A Contemporary Focus Highlight on Medication Safety & Regulatory Standards in the Oncology Setting

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Hazardous Drug Safety and Compliance Officer

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Medication Safety and Compliance Officer
Objectives

Monoclonal Antibodies in the USP <800> Setting at Moffitt Cancer Center

• Review changes to the National Institute for Occupational Health and Safety (NIOSH) List of Hazardous Drugs in Healthcare Settings as it applies to monoclonal antibodies
• Review Federal Register, Centers for Disease Control and Prevention (CDC), United States Pharmacopeia (USP) and NIOSH updates/guidance on monoclonal antibodies
• Describe one organization’s approach to safe handling of monoclonal antibodies

Regulatory Compliance in Context of Infusion Rate Changes Post-Adverse Drug Infusion-Related Reactions

• Describe the purpose of The Joint Commission, a regulatory body
• Examine MM.04.01.01 (Medication orders are clear and accurate) in reference to a post-adverse drug infusion-related reaction scenario
• Develop a workflow to support compliance with the updated MM.04.01.01 in reference to medication titration
Monoclonal Antibodies in the USP
<800> Setting at Moffitt Cancer Center
# 2016 NIOSH List of Hazardous Drugs in Healthcare Settings

## Table 1. Group 1: Antineoplastic drugs, including those with the manufacturer’s safe-handling guidance (MSHG)

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS classification</th>
<th>MSHG</th>
<th>Supplemental information</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>abiraterone</td>
<td>10:00 antineoplastic agents</td>
<td></td>
<td>Women who are pregnant or may be pregnant should not handle without protection (e.g., gloves); FDA Pregnancy Category X</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>ado-trastuzumab emtansine</td>
<td>10:00 antineoplastic agents</td>
<td>Yes</td>
<td>Conjugated monoclonal antibody; FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>afatinib*</td>
<td>10:00 antineoplastic agents</td>
<td></td>
<td>Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
</tbody>
</table>

2016 NIOSH List of Hazardous Drugs in Healthcare Settings

Table 1 (Continued) Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS classification</th>
<th>MSHG</th>
<th>Supplemental information</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>bosutinib</td>
<td>10:00 antineoplastic agents</td>
<td></td>
<td>FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>brentuximab</td>
<td>10:00 antineoplastic agents</td>
<td>yes</td>
<td>Conjugated monoclonal antibody; FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>vedotin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 2016 NIOSH List of Hazardous Drugs in Healthcare Settings

<table>
<thead>
<tr>
<th>Drug</th>
<th>Type of Antineoplastic Agents</th>
<th>Pregnancy Category</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>gemcitabine</td>
<td>10:00 antineoplastic agents</td>
<td>yes</td>
<td>FDA Pregnancy Category D, <a href="https://www.dailymed.nlm.nih.gov">DailyMed; DrugBank</a></td>
</tr>
<tr>
<td>gemtuzumab ozogamicin</td>
<td>10:00 antineoplastic agents</td>
<td>yes</td>
<td>FDA Pregnancy Category D, <a href="https://www.dailymed.nlm.nih.gov">DailyMed; DrugBank</a></td>
</tr>
<tr>
<td>pertuzumab</td>
<td>10:00 antineoplastic agents</td>
<td></td>
<td>Black Box warning on embryo-fetal death and birth defects; FDA Pregnancy Category D</td>
</tr>
</tbody>
</table>

Moffitt’s Response to the 2016 NIOSH Publication

For streamlined compounding

For streamlined administration

All MABs will be treated as Hazardous
Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.
Monoclonal Antibodies

Seven commenters opposed the inclusion of biological drug products (monoclonal antibodies) on the List.

Comment: The language in the section titled “Application” indicates that the draft Policy and Procedures do not apply to healthcare workers who handle recombinant therapeutic proteins. Therefore, all recombinant therapeutic proteins should be excluded from the List unless “science-based or product-specific circumstances dictate otherwise.”

Comment: Monoclonal antibodies (i.e., therapeutic proteins) are of such a large molecular weight that they do not pose a realistic risk to healthcare workers. For example, monoclonal antibodies are too large to be absorbed through skin contact, and if ingested, they would be destroyed by digestion; if inhaled, the pulmonary system would prevent absorption. Consequently, these drugs are all administered by injection. The only potential risk to healthcare workers is of an accidental needle stick, which would not inject a pharmacologically active dose.

Comment: The draft Policy and Procedures should include a methodology describing how NIOSH evaluates monoclonal antibodies.

