Pharmacy Access Office Hours

November 21, 2019

Focus Topic:
Compliance with USP 800 Rules

This session is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $6,375,000. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.
Webinar Logistics

We strongly recommend calling in **on your telephone**

**Phone**: 866-469-3239

**Access Code**: 632 274 023 #

**Your Attendee ID**: Listed below the access code in the box under “Select Audio Connection”.

To ask/answer a question, or share a comment, please use the Chat box on the right hand side of the screen.

You can download **these slides** on Noddlepod, & from NACHC’s 340B/ Rx webpage:


Or go to NACHC.org and search 340B.
Operational Updates

Focus Topic – USP 800 Compliance

Q&A – Federal/ State split of Medicaid savings

And Comment Box discussions throughout...
OPERATIONAL UPDATES

Colleen Meiman
Senior Policy Advisor
National Association of Community Health Centers
cmeiman@nachc.org
Environmental Scan

• Capitol Hill
  • Many proposals on drug pricing, but also many roadblocks
  • Only one proposal addressed 340B, and that provision was removed.

• HHS
  • Many proposals on drug pricing, but also many roadblocks.
  • No proposals specific to 340B.

• HRSA Office of Pharmacy Affairs
  • Delays in issuing initial audit findings
  • Temporary hold on conducting audits appears to be over.
HRSA OPA – Other Notes

• **Common area of audit findings:** Clinic-Administered Drugs (CADs)
  - April 2019 Office Hours discussed general compliance for CADs
  - Sept. 2019 Office Hours discussed the value of, and strategies for, managing compliance for CADs
    
    *Recordings and slides for both are available on NACHC 340B website.*

• **Registering new sites:** Tomorrow – Fri 11/22 – is the deadline for registering new health center sites to become eligible to participate in 340B starting Jan 1, 2020.
  - Any requests submitted after Friday will not be eligible until April 1, 2020.
  - The site must be active in EHB in order to register for 340B.
Discriminatory Contracting

• To date, six states have passed laws restricting discriminatory contracting under 340B.

• Currently exploring whether these laws apply to Medicare Part D and Medicare Advantage plans.

• Hearing reports nationally that a national chain pharmacy is increasing its dispensing fee based on length of fill (30/ 60/ 90 days.)*

* Remember that your contract terms likely prohibit you from discussing contract/ any reimbursement details outside of your organization.
Future Learning Opportunities

• **December 19 Office Hours** – A Model for Implementing SFS at a Contract Pharmacy

• **January 16 Office Hours** – Preparing for an Avoiding PBM Audits (tentative)

• **February 10-12:** 340B Coalition Conference in San Diego – will feature **four** sessions specifically for FQHCs.
  - Sue Veer at 340B Rx@carolinahealthcenters.org is coordinating sessions.
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/YJHSBXY

(Your responses help us demonstrate to BPHC that these sessions are a valuable use of their funding.)
The New “USP 800” Requirements

Dwight DeVera, RxTransparent
USP General Chapter <800>
Hazardous Drugs –
Handling in Healthcare Settings
What is <USP 800>

Rules designed to protect healthcare workers against the long term repercussions of exposure to hazardous drugs

Hazardous Drug Types
- Antineoplastic
- Non-antineoplastic
- Reproductive risk only

Timeline
- Final version published Feb 2016
- Original enforcement date July 2018
- New Enforcement date Dec 2019

Risks
- Carcinogenicity (causing cancer in otherwise healthy cells)
- Cytotoxicity (toxic to cells)
- Fertility impairment or reproductive toxicity
- Genotoxicity (causing mutations)
- Organ toxicity
- Teratogenicity (causing mutations in embryos or fetuses)
<800> Ops Objectives
Antineoplastic HDs and all HD APIs must be unpacked in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.
Receiving

Storing

Manipulating

Administration

Disposal

HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. The manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.

• Compounding Antineoplastic HDs must be stored separately from non-HDs
• Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator
• HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding
Engineering controls are required to protect the preparation from cross-contamination and microbial contamination

- A containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs.
- The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed.
- Supplement Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC.
HDs must be administered safely using protective medical devices and techniques.

- Appropriate PPE must be worn when administering HDs
- After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration
- CSTDs must be used for administration of antineoplastic HDs when the dosage form allows
- Techniques and ancillary devices that minimize the risk posed by open systems must be used when administering HDs through certain routes
All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned.

