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

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MOFFITT CANCER CENTER

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)

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

NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161

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)

Drug	AHFS classification	MSHG	Supplemental information	Links
bosutinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed; DrugBank
brentuximab vedotin	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	DailyMed; DrugBank

NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161

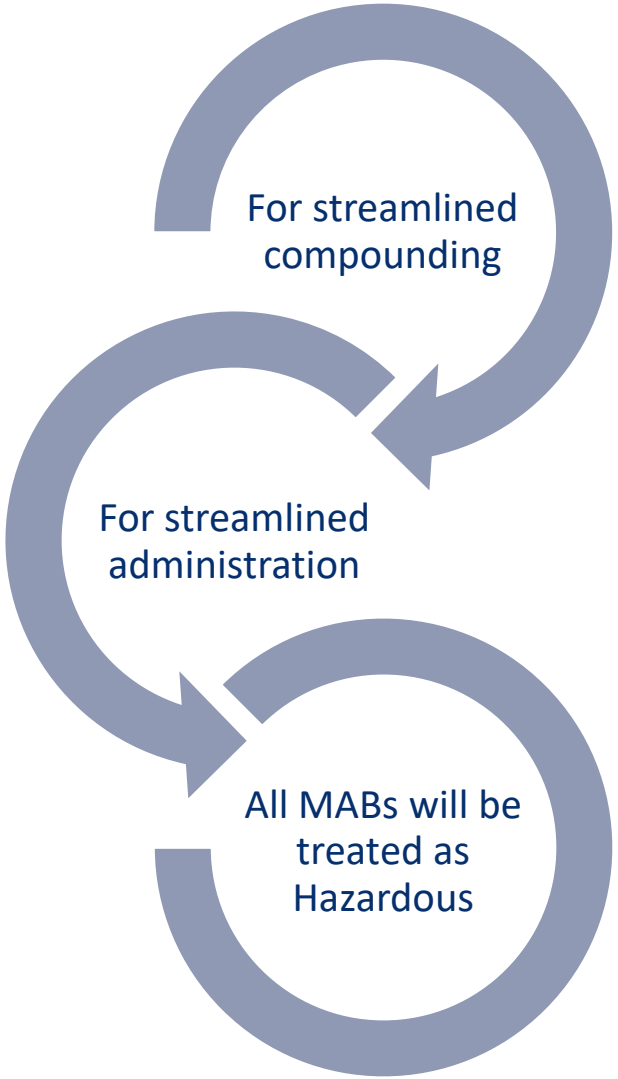
2016 NIOSH List of Hazardous Drugs in Healthcare Settings

gemcitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank
gemtuzumab ozogamicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed; DrugBank

agents			
pertuzumab	10:00 antineoplastic agents	Black Box warning on embryo-fetal death and birth defects; FDA Pregnancy Category D	DailyMed; DrugBank