NIOSH response: NIOSH applies the same methodology for evaluating each drug approved by the FDA Center for Drug Evaluation and Research, regardless of class. The definition of a hazardous drug in the draft Procedures recognizes that the molecular properties of a drug, such as the molecular weight, may substantially limit the potential for adverse health effects. NIOSH may consider molecular weight along with the other intrinsic molecular properties of a drug that affect the hazard a drug poses. While some large molecular weight drugs may have low bioavailability by relevant routes of exposure, other factors in the characterization of the hazard are considered as well. Therefore, in accordance with the draft Procedures, some monoclonal antibodies may not meet the NIOSH definition of the term “hazardous drug.” Because the list of drugs proposed for placement on the List has been updated based on the draft Procedures, the monoclonal antibodies bevacizumab and trastuzumab are no longer proposed for placement on the List. Blinatumomab continues to be proposed for placement and other monoclonal antibodies that have properties meeting the NIOSH definition of a hazardous drug will remain on the List.
**2020 Draft NIOSH List of Hazardous Drugs in Healthcare Settings**

### Table 1. Drugs that contain MSHI in the package insert and/or meet the NIOSH definition of a hazardous drug and are classified by the NTP as “known to be a human carcinogen,” and/or classified by the IARC as “carcinogenic” or “probably carcinogenic.”

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS classification</th>
<th>MSHI</th>
<th>Supplemental Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>trastuzumab</td>
<td>10:00 antineoplastic agents</td>
<td>yes</td>
<td>Monoclonal antibody conjugated to mertansine (emtansine)</td>
</tr>
<tr>
<td>emtansine</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 2. Drugs that meet the NIOSH definition of a hazardous drug but are not drugs that have MSHI or are classified by the NTP as “known to be a human carcinogen,” or classified by the IARC as “carcinogenic” or “probably carcinogenic.” (some also may have adverse development and/or reproductive effects)

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS classification</th>
<th>Supplemental Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>anastrozole</td>
<td>68.16.04 antiestrogens; 10:00 antineoplastic agents</td>
<td>Only met the NIOSH criteria as a developmental and/or reproductive hazard</td>
</tr>
<tr>
<td>apomorphine</td>
<td>28:36.20.08 Nonergot-derivative dopamine receptor agonists</td>
<td>Genotoxic in several in vitro assays</td>
</tr>
<tr>
<td>axitinib</td>
<td>10:00 antineoplastic agents</td>
<td>Teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposures</td>
</tr>
<tr>
<td>bexarotene</td>
<td>10:00 antineoplastic agents</td>
<td>Only met the NIOSH criteria as a developmental and/or reproductive hazard</td>
</tr>
<tr>
<td>bicalutamide</td>
<td>10:00 antineoplastic agents</td>
<td></td>
</tr>
<tr>
<td>blinatumomab</td>
<td>10:00 antineoplastic agents</td>
<td>Organ Toxicity at Low Dose - Neurotoxicity</td>
</tr>
</tbody>
</table>

## 2020 Draft NIOSH List of Hazardous Drugs in Healthcare Settings

<table>
<thead>
<tr>
<th>Drug</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacillus Calmette Guerin (BCG)</td>
<td>BCG was removed from the NIOSH list because it is an infectious agent and not classified as a drug by FDA. For handling recommendations see drug package insert.</td>
</tr>
<tr>
<td>paliperidone</td>
<td>NIOSH reviewed data from studies provided by the manufacturer and determined it is unlikely that paliperidone poses a carcinogenic, reproductive, or developmental hazard to workers in a healthcare setting and is no longer considered a hazardous drug by NIOSH.</td>
</tr>
<tr>
<td>pertuzumab</td>
<td>NIOSH reviewed data concerning the developmental effects related to pertuzumab treatment and has determined that it is unlikely that pertuzumab poses a reproductive threat to workers in healthcare settings and is no longer considered a hazardous drug by NIOSH.</td>
</tr>
</tbody>
</table>
Revision Bulletin: July 1, 2020

Revision Bulletins:
• Published in USP-NF by the first of each month
• Includes notices that provides reasons for changes and official dates of the change to any USP publications/standards/monographs
Recent NIOSH Activity: April 2023

Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings

Purpose:
- How the NIOSH list is developed
- How the NIOSH list is updated
- How to request reevaluations

Recent NIOSH Activity: April 2023

Update on the NIOSH List of Hazardous Drugs in Healthcare Settings 2023

In 2020, NIOSH requested public comments on the updated draft *NIOSH List of Hazardous Drugs in Healthcare Settings, 2020*, the draft *NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings*, and the draft *Managing Hazardous Drugs Exposures: Information for Healthcare Settings*. There was a 60-day public comment period open from May 1st, 2020 to June 30th, 2020. The *NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings* and *Managing Hazardous Drugs Exposures: Information for Healthcare Settings* have been published. When the *NIOSH List of Hazardous Drugs in Healthcare Settings, 2023*, has been finalized it will be published to the NIOSH website.

