



Controlled Substance Action Plan

June 11, 2012

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CCSF v. Purdue Pharma,
et al. 3:18-CV-7591

WAG-MDL-01662

Admitted: 6/02/2022

Agenda



- Overview
- Review updated policies & procedures
- Future Enhancements
- Call to action and next steps

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- Due to recent action taken by the DEA, select policies and procedures have been updated to ensure our pharmacists and stores are compliant when dispensing controlled substances.
- Corresponding enhancements include:
 - Update to the Good Faith Dispensing Guidelines
 - Revised Ordering Procedures for Controlled Substances
 - Drug Utilization Review Enhancements



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Good Faith Dispensing Policy



- The Good Faith Dispensing Policy has been updated to provide Pharmacists additional resources for making decisions when dispensing controlled substance prescriptions.
- The following components have been updated:
 - Prescription Validation Procedures
 - Roles and Responsibilities of each pharmacy team member
- Pathway to Good Faith Dispensing Policy
 - *Storenet > RxOps > Pharmacy Policies and Procedures > Filling Prescriptions > Controlled Substance Prescriptions and Good Faith Dispensing*

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Validation Procedures for Good Faith Dispensing (GFD)



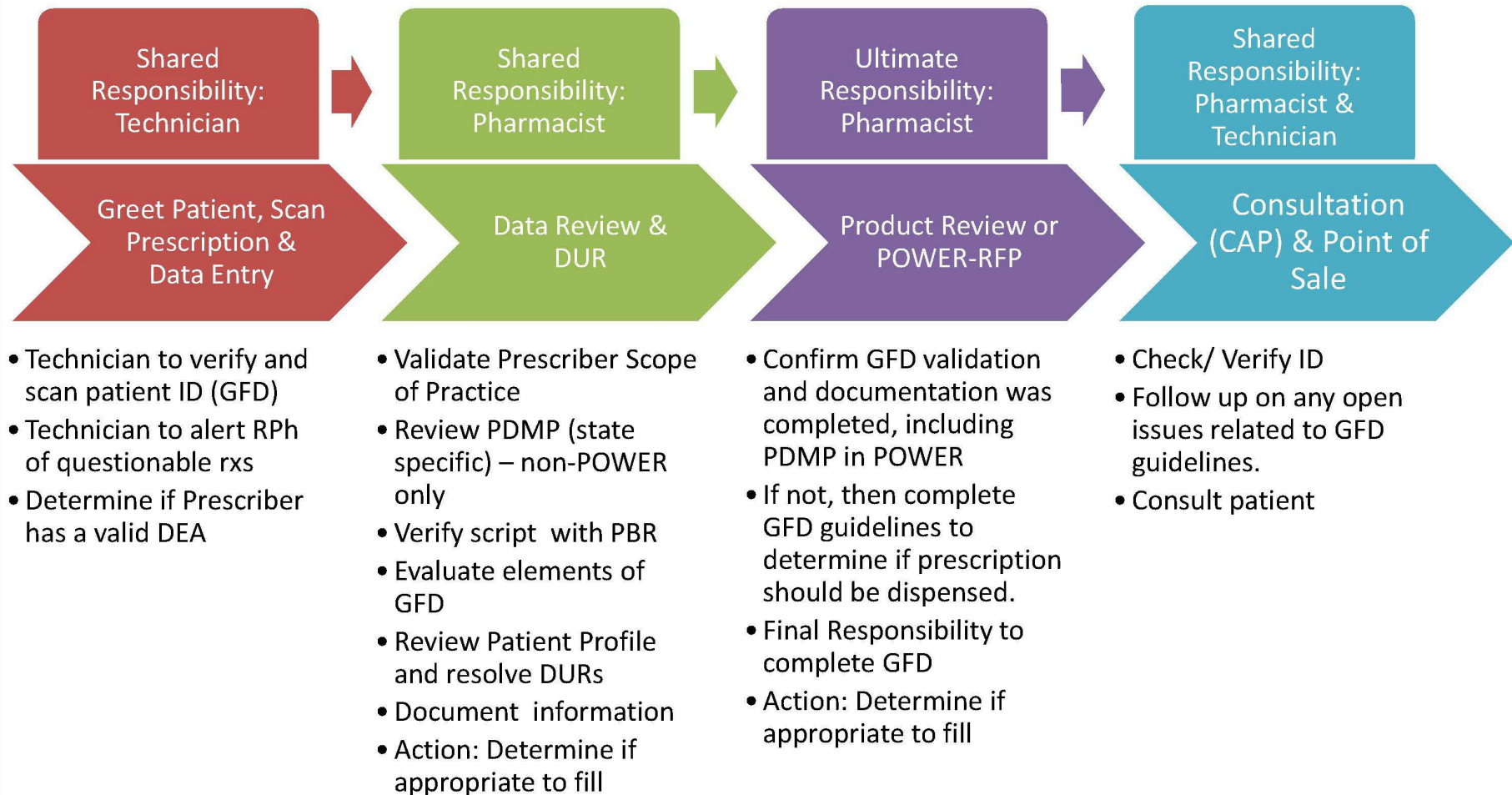
Validation Tools

- 1. Patient ID**
 - Verify and Document ID if the patient doesn't have a relationship with the pharmacy
 - Follow state specific guidelines
- 2. Prescriber**
 - Verify Prescriber DEA number
 - Use DEA website if necessary
- 3. PDMP**
 - Utilize to obtain additional information to help determine validity of prescription
 - State specific
- 4. Data/DUR Review**
 - Review patient profile to resolve and document any associated DURs
- 5. Evaluate GFD guidelines**
 - Ensure usual course of professional practice
 - Verify noticeable trends with prescribers or patients
 - Verify prescriptions have not been altered or forged

Actions after Validation

- 6. Document**
 - Document all efforts used to validate good faith dispensing
- 7. RPh Action**
 - Determine how to proceed after using GFD guidelines:
 - Dispense
 - Not valid to dispense
 - Refuse to dispense
- 8. Notify DEA**
 - Notify local DEA office of refusal to fill if prescription is forged, altered or issued outside of usual course of professional practice