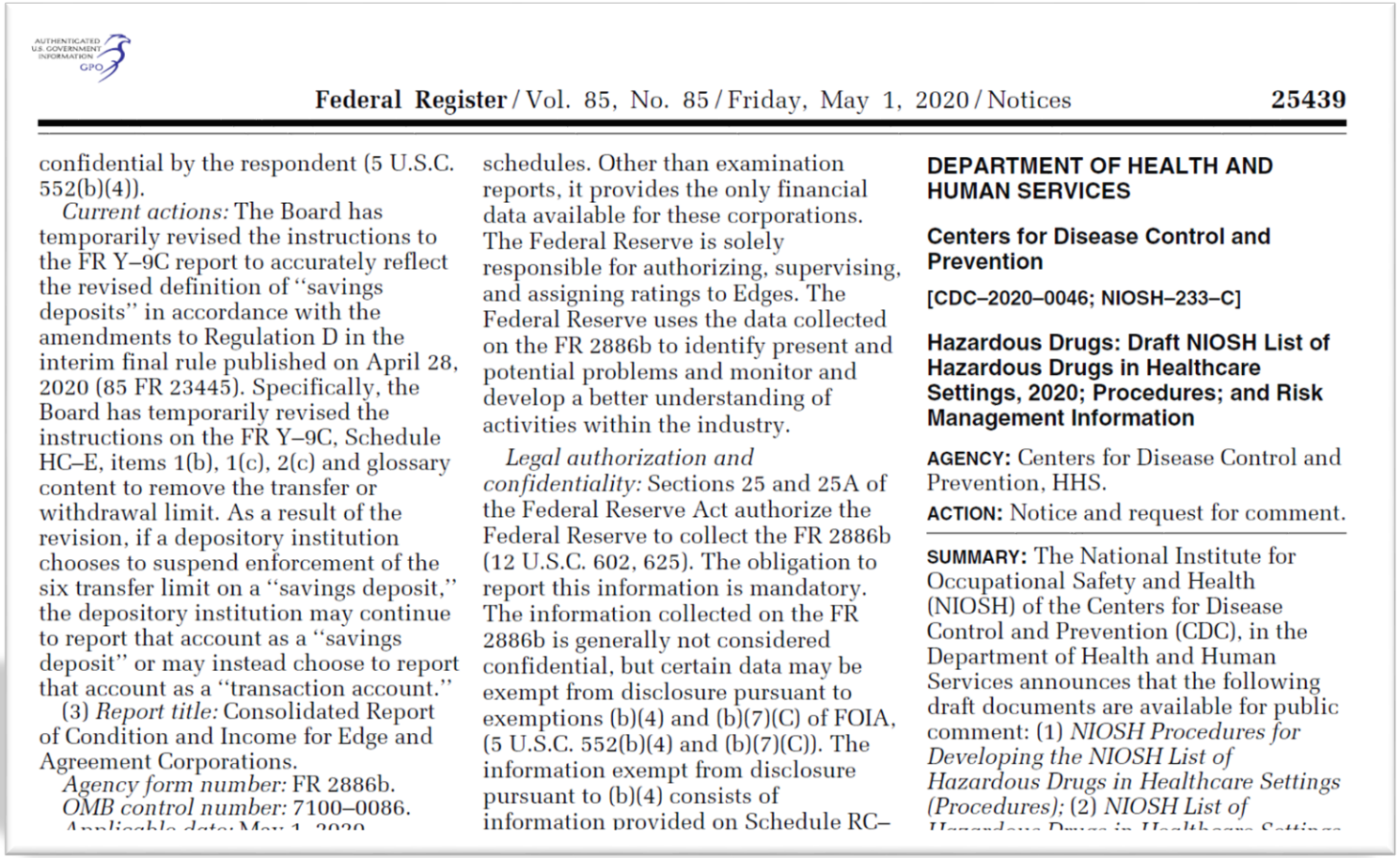
NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161

Moffitt's Response to the 2016 NIOSH Publication



Federal Register

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.



confidential by the respondent (5 U.S.C. 552(b)(4)).

Current actions: The Board has temporarily revised the instructions to the FR Y–9C report to accurately reflect the revised definition of "savings deposits" in accordance with the amendments to Regulation D in the interim final rule published on April 28, 2020 (85 FR 23445). Specifically, the Board has temporarily revised the instructions on the FR Y–9C, Schedule HC–E, items 1(b), 1(c), 2(c) and glossary content to remove the transfer or withdrawal limit. As a result of the revision, if a depository institution chooses to suspend enforcement of the six transfer limit on a "savings deposit," the depository institution may continue to report that account as a "savings deposit" or may instead choose to report that account as a "transaction account."

(3) *Report title:* Consolidated Report of Condition and Income for Edge and Agreement Corporations.

Agency form number: FR 2886b.

OMB control number: 7100–0086.

Applicable date: May 1, 2020

schedules. Other than examination reports, it provides the only financial data available for these corporations. The Federal Reserve is solely responsible for authorizing, supervising, and assigning ratings to Edges. The Federal Reserve uses the data collected on the FR 2886b to identify present and potential problems and monitor and develop a better understanding of activities within the industry.

Legal authorization and confidentiality: Sections 25 and 25A of the Federal Reserve Act authorize the Federal Reserve to collect the FR 2886b (12 U.S.C. 602, 625). The obligation to report this information is mandatory. The information collected on the FR 2886b is generally not considered confidential, but certain data may be exempt from disclosure pursuant to exemptions (b)(4) and (b)(7)(C) of FOIA, (5 U.S.C. 552(b)(4) and (b)(7)(C)). The information exempt from disclosure pursuant to (b)(4) consists of information provided on Schedule RC–

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2020–0046; NIOSH–233–C]

Hazardous Drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020; Procedures; and Risk Management Information

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice and request for comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services announces that the following draft documents are available for public comment: (1) *NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings (Procedures);* (2) *NIOSH List of*

Citation: 85 FR 25439

Federal Register

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.'' Accordingly, the monoclonal antibodies bevacizumab, blintumomab, and trastuzumab should not be placed on the *List,* and pertuzumab should be removed from Table 1.