NIOSH Publications

How I feel:

It’s been 84 years...
May 9, 2023
The manufacturers of trabectedin, inotuzumab ozogamycin, polatuzumab vedotin, enfortumab vedotin, trastuzumab deruxtecan, sacituzumab govitecan, loncastuximab tesirine, melphalan flufenamide, belantamab mafodotin, and tisotumor vedotin-tftv recommend that they be handled as hazardous drugs. Therefore, NIOSH considers these drugs to be included in Table 1 of the NIOSH list of hazardous drugs. For additional information, see the package inserts for these drugs.

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS Classification</th>
<th>Links</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>inotuzumab ozogamycin</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>August 17, 2017</td>
</tr>
<tr>
<td>polatuzumab vedotin</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>June 10, 2019</td>
</tr>
<tr>
<td>enfortumab vedotin</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>December 18, 2019</td>
</tr>
<tr>
<td>trastuzumab deruxtecan</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>December 20, 2019</td>
</tr>
<tr>
<td>sacituzumab govitecan</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>May 12, 2020</td>
</tr>
<tr>
<td>Loncastuximab tesirine</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>May 28, 2021</td>
</tr>
<tr>
<td>melphalan flufenamide</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>May 28, 2021</td>
</tr>
<tr>
<td>belantamab mafodotin</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>May 28, 2021</td>
</tr>
<tr>
<td>tisotumor vedotin-tftv</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>March 23, 2022</td>
</tr>
<tr>
<td>lurbinectedin</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>May 9, 2023</td>
</tr>
<tr>
<td>mirvetuximab soravtansine</td>
<td>10:00 Antineoplastic Agents</td>
<td><a href="https://www.cdc.gov/niosh/docs/2016-161/default.html">DailyMed</a></td>
<td>May 9, 2023</td>
</tr>
</tbody>
</table>
These will continue to be treated as hazardous:

- Blinatumomab (Draft 2020 list)
- Pertuzumab (2016 list - current official list)

**Monoclonals**

**Antineoplastic Antibody/Drug Conjugates**
Considerations

Pre-approval Investigational Monoclonals

Monoclonals approved post Draft 2020
Proposed Changes for Non-Hazardous Monoclonal Handling at Moffitt: Based on an Assessment of Risk

Storage
- Does not need to be stored in negative pressure room
- Allowed to be stored in a negative pressure room, but shall maintain its own refrigerator, its own shelf in a refrigerator, or its own shelf/storage bin at room temperature

Compounding
- No Closed-System Transfer Device (CSTD) required
- Allowed to be compounded in a Class II A BSC once it is dedicated/designated, continue to wear full PPE in the HD buffer room
- If a Class II A BSC that was previously being utilized for HD compounding is now needed to compound non-hazardous monoclonal, perform a full hood cleaning per policy prior to compounding
## Moffitt Pharmacy Department: Compounding Tool

### BD PhaSeal / Texium Recommended Pharmacy Guidelines (V 2-2022)

<table>
<thead>
<tr>
<th>Treatment Type</th>
<th>Red Cap</th>
<th>Texium Injector</th>
<th>PhaSeal Injector</th>
<th>PhaSeal Connector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous (IV) Push in Syringe</td>
<td>No</td>
<td>No</td>
<td>Yes (1) Injector per Syringe</td>
<td>Yes (1) Connector ONLY</td>
</tr>
<tr>
<td>Subcutaneous (SubQ) and Intramuscular (IM) Injection in Syringe</td>
<td>No</td>
<td>No</td>
<td>Yes (1) Injector per Syringe</td>
<td>Yes (1) Connector per Syringe</td>
</tr>
<tr>
<td>mABs Subcutaneous (SubQ) Injection in Syringe</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>mABs on Primary Line (with or without filter) Primed with Drug</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>mABs on Secondary Line Primed with Diluent</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>mABs/Drug Conjugates</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Proposed Changes for Non-Hazardous Monoclonal Handling at Moffitt: Based on an Assessment of Risk

Dispensing

- Dispensed in a single bag
- No HD handling auxiliary stickers
- No CSTD

Administration

- Nursing partnership/buy-in needed
- For non-hazardous monoclonals that do not meet the Moffitt definition of a high-risk medication, no high-risk precautions needed e.g., no independent nursing double checks
- No HD PPE needed, administer per standard precautions
Final Thoughts

• Multiple agencies with guidance relating to hazardous drug safety
• Monoclonal antibody safe handling has been a confusing topic and there are various approaches that can be taken
• A thorough review is recommended when institutions are completing their assessment of risk and determining how medications shall be handled
• Measures should be put into place to avoid pharmacy and nursing confusion when implementing changes
Regulatory Compliance in Context of Infusion Rate Changes Post-Adverse Drug Infusion-Related Reactions
Objectives

Monoclonal Antibodies in the USP <800> Setting at Moffitt Cancer Center

• Review changes to the National Institute for Occupational Health and Safety (NIOSH) List of Hazardous Drugs in Healthcare Settings as it applies to monoclonal antibodies
• Review Federal Register, Centers for Disease Control and Prevention (CDC), United States Pharmacopeia (USP) and NIOSH updates/guidance on monoclonal antibodies
• Describe one organization’s approach to safe handling of monoclonal antibodies

Regulatory Compliance in Context of Infusion Rate Changes Post-Adverse Drug Infusion-Related Reactions

• Describe the purpose of The Joint Commission, a regulatory body
• Examine MM.04.01.01 (Medication orders are clear and accurate) in reference to a post-adverse drug infusion-related reaction scenario
• Develop a workflow to support compliance with the updated MM.04.01.01 in reference to medication titration
The Joint Commission – Non-Governmental Regulatory Body

- Country's oldest and largest standards-setting and accrediting body in healthcare
  - Hospital
  - Home care
  - Nursing care center
  - Behavioral health care
  - Ambulatory care
  - Laboratory services

- Improves the quality of patient care by establishing a consistent approach in clinical processes which reduces the risk of error.

- Accreditation serves as a prerequisite to:
  - Qualify for Medicare and Medicaid certification without undergoing a separate quality inspection
  - Eligibility for insurance reimbursement
  - Participation in managed care plans or contract bidding

- Medication-focused standards:
  - Medication Management (MM)
  - National Patient Safety Goal (NPSG)

https://www.jointcommission.org/who-we-are/facts-about-the-joint-commission/
Medication Management (MM) Chapter

• Medication management is an important component in the palliative, symptomatic, and curative treatment of many diseases and conditions

• The Joint Commission’s Medication Management chapter provides a framework for an effective and safe medication management system.
  • Planning
    • Medication Planning (MM.01.01.01, MM.01.01.03)
    • Look-alike/Sound-alike Medications (MM.01.02.01)
  • Selection and Procurement (MM.02.01.01)
  • Storage (MM.03.01.01, MM.03.01.03, MM.03.01.05)
  • Ordering and Transcribing (MM.04.01.01)
  • Preparing and Dispensing (MM.05.01.01, MM.05.01.07, MM.05.01.09, MM.05.01.11, MM.05.01.13, MM.05.01.17, MM.05.01.19)
  • Administration (MM.06.01.01, MM.06.01.03, MM.06.01.05)
  • Monitoring (MM.07.01.03)
  • Evaluation (MM.08.01.01)
  • Antimicrobial Stewardship (MM.09.01.01)
The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical The Joint Commission Perspectives®. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO HOSPITAL ACCREDITATION PROGRAM

Effective January 1, 2021
Chapter: Medication Management

MM.04.01.01: Medication orders are clear and accurate.

Rationale: Not applicable.

Introduction: Introduction to Standard MM.04.01.01

Medication errors may occur when staff are communicating or transcribing medication orders. Verbal and telephone orders are particularly susceptible to error. The hospital is responsible for reducing the potential for medication errors and the misinterpretation of these medication orders. As part of this process, the hospital determines the required elements of a medication order, the type of medication orders that are deemed acceptable for use, and the actions to take when medication orders are incomplete, illegible, or unclear. Clear understanding and communication between staff members who are involved in the medication process are essential.