Everyone Plays a Role in the GFD Process



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Ordering Controlled Substances



- Controlled Substance Ordering procedures have been updated to minimize risk.
- The following changes have been implemented:
 - Manual Orders to DC and Cardinal will no longer be accepted.
 - All Controlled Substance orders will be required to be processed through SIMS, including requests for specific manufacturers
 - *StoreNet > SIMS > Rx Inventory Management > Ordering > Controlled Drugs > Ordering Specific Manufacturer*
 - Maximum Ordering Quantities
 - Store specific order limits
 - Chainwide order limits
 - Orders exceeding the maximum quantities
 - Pharmacy Managers must contact their Pharmacy Supervisor for approval
 - If approved, the Pharmacy Supervisor will approve and submit the order

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Enhanced Drug Utilization Review



- A DUR enhancement has been made to alert pharmacists to review a patient's profile and utilize Good Faith Dispensing procedures when dispensing select controlled substances.
 - A **Major DUR** will flag when a patient has been prescribed medications, that in combination, have a high potential for abuse.
 - The following message will appear to the pharmacist: *"A strong association appears to exist between illicit use of Carisoprodol in combination with narcotic analgesics such as oxycodone and benzodiazepines such as alprazolam....."*
- The pharmacist completing the DUR must then adhere to the Good Faith Dispensing policy.



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Future Enhancements



- We will be developing additional tools to assist in our compliance efforts. These include:
 - Index Reporting
 - Updated Inventory Dashboard
 - Additional inventory system controls (SIMS)
 - Controlled Substance investigation process
 - IT enhancements to streamline current manual processes
 - Good Faith Dispensing PPL Policy Acknowledgement and PPL Training



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Call to Action



- Store leadership are to:
 - Reinforce the following information with all pharmacy team members:
 - Updated Good Faith Dispensing Policy
 - Updated controlled substance ordering procedures
 - Enhanced Drug Utilization Review
 - Support your pharmacists in making good faith decisions

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Questions



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