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.*

Citation: 85 FR 25439

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."

Drug	AHFS classification	MSHI	Supplemental Information[11]
trastuzumab emtansine	10:00 antineoplastic agents	yes	Monoclonal antibody conjugated to mertansine (emtasine)

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)

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

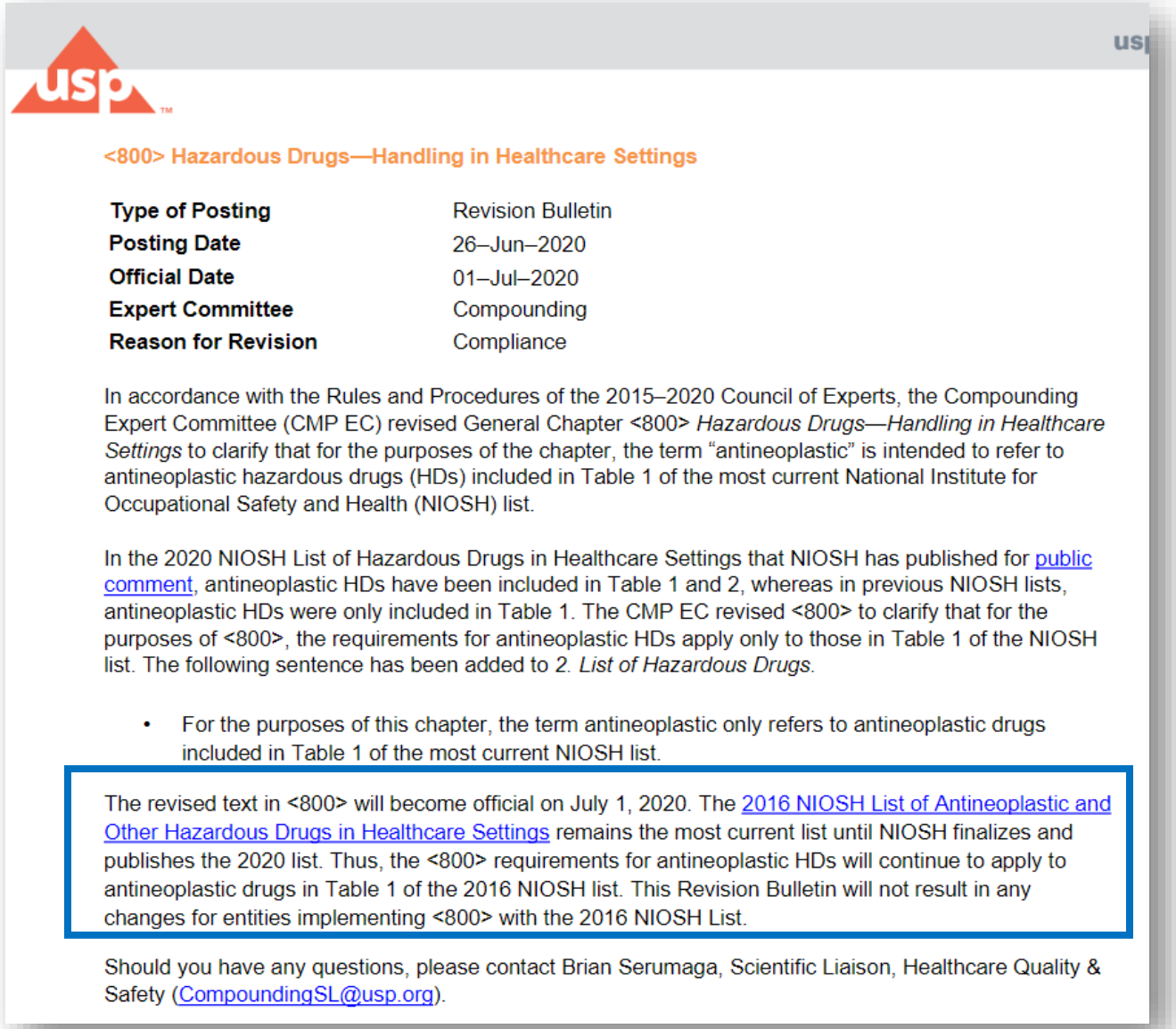
NIOSH [2020]. NIOSH list of hazardous drugs in healthcare settings 2020. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP, Ovesen JL, Whittaker C. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2020 (Supersedes 2016-161)

2020 Draft NIOSH List of Hazardous Drugs in Healthcare Settings

Drugs removed from the *List*	
Drug	**Notation**
Bacillus Calmette Guerin (BCG)	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.
paliperidone	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.
pertuzumab	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.

NIOSH [2020]. NIOSH list of hazardous drugs in healthcare settings 2020. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP, Ovesen JL, Whittaker C. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2020 (Supersedes 2016-161)

USP Posting: Revision Bulletin July 1, 2020



<800> Hazardous Drugs—Handling in Healthcare Settings

Type of Posting	Revision Bulletin
Posting Date	26–Jun–2020
Official Date	01–Jul–2020
Expert Committee	Compounding
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Compounding Expert Committee (CMP EC) revised General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings* to clarify that for the purposes of the chapter, the term "antineoplastic" is intended to refer to antineoplastic hazardous drugs (HDs) included in Table 1 of the most current National Institute for Occupational Safety and Health (NIOSH) list.

In the 2020 NIOSH List of Hazardous Drugs in Healthcare Settings that NIOSH has published for public comment, antineoplastic HDs have been included in Table 1 and 2, whereas in previous NIOSH lists, antineoplastic HDs were only included in Table 1. The CMP EC revised <800> to clarify that for the purposes of <800>, the requirements for antineoplastic HDs apply only to those in Table 1 of the NIOSH list. The following sentence has been added to *2. List of Hazardous Drugs*.

- For the purposes of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH list.

The revised text in <800> will become official on July 1, 2020. The 2016 NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings remains the most current list until NIOSH finalizes and publishes the 2020 list. Thus, the <800> requirements for antineoplastic HDs will continue to apply to antineoplastic drugs in Table 1 of the 2016 NIOSH list. This Revision Bulletin will not result in any changes for entities implementing <800> with the 2016 NIOSH List.

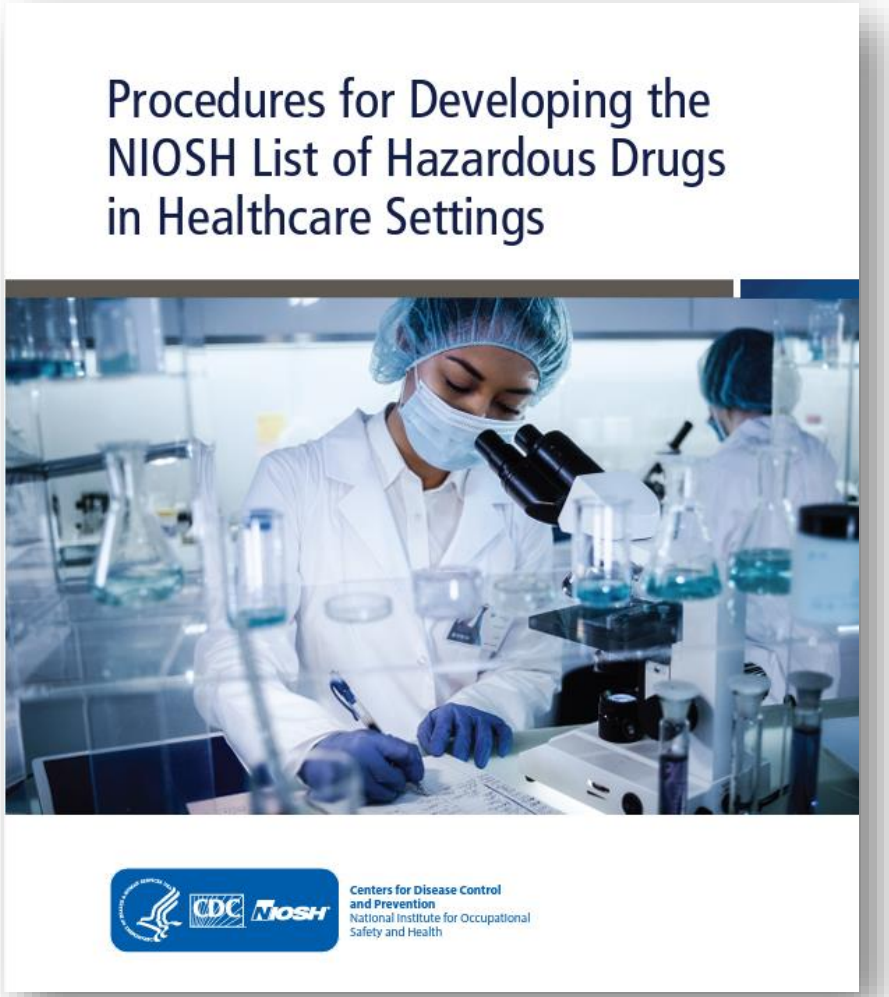
Should you have any questions, please contact Brian Serumaga, Scientific Liaison, Healthcare Quality & Safety (CompoundingSL@usp.org).

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

Revision bulletin can be found at: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-800-rb-notice-20200626.pdf

Recent NIOSH Activity: April 2023



Purpose:

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

NIOSH [2023]. Procedures for developing the NIOSH list of hazardous drugs in healthcare settings. By Whittaker C, Ovesen JL, MacKenzie BA, Hartley T, Berry KA, Piacentino J. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023-129, https://doi.org/10.26616/NIOSHPUB2023129.

Recent NIOSH Activity: April 2023

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

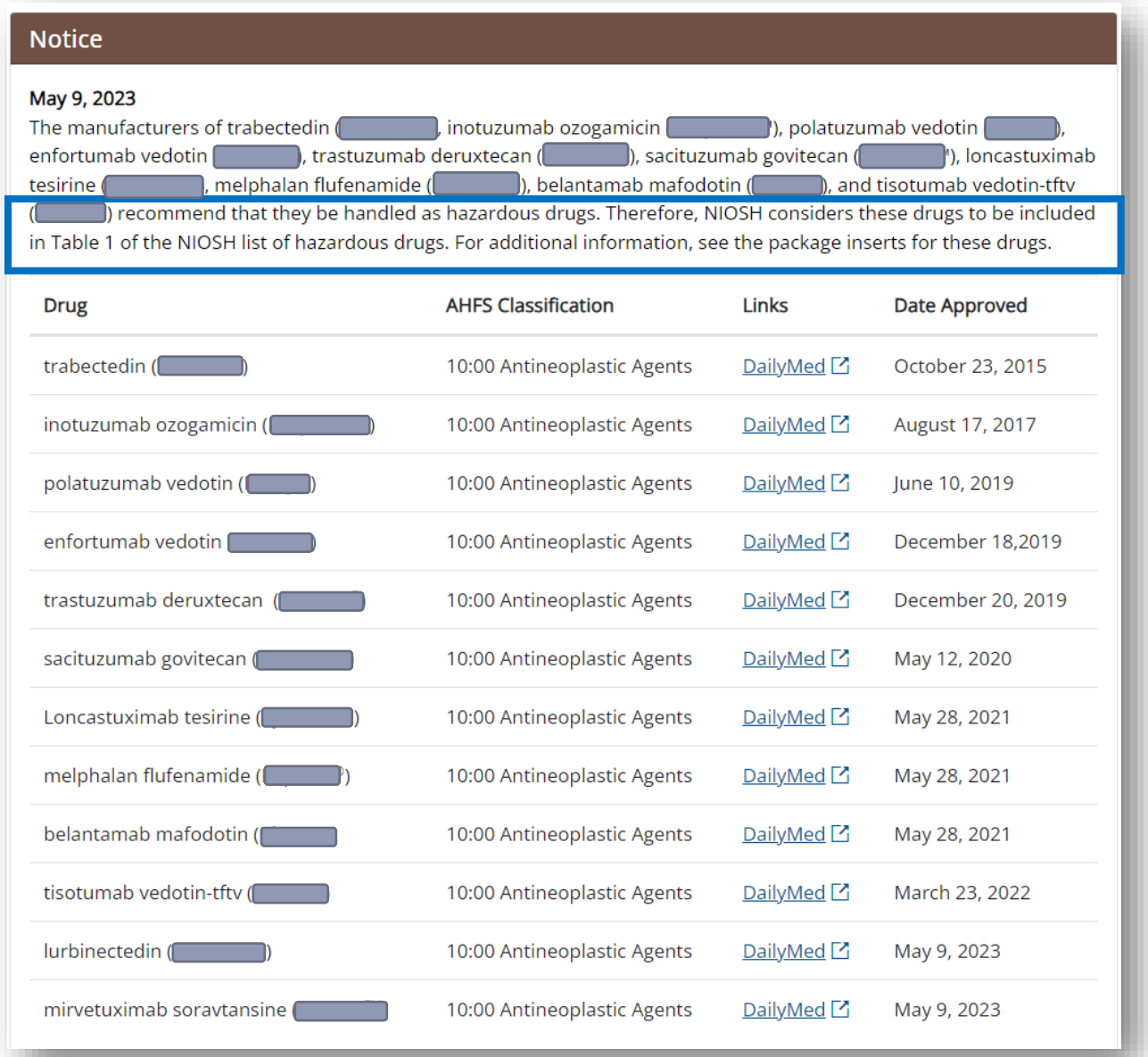
In 2020, NIOSH requested public comments on the updated draft *NIOSH List of Hazardous Drugs in Healthcare Settings, 2020,* the draft *NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings,* and the draft *Managing Hazardous Drugs Exposures: Information for Healthcare 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:

NIOSH Image from website: https://www.cdc.gov/niosh/topics/hazdrug/, last updated April 25, 2023
Meme image: www.knowyourmeme.com

CDC Notice



Notice

May 9, 2023

The manufacturers of trabectedin ([redacted]), inotuzumab ozogamicin ([redacted]), polatuzumab vedotin ([redacted]), enfortumab vedotin ([redacted]), trastuzumab deruxtecan ([redacted]), sacituzumab govitecan ([redacted]), loncastuximab tesirine ([redacted]), melphalan flufenamide ([redacted]), belantamab mafodotin ([redacted]), and tisotumab vedotin-tftv ([redacted]) 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.

Drug	AHFS Classification	Links	Date Approved
trabectedin ([redacted])	10:00 Antineoplastic Agents	DailyMed	October 23, 2015
inotuzumab ozogamicin ([redacted])	10:00 Antineoplastic Agents	DailyMed	August 17, 2017
polatuzumab vedotin ([redacted])	10:00 Antineoplastic Agents	DailyMed	June 10, 2019
enfortumab vedotin [redacted]	10:00 Antineoplastic Agents	DailyMed	December 18,2019
trastuzumab deruxtecan ([redacted])	10:00 Antineoplastic Agents	DailyMed	December 20, 2019
sacituzumab govitecan ([redacted])	10:00 Antineoplastic Agents	DailyMed	May 12, 2020
Loncastuximab tesirine ([redacted])	10:00 Antineoplastic Agents	DailyMed	May 28, 2021
melphalan flufenamide ([redacted])	10:00 Antineoplastic Agents	DailyMed	May 28, 2021
belantamab mafodotin ([redacted])	10:00 Antineoplastic Agents	DailyMed	May 28, 2021
tisotumab vedotin-tftv ([redacted])	10:00 Antineoplastic Agents	DailyMed	March 23, 2022
lurbinectedin ([redacted])	10:00 Antineoplastic Agents	DailyMed	May 9, 2023
mirvetuximab soravtansine [redacted]	10:00 Antineoplastic Agents	DailyMed	May 9, 2023

Citation: image from website: https://www.cdc.gov/niosh/docs/2016-161/default.html; last updated April 27, 2023

These will continue to be treated as hazardous:

Monoclonals

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

Antineoplastic Antibody/Drug Conjugates

- trabectedin ([redacted])
- inotuzumab ozogamicin ([redacted])
- polatuzumab vedotin ([redacted])
- enfortumab vedotin ([redacted])
- trastuzumab deruxtecan ([redacted])
- sacituzumab govitecan ([redacted])
- Loncastuximab tesirine ([redacted])
- melphalan flufenamide ([redacted])
- belantamab mafodotin ([redacted])
- tisotumab vedotin-tftv ([redacted])
- lurbinectedin ([redacted])
- mirvetuximab soravtansine ([redacted])

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)

Treatment Type	Red Cap	Texium Injector	PhaSeal Injector	PhaSeal Connector
Intravenous (IV) Push in Syringe	No	No	Yes (1) Injector per Syringe	Yes (1) Connector ONLY
Subcutaneous (SubQ) and Intramuscular (IM) Injection in Syringe	No	No	Yes (1) Injector per Syringe	**Yes** **(1) Connector per Syringe**
mABs Suncutaneous (SubQ) Injection in Syringe	**Yes**	No	No	No
mABs on Primary Line (with or without filter) Primed with Drug	**Yes**	No	No	No
mABs on Secondary Line Primed with Diluent	**Yes**	No	No	No
mABs/Drug Conjugates Ipnastuximab tesirine-lpyl, Mevetumomab pasudotox-tdfk	No	No	Yes	Yes

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/
https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-benefits-of-joint-commission-accreditation/

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 E-dition. Medication Management Chapters. 2023.

The Joint Commission

Prepublication Requirements

• Issued May 20, 2020 •

Joint Commission Requirement

MM.04.01.01, EP 2 Revisions

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

MM.04.01.01 Element of Performance (EP) 2

Chapter: Medication Management

Updated EP effective since January 2021

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.

2 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

New	FSA	CMS	DOC	ESP
		§482.23(c)(3) §482.23(c)(1)	D	ESP-1

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

The Joint Commission E-dition. Medication Management Chapters. 2023.
https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/medication-management-mm/000002114/

Primary Settings Where Titration Orders Are Used

Critical Care

Infusion Center

https://www.google.com/url?sa=i&url=https%3A%2F%2Fbaycare.org%2Fhospitals%2Fst-josephs-hospital%2Fservices%2Fcancer%2Fadult-infusion-center&psig=AOvVaw2tZWTTOd4rUKx5B0yNajIy&ust=1695998419530000&source=images&cd=vfe&opi=89978449&ved=0CBAQjRxqFwoTCIi187bFzYEDFQAAAAAdAAAAABAE
https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.bmj.com%2Fcareers%2Farticle%2Fthe-complete-guide-to-becoming-an-intensive-care-medicine-doctor&psig=AOvVaw0u8jAgPnGqwXhEpdAz3qWh&ust=1695997953292000&source=images&cd=vfe&opi=89978449&ved=0CBAQjRxqFwoTCLDWzNXFzYEDFQAAAAAdAAAAABAE

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

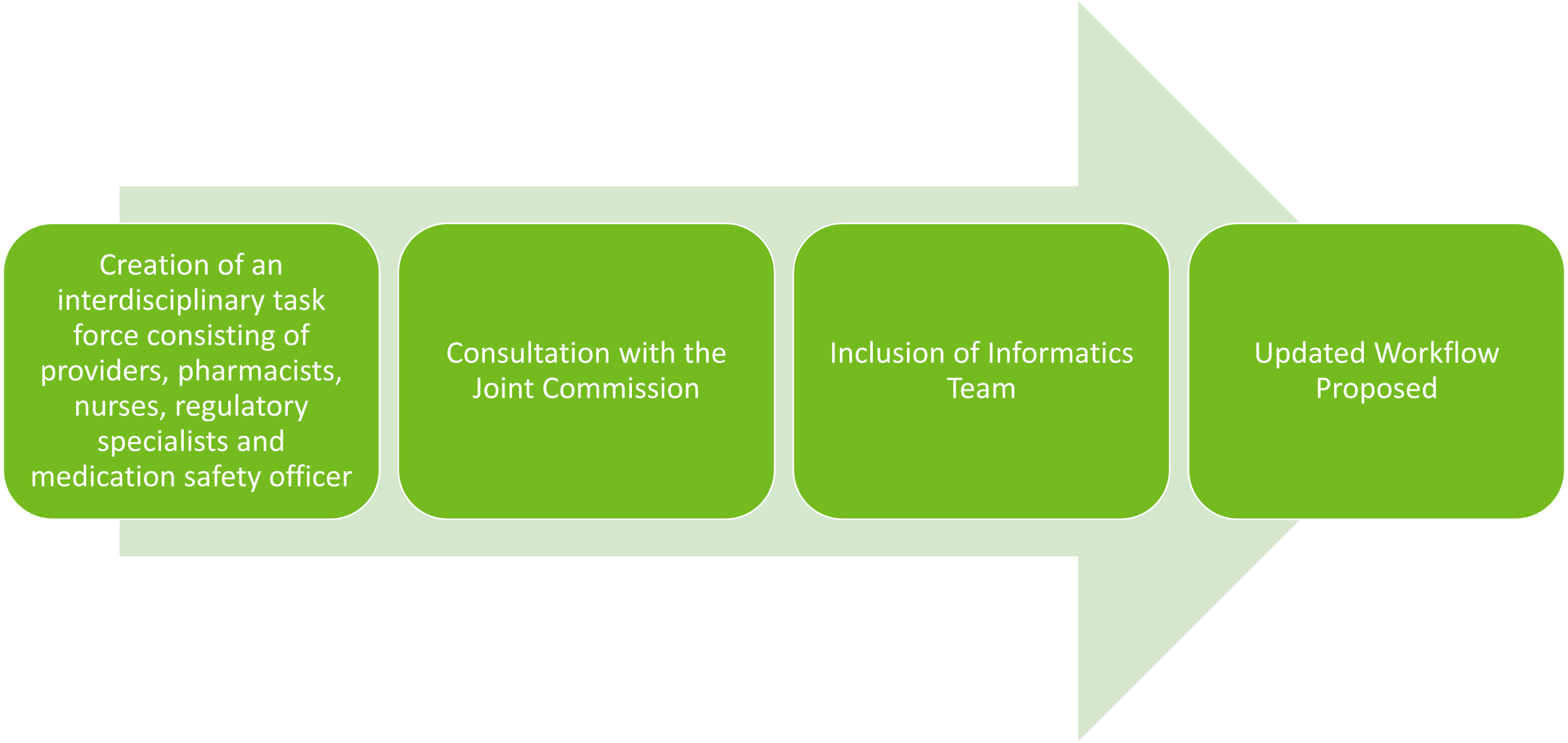
Incomplete Titration Medication Order Entry

- 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



Proposed Workflow

A patient is receiving chemotherapy or biotherapy in an outpatient setting

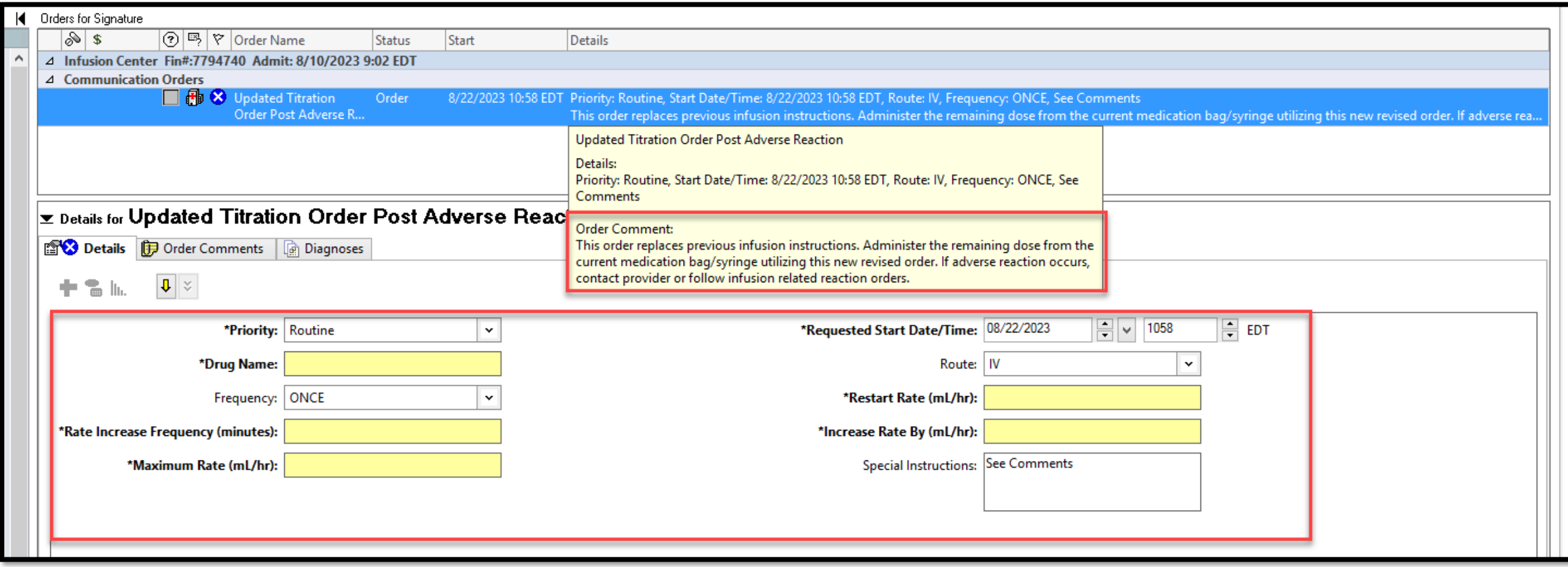
Patient experiences an adverse drug infusion-related reaction

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



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!