The hospital follows a written policy that defines the following:
- The minimum required elements of a complete medication order, which must include medication name, medication dose, medication route, and medication frequency
- When indication for use is required on a medication order
- The precautions for ordering medications with look-alike or sound-alike names
- Actions to take when medication orders are incomplete, illegible, or unclear
- For medication titration orders, required elements include the medication name, medication route, initial rate of infusion (dose/unit of time), incremental units to which the rate or dose can be increased or decreased, how often the rate or dose can be changed, the maximum rate or dose of infusion, and the objective clinical measure to be used to guide changes

Note: Examples of objective clinical measures to be used to guide titration changes include blood pressure, Richmond Agitation-Sedation Scale (RASS), and the Confusion Assessment Method (CAM).

EP Attributes

<table>
<thead>
<tr>
<th>New</th>
<th>FSA</th>
<th>CMS</th>
<th>DOC</th>
<th>ESP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>§482.23(c)(3)</td>
<td></td>
<td>D</td>
</tr>
<tr>
<td></td>
<td></td>
<td>§482.23(c)(1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Updated EP effective since January 2021
MM.04.01.01 Element of Performance (EP) 2

• MM.04.01.01: Medication orders are clear and accurate.
  • For medication titration orders, required elements include
    • Medication name
    • Medication route
    • Initial rate of infusion (dose/unit of time)
    • Incremental units to which the rate or dose can be increased or decreased
    • How often the rate or dose can be changed
    • The maximum rate or dose of infusion
    • The objective clinical measure to be used to guide changes
      • Note: Examples of objective clinical measures to be used to guide titration changes include blood pressure, Richmond Agitation–Sedation Scale (RASS), and the Confusion Assessment Method (CAM).

Updated EP effective since January 2021

Primary Settings Where Titration Orders Are Used

Critical Care

Infusion Center
Think About a Scenario Where...

A patient is receiving chemotherapy or biotherapy in an outpatient setting

Patient experiences an adverse drug infusion-related reaction

Nurse taking care of the patient stops the infusion and the care team manages adverse drug infusion-related reaction signs/symptoms

After the resolution of the adverse drug infusion-related reaction, the patient is set to be rechallenged with the same medication

A provider gives an order to a nurse to rechallenge the patient at a lower infusion rate. If tolerated, the rate is increased periodically
How is The One-Time Titration Order Entered into The EHR?

- Provider Note
- Nursing Note based on verbal order from a provider
- Formal Medication Order Entry?
- Not charted at all?
Identified Opportunities - Titration Medication Order Entry

Incomplete Titration Medication Order Entry

- e.g., Generic order entry (Start at half rate. If tolerated for 30 minutes, double the rate)
- e.g., Order entered without all required components

Medication Orders Not Signed by Providers

Clinic Teams Unable to Review Care Provided at the Follow-up Clinic Appointment
Addressing Safety and Regulatory Opportunities

- Creation of an interdisciplinary task force consisting of providers, pharmacists, nurses, regulatory specialists and medication safety officer
- Consultation with the Joint Commission
- Inclusion of Informatics Team
- Updated Workflow Proposed
Proposed Workflow

A patient is receiving chemotherapy or biotherapy in an outpatient setting

Patient experiences an adverse drug infusion-related reaction

Nurse taking care of the patient stops the infusion and the care team manages adverse drug infusion-related reaction signs/symptoms

After the resolution of the adverse drug infusion-related reaction, the patient is set to be rechallenged with the same medication

A provider enters a new complete Titration Medication Order for the nurse to follow. Note: This order doesn’t require pharmacist verification
Screenshot of One-Time Titration Order

Order Details:
- **Order Name**: Not specified
- **Status**: Not specified
- **Start**: 8/22/2023 10:58 EDT
- **Details**: [Infusion Center: 7794740 Admit: 8/10/2023 9:02 EDT]

**Communication Orders**:
- Updated Titration Order
- Post Adverse Reaction
- Order Notes: This order replaces previous infusion instructions. Administer the remaining dose from the current medication bag/syringe utilizing this new revised order. If adverse reaction occurs, contact provider or follow infusion related reaction orders.

**Request Details**:
- **Requested Start Date/Time**: 08/22/2023 10:58 EDT
- **Route**: IV
- **Restart Rate (mL/hr)**: Not specified
- **Increase Rate By (mL/hr)**: Not specified
- **Special Instructions**: See Comments

**Order Comments**:
- [Updated Titration Order Post Adverse Reaction]
Final Thoughts

• Multiple ways to achieve regulatory compliance
• Methods chosen should promote patient safety and cater to the clinical needs of patients
• Methods chosen should not hinder staff operations and allow their work to be done as safely and simply as possible
• Standardization of the process across all areas and professions should be a priority
Thank you!