- The entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection
- All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination
- The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials
Personal Protective Equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues

- Disposable PPE must not be re-used
- Reusable PPE must be decontaminated and cleaned after use
Products Policies & Procedures

<800> Goals
• Patient Safety
• Worker Provider Safety
• Environmental Impact

<800> Considerations
• Where will activity be performed?
• Who is permitted to perform activity?
  (Training & Complexity)
• PPE By Activity
• Hygiene
<USP800> Organizational

Identify and designate a qualified and trained person to oversee HD handling:

- Compliance with <800> and other applicable laws
- Ensuring competency of personnel
- Ensuring environmental control of compounding areas
- Communicating rational for risk-prevention policies
- Communicating risks that may compromise safety
- Reporting potentially hazardous situations
- Oversight of facility monitoring
- Preparation of reports of testing and sampling
- Acting on reports
Continuous Assessment of Risk

Antineoplastic agents requiring sterile compounding
Non Antineoplastic agents requiring sterile compounding
Final dosage forms with possible administration risks
Final dosage forms oral tablets and capsules

Drug
Form
Packaging
Manipulation
Documentation
Annual Review
<USP 800>

Receive | Unpack | Store

PPE Consideration

Operations

Incident

Engineering Controls

Operations

Receiving

Standard Gloves

Unpacking

Chemo Gloves

Respiratory

Neutral Negative Pressure Non Compounding Environment

Eye/Face

Compounded Antineoplastic Stored Separately

Refrigerated HDs Require Separate Refrigerator

Non Sterile Compounding HDs Stored Separately

Storing
Administer Part 2
Disposal & Cleaning

<USP 800>

- **Disposal & Cleaning**
  - Metabolites in Body Fluids
    - Chemo Gloves
    - Gowns
    - Eye / Face if Possibility of Splash
    - Respiratory if Inhalation Potential
  - Drug Contaminated Waste
    - Chemo Gloves
    - Gowns
    - Eye / Face if Possibility of Splash
    - Respiratory if Inhalation Potential
  - Spills
    - Chemo Gloves
    - Gowns
    - Eye / Face
    - Respiratory
In Practice

52 Products

- Warfarin
- Paroxetine
- Fluconazole
- Dutasteride
- Spironolactone
- Depakote
- Methotrexate
- Dronedarone

Methotrexate

Dutasteride

Paroxetine

Fluconazole

Spironolactone

Depakote

Methotrexate

Dronedarone

Warfarin
<table>
<thead>
<tr>
<th>Non Antineoplastic – 4,110</th>
<th>Antineoplastic – 2,046</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.00 antineoplastic agents</td>
<td>80:12 vaccines</td>
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<td>68:16:04 estrogens</td>
<td>2042</td>
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<td>28:12:92 anticonvulsants- sants, miscellaneous</td>
<td></td>
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<tr>
<td>24:32:20 mineralo- corticoid receptor antagonists</td>
<td></td>
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<tr>
<td>92:44 immunosup- pressive agents</td>
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</tr>
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<td>28:12:12 hydantoins</td>
<td></td>
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<tr>
<td>68:32 progestins</td>
<td></td>
</tr>
<tr>
<td>8:18:08 antiretroviral agents</td>
<td></td>
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<td>28:16:08:04 atypical anti-psychotics</td>
<td></td>
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<tr>
<td>68:16:12 estrogen agonists-antagonists</td>
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<td>28:16:08:04 atypical antipsychotics</td>
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<td>68:36:08 antithyroid agents</td>
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<td>28:18:08.20 nucleoside and reverse transcrip- tase inhibitors</td>
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<td>8:18:08.16 nonnucleo- side reverse transcrip- tase inhibitors</td>
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<td>92:36 disease-modi- fying antirheumatic agents</td>
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<tr>
<td>92:44 immunosup- pressants</td>
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<td>8:18:32 nucleosides and nucleotides</td>
<td></td>
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<td>8:12:08 chloram- phenicols</td>
<td></td>
</tr>
<tr>
<td>92:20 biologic re- sponse modulators</td>
<td></td>
</tr>
<tr>
<td>28:36 antiparkinsonian agents</td>
<td></td>
</tr>
<tr>
<td>92:36 disease modi- fying antirheumatic drugs</td>
<td></td>
</tr>
<tr>
<td>92:56 protective agents</td>
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<td>68:20.06 incretin mimetics</td>
<td></td>
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<td>28:36.08 non-ergot- derivative dopamine receptor agonists</td>
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<tr>
<td>68:36:08 antithyroid agents</td>
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<td>68:08 androgens</td>
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<tr>
<td>12:16:04:04 non-select- tive alpha-andrenergic blocking agents</td>
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<tr>
<td>92:20 immunomodula- tory agents</td>
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<tr>
<td>84:16 cell stimulants and proliferants</td>
<td></td>
</tr>
<tr>
<td>92:20 biologic response modifiers</td>
<td></td>
</tr>
<tr>
<td>24:06.92 antilipemic agents, miscellaneous</td>
<td></td>
</tr>
<tr>
<td>64:00 heavy metal antagonists</td>
<td></td>
</tr>
</tbody>
</table>

115 Products

| 28:12.92 anticonvulsive- sants, miscellaneous | 917 |
| 20:12.04.08 coumarin derivatives | 764 |
| 28:12.08 benzodiaz- epines | 627 |
| 28:16:04:20 selective serotonin uptake inhibitors | 582 |
| 8:14:08 azoles | 563 |
| 28:24.08 benzodiaz- epines | 382 |
| 28:16:08:04 atypical antipsychotics | 281 |
| 68:08 androgens | 224 |
| 84:16 cell stimulants and proliferants | 175 |
| 92:08 5-alpha reductase inhibitors | 160 |
| 28:12.92 anticonvulsants, miscellaneous | 158 |
| 56:28.28 prostaglandins | 146 |
| 8:18:32 nucleosides and nucleotides | 120 |
| 76:00 oxytocics | 83 |
| 92:08 5-alpha reductase inhibitors | 70 |
| 92:16 anti-gout agents | 62 |
| 92:24 bone resorption inhibitors | 62 |
| 28:12.92 anticonvulsive- sants, miscellaneous | 27 |
| 88:04 vitamin A | 23 |
| 68:29:04 somostatin agonists | 19 |
| 48:48 vasodilating agents | 17 |
| 24:12.92 vasodilating agents, miscellaneous | 16 |
| 68:16:12 estrogen agonist-antagonists | 16 |
| 68:18 gonadotropins | 7 |
| 28:36.20:04 ergot- derivative dopamine receptor agonists | 7 |
| 24:06.92 antilipemic agents, miscellaneous | 6 |
| 24:04.04 antiarrhythmics | 6 |
| 8:12:28 glycopeptidest | 4 |
| 92:32 complement inhibitors | 3 |
| 92:40 gonadotropin- releasing hormone antagonists | 3 |
| 68:12 contraceptives | 3 |
| 76:00 oxytocics | 2 |
| 84:92 skin and mucous membrane agents, miscellaneous | 2 |
| 20:16 hematopoietic agents | 1 |

49 Products

| 10:00 Antineoplastic agents | 2042 |
| 80:12 vaccines | 4 |
| 68:16:04 estrogens | 1332 |
| 28:12:92 anticonvulsive- sants, miscellaneous | 865 |
| 24:32:20 mineralo- corticoid receptor antagonists | 378 |
| 92:44 immunosup- pressive agents | 369 |
| 28:12:12 hydantoins | 182 |
| 68:32 progestins | 162 |
| 8:18:08 antiretroviral agents | 113 |
| 28:16:08:04 atypical anti-psychotics | 113 |
| 68:16:12 estrogen agonists-antagonists | 67 |
| 28:16:08:04 atypical antipsychotics | 65 |
| 68:36:08 antithyroid agents | 60 |
| 8:18:08.20 nucleoside and reverse transcrip- tase inhibitors | 52 |
| 8:18:08.16 nonnucleo- side reverse transcrip- tase inhibitors | 49 |
| 92:36 nucleosides and nucleotides | 45 |
| 92:36 disease-modi- fying antirheumatic agents | 44 |
| 92:44 immunosup- pressants | 43 |
| 8:18:32 nucleosides and nucleotides | 23 |
| 8:12:08 chloram- phenicols | 22 |
| 92:20 biologic re- sponse modulators | 22 |
| 28:36 antiparkinsonian agents | 16 |
| 92:36 disease modi- fying antirheumatic drugs | 15 |
| 92:56 protective agents | 15 |
| 68:20.06 incretin mimetics | 12 |
| 28:36.08 non-ergot- derivative dopamine receptor agonists | 10 |
| 68:36:08 antithyroid agents | 10 |
| 68:08 androgens | 5 |
| 5 | |
| 12:16:04:04 non-select- tive alpha-andrenergic blocking agents | 5 |
| 92:20 immunomodula- tory agents | 4 |
| 84:16 cell stimulants and proliferants | 4 |
| 92:20 biologic response modifiers | 4 |
| 24:06.92 antilipemic agents, miscellaneous | 2 |
| 64:00 heavy metal antagonists | 2 |

52 Products

| 49 Products |
| 52 Products |
| Reproductive Risk – 5,538 |
| Non Antineoplastic – 4,110 |
The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs, which must include any item on the current NIOSH list that the entity handles. The entity’s list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity’s list.

The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. If the information indicates that the drug is hazardous until more information is available.

### TABLE OF CONTENTS

**ASSESSMENT OF RISK TABLE 1**

**ASSESSMENT OF RISK TABLE 2**

**HD BY FACILITY DEMO HOSPITAL**

**HD BY FACILITY DEMO HOSPITAL**

---

### Annual Process

- Manual
- Prone to Error
- Non-repeatable

---

**Automated with RXTransparent**
The RXTransparent platform has identified that there is new or updated information Hazardous Drug Transactions that affect your facilities. Please Login to the RXTransparent Analytics Platform for more information.

The following is a breakdown of the products affecting your organization and your last transaction volume by package size:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product</th>
<th>NDC</th>
<th>Strength</th>
<th>Package</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mylan Institutional LLC</td>
<td>METHOTREXATE SODIUM</td>
<td>67457-467-21</td>
<td>25mg/1mL</td>
<td>Methotrexate Sodium 25mg/1mL Solution for injection</td>
<td>10</td>
</tr>
</tbody>
</table>

Login to the RXTransparent Analytics platform or mobile app for more information about this drug shortage.

RXTransparent<USP>800
Phone: (646)783-3172
www.rxtransparent.com/
USP <800> In Practice
# Acknowledge Notifications

## USP<sup>®</sup>800+ Facility Hazardous Drugs

<table>
<thead>
<tr>
<th>Facility</th>
<th>Labeler</th>
<th>NDC</th>
<th>Product</th>
<th>Form</th>
<th>Strength</th>
<th>Package</th>
<th>AHFS Class</th>
<th>AoR Link</th>
<th>Acknowledged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highlands</td>
<td>Allergan, Inc.</td>
<td>0023-9163-30</td>
<td>cyclosporine</td>
<td>EMULSION</td>
<td>.5mg/mL</td>
<td>10 VIAL, SINGLE-USE in 1 TRAY (0023-9163-30) &gt; .4 mL in 1 VIAL, SINGLE-USE</td>
<td>92.44 Immunosuppressive agents</td>
<td>24:04:04</td>
<td></td>
</tr>
<tr>
<td>Highlands</td>
<td>sanofi-aventis U.S. LLC</td>
<td>0024-4142-10</td>
<td>dronedarone</td>
<td>TABLET, FILM COATED</td>
<td>400mg/1</td>
<td>10 BUSTER PACK in 1 BOX (0024-4142-10) &gt; 10 TABLET, FILM COATED in 1 BUSTER PACK</td>
<td>24:04:04 antiarrhythmics</td>
<td>68:16:04</td>
<td></td>
</tr>
<tr>
<td>Highlands</td>
<td>Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.</td>
<td>0046-0872-21</td>
<td>estrogens, esterified</td>
<td>CREAM</td>
<td>.625mg/1</td>
<td>1 TUBE, WITH APPLICATOR in 1 CARTON (0046-0872-21) &gt; 30 g in 1 TUBE, WITH APPLICATOR</td>
<td>68.16.04 estrogens</td>
<td>28:16:08:04 atypical antipsychotics</td>
<td></td>
</tr>
<tr>
<td>Highlands</td>
<td>Roerg</td>
<td>0049-3920-83</td>
<td>ziprasidone</td>
<td>INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION</td>
<td>20mg/mL</td>
<td>10 VIAL, SINGLE-DOSE in 1 CARTON (0049-3920-83) &gt; 1 mL in 1 VIAL, SINGLE-DOSE (0049-3920-80)</td>
<td>28:16:08:04 atypical antipsychotics</td>
<td>28:16:08:04 atypical antipsychotics</td>
<td></td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0168-75</td>
<td>warfarin</td>
<td>TABLET</td>
<td>4mg/1</td>
<td>10 BUSTER PACK in 1 CARTON (0056-0168-75) &gt; 10 TABLET in 1 BUSTER PACK (0056-0168-01)</td>
<td>20:12:04:8 coumarin derivatives</td>
<td>20:12:04:8 coumarin derivatives</td>
<td></td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0169-75</td>
<td>warfarin</td>
<td>TABLET</td>
<td>1mg/1</td>
<td>10 BUSTER PACK in 1 CARTON (0056-0169-75) &gt; 10 TABLET in 1 BUSTER PACK (0056-0169-01)</td>
<td>20:12:04:8 coumarin derivatives</td>
<td>20:12:04:8 coumarin derivatives</td>
<td></td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0170-75</td>
<td>warfarin</td>
<td>TABLET</td>
<td>2mg/1</td>
<td>10 BUSTER PACK in 1 CARTON (0056-0170-75) &gt; 10 TABLET in 1 BUSTER PACK (0056-0170-01)</td>
<td>20:12:04:8 coumarin derivatives</td>
<td>20:12:04:8 coumarin derivatives</td>
<td></td>
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<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0172-75</td>
<td>warfarin</td>
<td>TABLET</td>
<td>5mg/1</td>
<td>10 BUSTER PACK in 1 CARTON (0056-0172-75) &gt; 10 TABLET in 1 BUSTER PACK (0056-0172-01)</td>
<td>20:12:04:8 coumarin derivatives</td>
<td>20:12:04:8 coumarin derivatives</td>
<td></td>
</tr>
</tbody>
</table>
### Group 1: Antineoplastic drugs (AHFS Classification 10:00) [ASHP/AHFS DI 2016].

Note that many of these drugs may also pose a reproductive risk for susceptible populations (Table 1).

<table>
<thead>
<tr>
<th>AFHS Class</th>
<th>Drug</th>
<th>NDC</th>
<th>Strength</th>
<th>Package</th>
<th>Form</th>
<th>Risk of Exposure</th>
<th>SuppInfo</th>
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</thead>
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<tr>
<td>10:00</td>
<td>tamoxifen</td>
<td>0591-2472-60</td>
<td>10mg/1</td>
<td>60 TABLET in 1 BOTTLE, PLASTIC (0591-2472-60)</td>
<td>TABLET</td>
<td>Low High if manipulated</td>
<td>IARC Group 1 carcinogens; NTP*; FDA Pregnancy Category D</td>
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<td>10:00</td>
<td>anastrozole</td>
<td>16729-035-10</td>
<td>1mg/1</td>
<td>30 TABLET in 1 BOTTLE, PLASTIC (16729-035-10)</td>
<td>TABLET</td>
<td>Low High if manipulated</td>
<td>FDA Pregnancy Category X</td>
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<tr>
<td>10:00</td>
<td>hydroxyurea</td>
<td>49884-724-01</td>
<td>500mg/1</td>
<td>100 CAPSULE in 1 BOTTLE (49884-724-01)</td>
<td>CAPSULE</td>
<td>Low High if manipulated</td>
<td>Special warning on handling bottles and capsules; FDA Pregnancy Category D</td>
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<tr>
<td>10:00</td>
<td>anastrozole</td>
<td>51991-620-33</td>
<td>1mg/1</td>
<td>30 TABLET in 1 BOTTLE (51991-620-33)</td>
<td>TABLET</td>
<td>Low High if manipulated</td>
<td>FDA Pregnancy Category X</td>
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<tr>
<td>10:00</td>
<td>Megestrol Acetate</td>
<td>60432-126-08</td>
<td>40mg/ML</td>
<td>240 mL in 1 BOTTLE, PLASTIC (60432-126-08)</td>
<td>SUSPENSION</td>
<td>HIGH</td>
<td>Nursing should be discontinued if megestrol is required; women at risk of pregnancy should avoid exposure; FDA Pregnancy Category X</td>
</tr>
</tbody>
</table>
Questions for our speaker?

And please do the one-minute evaluation:

https://www.surveymonkey.com/r/YJHSBXY
USP General Chapter <800>
Hazardous Drugs – Handling in Healthcare Settings

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS®
What is <USP 800>

Rules designed to protect healthcare workers against the long term repercussions of exposure to hazardous drugs

Hazardous Drug Types
- Antineoplastic
- Non-antineoplastic
- