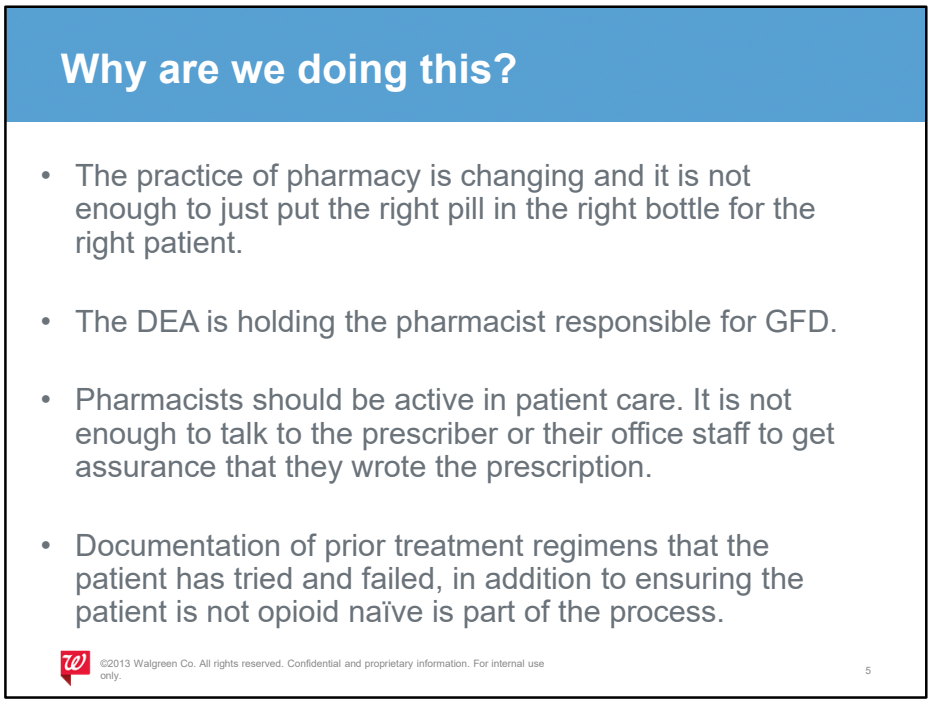
Now that we understand the validation steps for GFD, here is how everyone plays a role in the process.

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.

The goal is to have all elements of GFD confirmed throughout the filling process and prior to reaching the Product Review/RFP pharmacist.

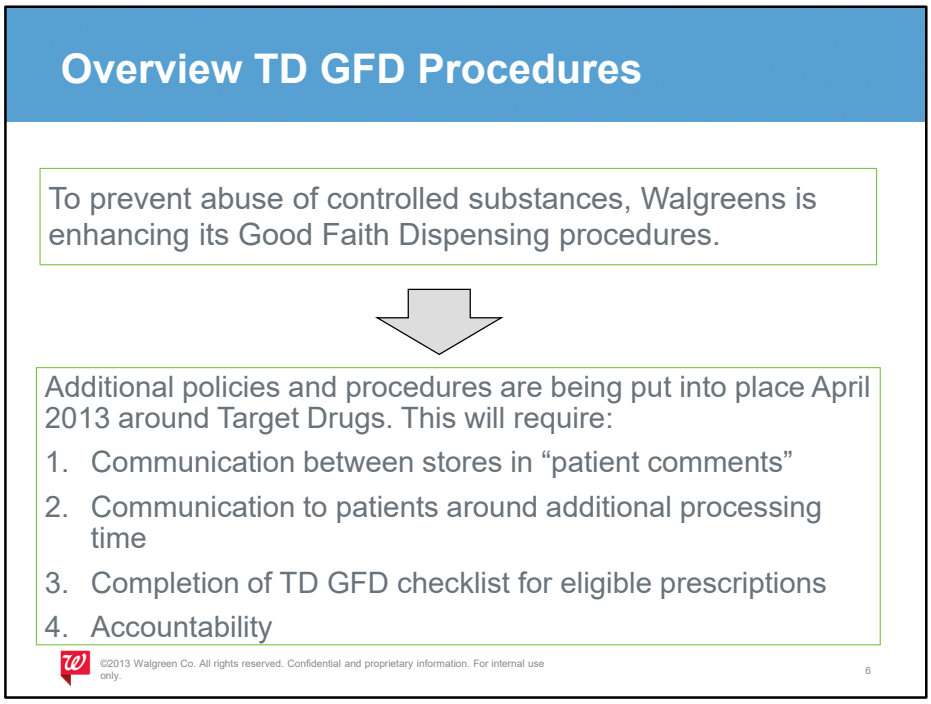
POWER: Only a pharmacist should perform the RFP process for C-II's. Technicians should **not** perform RFP on CIIs and must pass to a pharmacist to complete the RFP process.



The reality is, it's not enough to take the stance of: of "If I confirm with the doctor, I can fill the prescription"

It is not going to be enough to talk to the prescriber or their office staff to get assurance that they wrote the prescription. Getting documentation of prior treatment regimens that they have tried and failed in addition to ensuring the patient is not opioid naïve is part of the process. While all along documenting

An excerpt from the Orlando Sentinal: Paul Doering, a professor at the University of Florida's College of Pharmacy who served as an expert in the DEA's case against the two CVS stores, "Pharmacists traditionally could use the defense that they simply fill prescriptions on doctor's orders" … but "recent cases show pharmacists can no longer look the other way when dirty doctors write prescriptions that put thousands of the dangerous, addictive drugs in the hands of people who don't have a true, medical need."



Additional processes are being put into place to protect our pharmacists and the company. The GFDP that you learned about last summer has been updated to include dispensing practices that are uniform from store to store. This new policy was put into place in order to put a more rigorous and consistent process together in dispensing these Target Drugs. What we don't want to have happen is a prescription is refused at one Walgreen location only to be filled down the street at the next Walgreen location.

The target drugs we are going to begin with are the single entity Oxycodone, Hydromorphone Methadone and Other (which is optional and selected by the district) . These products require additional steps to be taken by the pharmacy staff.

Stores will be required to document in the patient comments if the prescription was denied.
Patients will be required to give the pharmacy additional processing time to allow for the additional steps to be completed
TD GFD checklist will be required for every oxy, hydromorphone, methadone and other (selected by the district) prescription.
Failure to comply will lead to disciplinary action up to and including termination

My stores will just stop filling completely, they will tell the patients they don't carry the drug…

All district and market leadership store visits will reinforce GFD. Leadership will need to be looking through the "refusal file" and the file of filled CII prescriptions and should look for:

Refusals

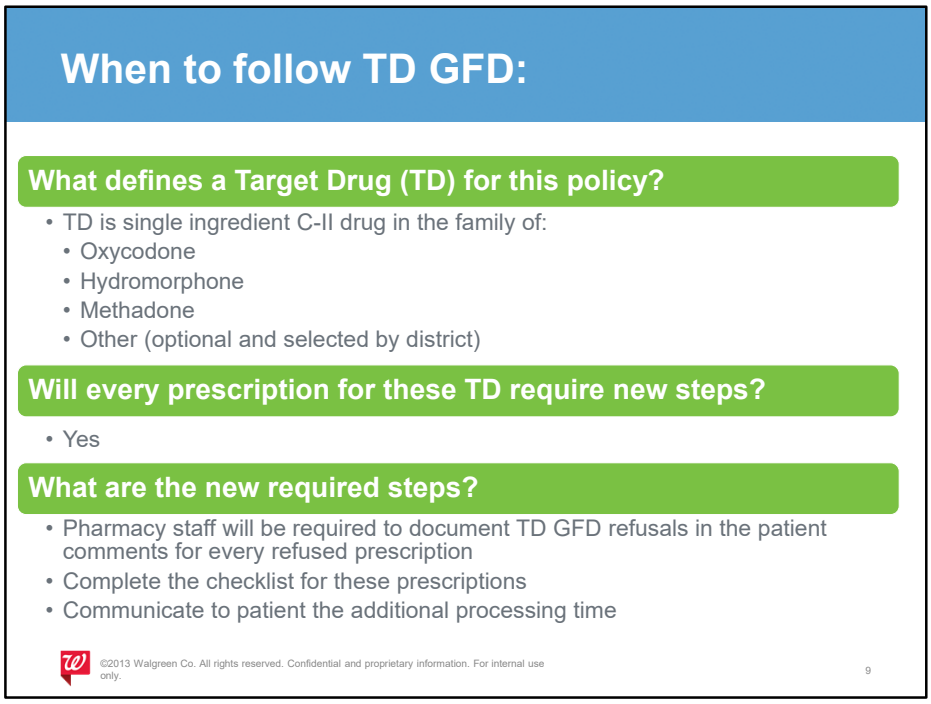
- Copies to the DEA of the faxed prescription, TD GFD checklist, and paperwork documentation

Filled

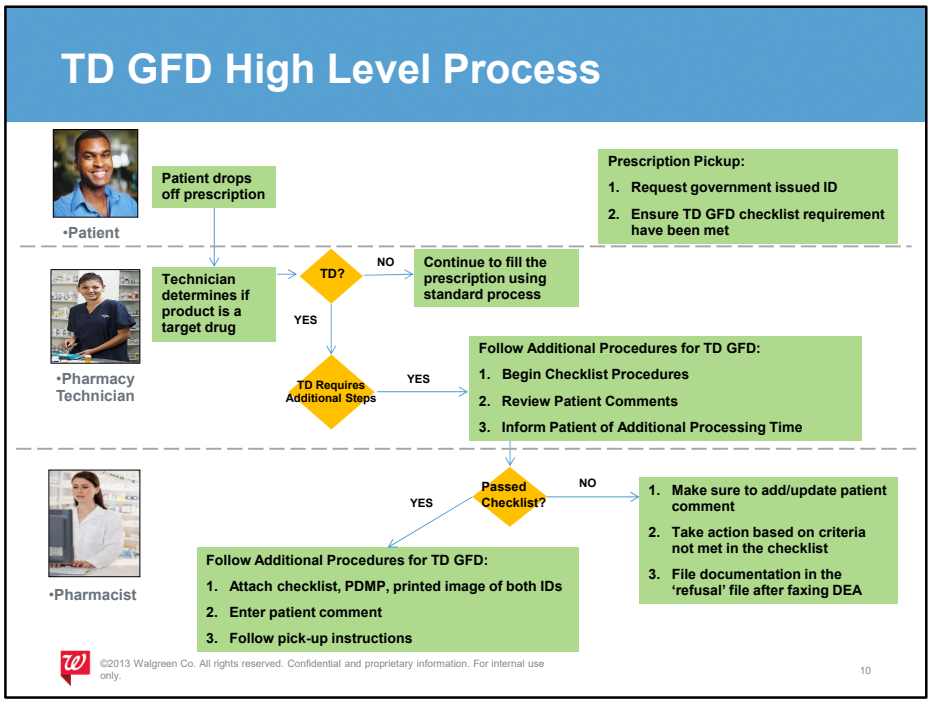
- TD GFD checklist and paperwork documentation attached to filled oxycodone, hydromorphone, methadone and other (optional and selected by the district) prescriptions in the CII files

It is unlikely that a full time pharmacist at that store would not dispense or refuse even one of these medications during the time between your visits to the stores. As district/market leaders, you will need to play an active role during your supervision visits to reinforce GFD and to ensure that the TD GFD is being followed.

TD GFD Procedures

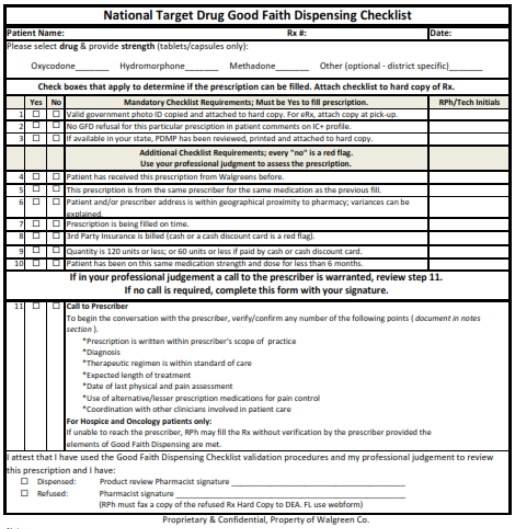


For this policy we are targeting just the single ingredient Oxy, Hydromorphone, Methadone and Other (optional and selected by the district) brand and generics products. Every prescription for these medications will require these new procedures. The TD GFD checklist will need to be completed, attached to the prescription if there is a refusal, a message will need to be entered into the patient's comment. Additionally, any refused prescription must be faxed to the DEA and the documentation of such action retained in the "refusal folder"



So here is what it is going to look like at the store.

Checklist



National 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 determine if the prescription can be filled. Attach checklist to hard copy of Rx.

	Yes	No	Mandatory Checklist Requirements; Must be Yes to fill prescription.	RPh/Tech Initials
1	☐	☐	Valid government photo ID copied and attached to hard copy. For eRx, attach copy at pick-up.	
2	☐	☐	No GFD refusal for this particular prescription in patient comments on IC+ profile.	
3	☐	☐	If available in your state, PDMP has been reviewed, printed and attached to hard copy.	
			Additional Checklist Requirements; every "no" is a red flag. Use your professional judgment to assess the prescription.	
4	☐	☐	Patient has received this prescription from Walgreens before.	
5	☐	☐	This prescription is from the same prescriber for the same medication as the previous fill.	
6	☐	☐	Patient and/or prescriber address is within geographical proximity to pharmacy; variances can be explained.	
7	☐	☐	Prescription is being filled on time.	
8	☐	☐	3rd Party Insurance is billed (cash or a cash discount card is a red flag).	
9	☐	☐	Quantity is 120 units or less; or 60 units or less if paid by cash or cash discount card.	
10	☐	☐	Patient has been on this same medication strength and dose for less than 6 months.	

If in your professional judgement a call to the prescriber is warranted, review step 11. If no call is required, complete this form with your signature.

11	☐	☐	**Call to Prescriber** To begin the conversation with the prescriber, verify/confirm any number of the following points (*document in notes section*). *Prescription is written within prescriber's scope of practice *Diagnosis *Therapeutic regimen is within standard of care *Expected length of treatment *Date of last physical and pain assessment *Use of alternative/lesser prescription medications for pain control *Coordination with other clinicians involved in patient care **For Hospice and Oncology patients only:** If unable to reach the prescriber, RPh may fill the Rx without verification by the prescriber provided the elements of Good Faith Dispensing are met.

I attest that I have used the Good Faith Dispensing Checklist validation procedures and my professional judgement to review this prescription and I have:

☐ Dispensed: Product review Pharmacist signature _____

☐ Refused: Pharmacist signature _____

(RPh must fax a copy of the refused Rx Hard Copy to DEA. FL use webform)

Proprietary & Confidential, Property of Walgreen Co.

Notes:

Checklist will be posted on StoreNet, stores will need to print out copies to have available for use.

Checklist (cont.)

There will be mandatory "Yes" boxes that the pharmacy staff must ensure are "Y":

	Yes	No	Mandatory Checklist Requirements; Must be Yes to fill prescription.	RPh/Tech Initials
1	☐	☐	Valid government photo ID copied and attached to hard copy. For eRx, attach copy at pick-up.	
2	☐	☐	No GFD refusal for this particular presciption in patient comments on IC+ profile.	
3	☐	☐	If available in your state, PDMP has been reviewed, printed and attached to hard copy.	

There will be mandatory Yes boxes that the pharmacy staff must ensure are Y.
We will need a valid government photo ID and a copy of that needs to be made and kept with the documentation. If this is an eRx prescription, then a copy of the photo ID can be done at pick-up. Who ever drops of the prescription, will need to present their ID.
There cannot be a GFD Refusal comment in the patient's comments **for this prescription** and if there is one from a different prescription, caution should be used before filling.
PDMP (if available in your state) must be run on each and every patient we dispense for these medications. Someone in each store needs to have access to the PDMP website until all necessary steps are completed for those that do not have access to the PDMP get it. If your state does not have an electronic PDMP, the pharmacists will have to rely on the GFD guidelines outlined in the GFD policy we updated last June.
There must be a valid DEA license for the prescriber. If there isn't, follow the refusal processes outlined in a later slide.

Checklist (cont.)

In the additional checklist section, caution should be used if questions are answered with a “No”:

			Additional Checklist Requirements; every "no" is a red flag. Use your professional judgment to assess the prescription.	
4	☐	☐	Patient has received this prescription from Walgreens before.	
5	☐	☐	This prescription is from the same prescriber for the same medication as the previous fill.	
6	☐	☐	Patient and/or prescriber address is within geographical proximity to pharmacy; variances can be explained.	
7	☐	☐	Prescription is being filled on time.	
8	☐	☐	3rd Party Insurance is billed (cash or a cash discount card is a red flag).	
9	☐	☐	Quantity is 120 units or less; or 60 units or less if paid by cash or cash discount card.	
10	☐	☐	Patient has been on this same medication strength and dose for less than 6 months.	
If in your professional judgement a call to the prescriber is warranted, review step 11. If no call is required, complete this form with your signature.				

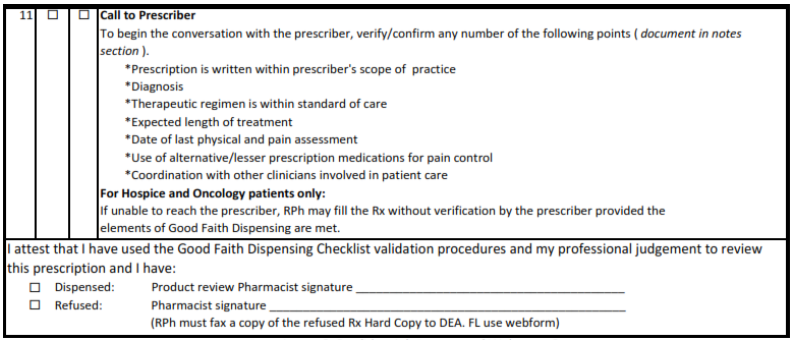
In the additional checklist section, these questions can be yes or no, but caution should be used if they are no, as they are considered “red flags”.
The geographical proximity question has intentionally been kept vague, as there may be a solid reason as to why the patient or the prescriber is not near the store. The pharmacist must use professional judgment after validating the reason for a proximity distance that is excessive.
For example, a Key West, FL may have patients that drive 3.5hr to the nearest large metro city/hospital. But, a patient that drives down to FL from New Jersey to get their prescription filled should be further evaluated before filling.

Filling the prescription ‘on time’ will need to be evaluated by the pharmacist, as there may be instances where a prescriber is raising the dosage for the patient causing them to run out earlier.

A checklist must be on file for every prescription for these meds, for each patient and each prescriber.

Checklist (cont.)

A call to the prescriber for any Target Drug prescription should be made if the pharmacist feels the call is warranted, regardless of the quantity prescribed.



11	☐	☐	**Call to Prescriber** To begin the conversation with the prescriber, verify/confirm any number of the following points (*document in notes section*). *Prescription is written within prescriber's scope of practice *Diagnosis *Therapeutic regimen is within standard of care *Expected length of treatment *Date of last physical and pain assessment *Use of alternative/lesser prescription medications for pain control *Coordination with other clinicians involved in patient care **For Hospice and Oncology patients only:** If unable to reach the prescriber, RPh may fill the Rx without verification by the prescriber provided the elements of Good Faith Dispensing are met.

I attest that I have used the Good Faith Dispensing Checklist validation procedures and my professional judgement to review this prescription and I have:

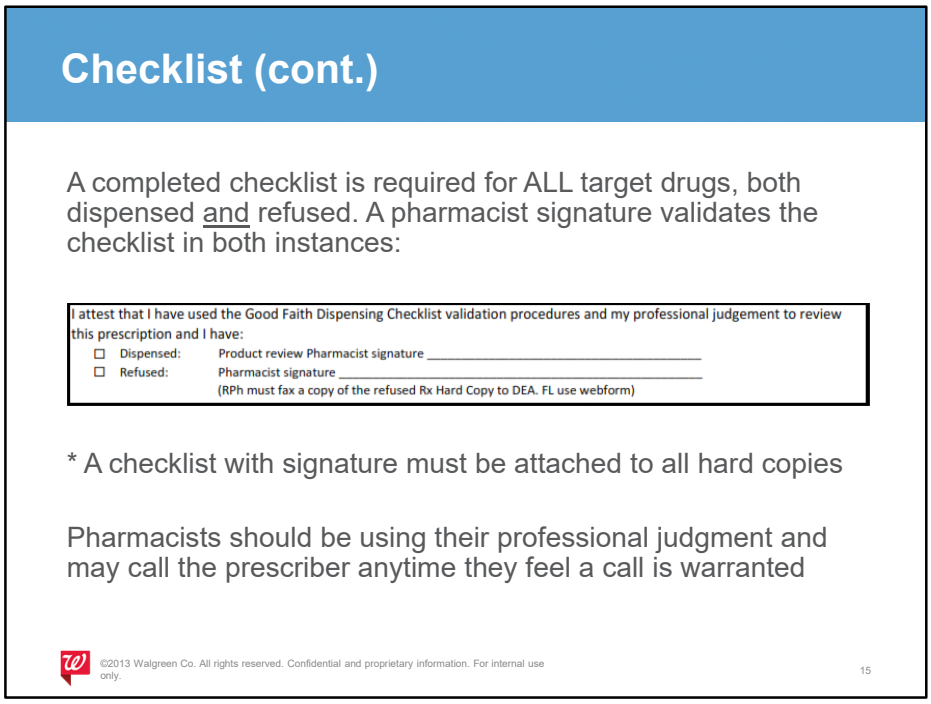
☐ Dispensed: Product review Pharmacist signature _____

☐ Refused: Pharmacist signature _____

(RPh must fax a copy of the refused Rx Hard Copy to DEA. FL use webform)

According to Title 21 of the Code of Federal Regulations, section 1306.04, pharmacists are required by the DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose…."a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)…"

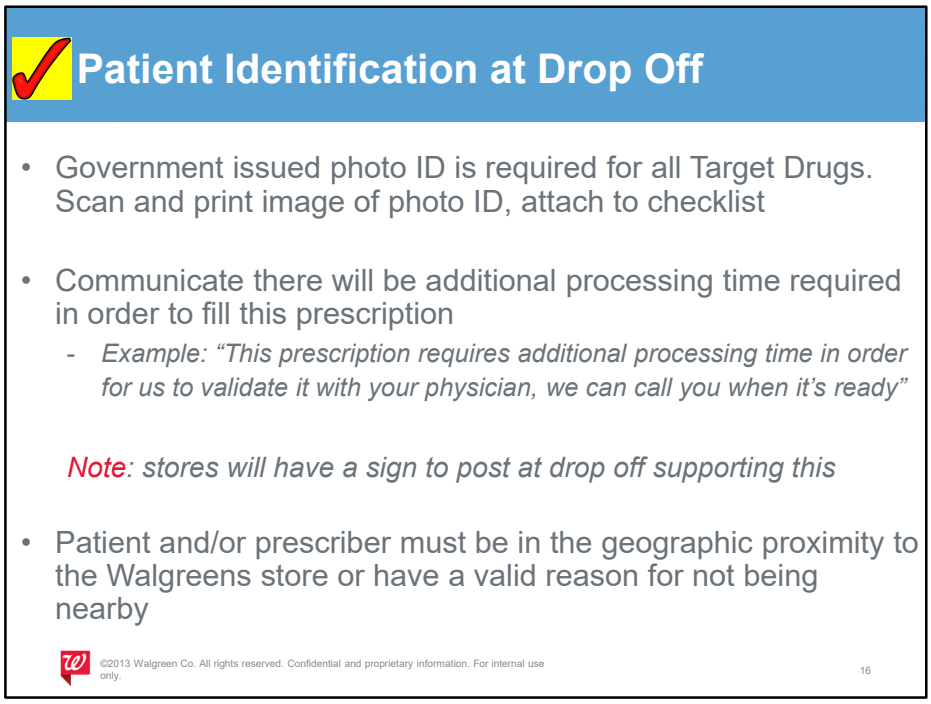
A call to the prescriber is warranted and should be made any time the pharmacist feels that more information is needed (such as: diagnosis and/or therapeutic regimen) in order to fill a prescription in good faith.



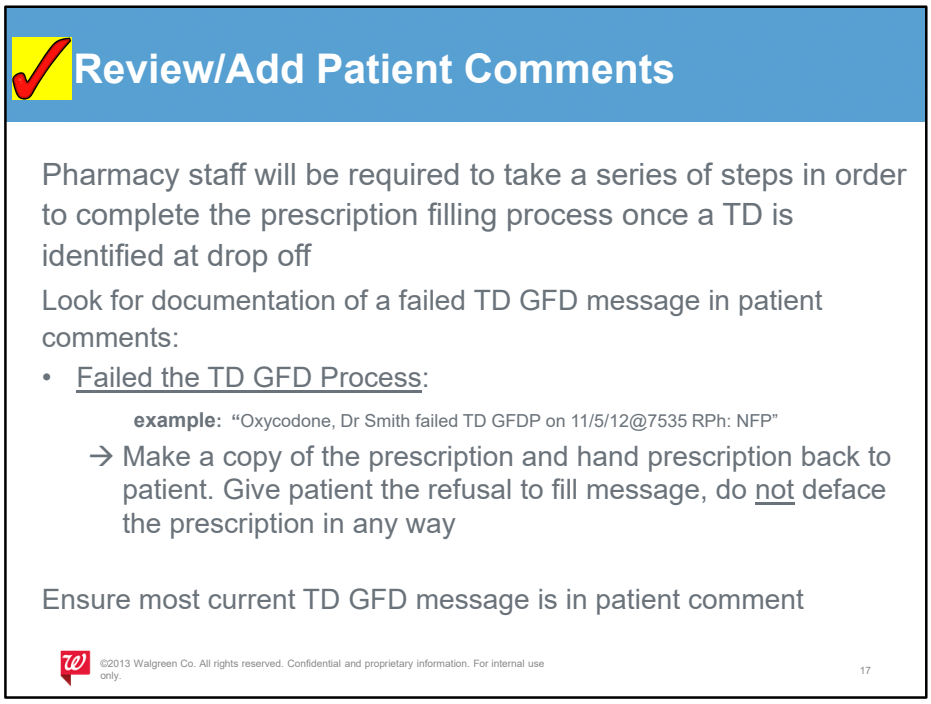
There will need to be documentation for both filled and refused prescriptions in the store. The market and district leadership will be looking for this on store visits.

It is going to be okay for a pharmacist to refuse to fill a prescription based on the elements of the checklist and their professional judgment. And they need to know they have both corporate and leadership's support on this. However, they cannot just tell the patients that they are out of stock or they don't fill for this drug.

How will you know, you ask? It would be unlikely that a full-time RPh at a store would not fill/refuse any of these products in the amount of time between your store visits. When you look through the files, there should be documentation from each RPH that works at that location. We will need full support of RXS, DM and CL level.



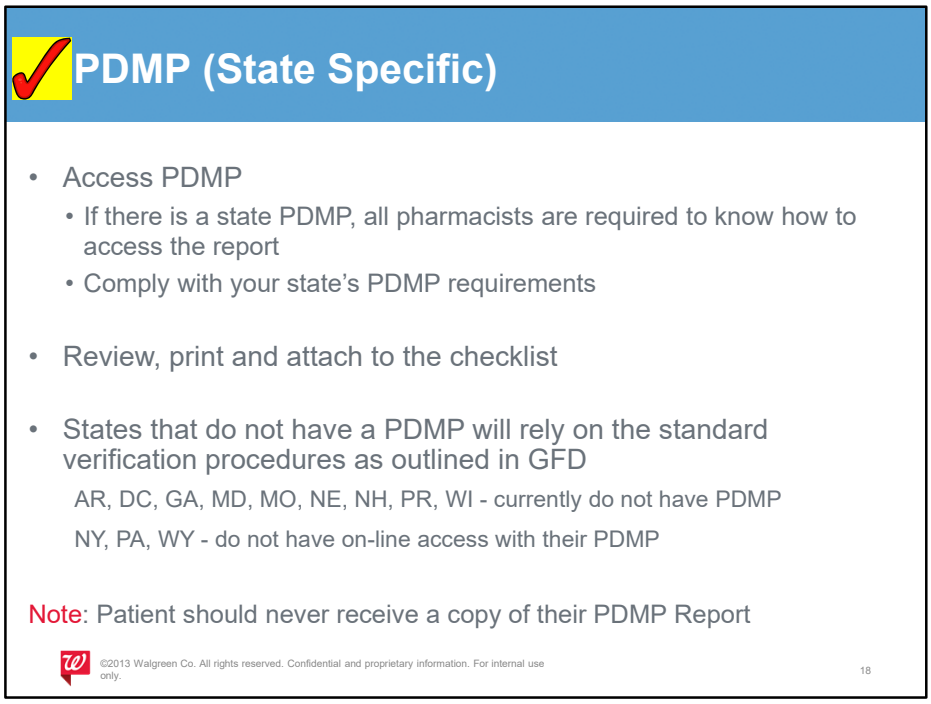
So, here is how it's going to look in the store, the tech gets the rx and they will request a photo ID which they will scan and print a copy of. They will let the patient know it will take extra time in order for them to fill.



After identifying that the prescription is for a TD, pharmacy staff must ensure that the prescription was not denied at another Walgreen location. The pharmacy staff should look in the patient comments for a note that they have failed a TD GFDP

Failed: a message is put into the patient comments by the pharmacist. The response to the patient needs to be "Walgreens is working hard to ensure the appropriate dispensing of certain pain medications. Based on my clinical review and professional judgment, this prescription does not meet the requirements we have put in place for dispensing these medications. Therefore, we cannot fill this prescription in good faith at this or any Walgreens. I apologize for any inconvenience." Give the hard copy back to the patient after making a copy of it that will be used to notify the DEA of the refusal to fill.

If there is a failed comment for this prescription say: "I am sorry, this prescription did not meet the requirements Walgreens had put in place for dispensing these medications, therefore we cannot fill this prescription in good faith at this location or any other Walgreens location. I apologize for any inconvenience."



Mandatory use of the PDMP website is required where PDMP is available. Every pharmacist must know how to access the PDMP and print a report for every TD GFDP prescription by patient.

Access is subject to change. AR and WI are expected to have access sometime in 2013.

The PDMP will be attached to the hard copy along with the checklist for any filled TD. If a member of law enforcement, the DEA or 3rd party auditor requests to see a hardcopy of a TD, all paperwork including the PDMP report should be removed prior to releasing the hard copy.

Again, PDMP report information should not be placed in public view nor should the reports be given to the patient.

Prescriber

- Verify patient and/or prescriber address is within the geographic area
- If the pharmacist determines that a call to the prescriber is warranted to satisfy their corresponding responsibility, they should contact the prescriber and document the findings on the checklist

➢ **Contacting the prescriber**:

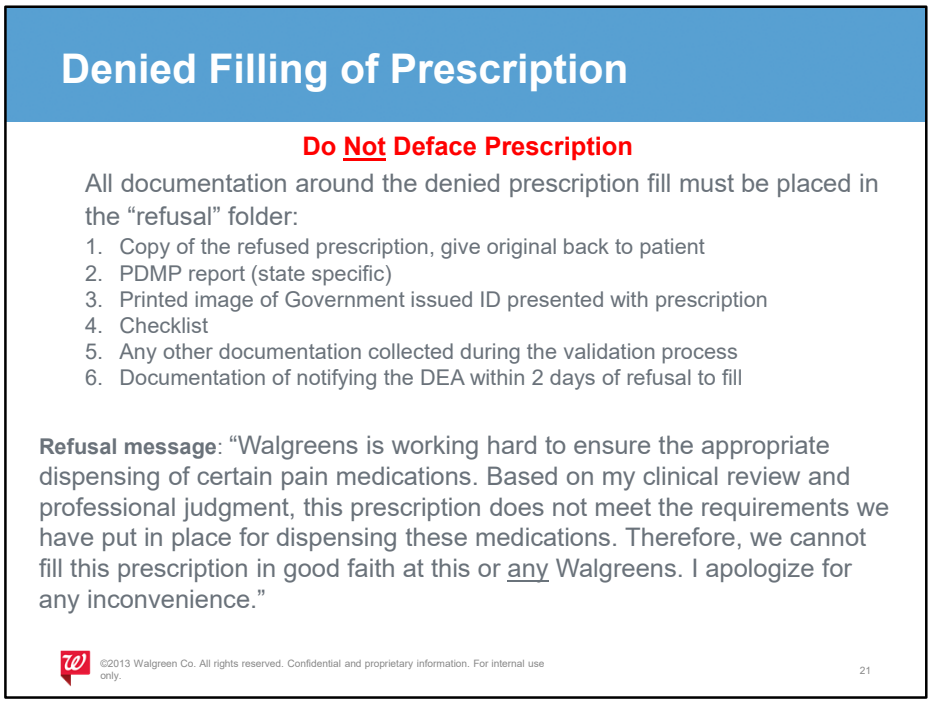
– Determine if the prescriber is issuing a prescription within their scope of practice.

– Substantiate the prescription therapeutic regimen with the prescriber.
Including but not limited to:

- Obtaining a diagnosis code, document it on the checklist
  - If diagnosis does not correspond to proposed prescription, discuss with the prescribing clinician if fulfillment is appropriate
- Length of treatment
- Date of last physical and pain assessment
- Date of next scheduled appointment
- Use of alternative/ lesser prescription medications for pain control
- Coordination across other clinicians involved in patient care

Dispensing and Selling TD Prescriptions

- If all points of the checklist are complete, the pharmacist can sign at the bottom and continue product review
- Attach the checklist and all documentation to the hard copy



It is very important that the pharmacy staff do not deface the prescriptions that they refuse to fill. Writing comments like "doctor under investigation" or other slanderous memos are not authorized. It is going to be a delicate situation as well, because there may be times where it is difficult to tell the legitimate pain patient, therefore delivering the refusal message is very important. Especially the last part, because if it's refused at one Walgreens, it is refused at the entire chain.

"Walgreens is working hard to ensure the appropriate dispensing of certain pain medications. Based on my clinical review and professional judgment, this prescription does not meet the requirements we have put in place for dispensing these medications. Therefore, we cannot fill this prescription in good faith at this or any Walgreens. I apologize for any inconvenience."

Accountability

Failure to comply with the GFD and TD GFD policies and procedures at any level will result in disciplinary action. In cases of serious misconduct, it may be necessary to escalate to a higher level of discipline in this process, up to and including termination.

Step 1 (VERBAL COUNSELING)

- Review GFD and TD GFD policy and procedures on StoreNet <insert link> with the pharmacist
- Review and acknowledge the policy acknowledgment

Step 2 (WRITTEN WARNING)

- Issue written warning to pharmacist
- Re-assign and acknowledge the GFD and TD GFD policy acknowledgment
- Review GFD and TD GFD training materials (PowerPoint & policies/procedures)

Accountability (cont.)

Step 3 (FINAL WRITTEN WARNING)

- Issue the final written warning to the pharmacist, DM and RXS
- Use the GFD and TD GFD training materials to develop an action plan for compliance with the GFD process
- The pharmacist should be suspended for one workweek coinciding with the pay week and be moved from his/her current location

Step 4 (TERMINATION)

**Discipline is active for a rolling 12-month period from the date the discipline is issued to a team member. If more than 12 months have elapsed since issuance of discipline, repeat the prior discipline step.*

All documentation related to GFD discipline process must be entered into the Talent Management Portal as discipline for misconduct.

Supporting Documents

- Full TD GFD policy posted on StoreNet
- GFD Sign
- Talking Points for patients, prescribers and managers
- Clinical Pain Management Document

Next Steps

- Review and familiarize yourselves with
  - New Target Drug GFD policy
  - Updated GFD policy
  - FAQs for patients and prescribers
  - Ensure all stores have a “refused” folder
    - Ensure staff is notifying DEA for every prescription they refuse to fill (not just fake/forged prescriptions)
- Communicate as necessary to your stores

Questions?

- Pharmacy Supervisors can direct questions to the Divisional Rx Integrity Managers:
  - Christopher (Chris) Dymon - East
  - Patricia (Patty) Daugherty - Midwest
  - Edward (Ed) Bratton - South
  - Eric Stahmann - West

OR

  - Rx Integrity E-mail: (rxintegrity@walgreens.com)

Special Thanks!

A special *"THANK YOU!"* to all of the pilot stores in:

- Florida
- Las Vegas
- Knoxville

Thank you for your support and feedback!!

Thank You!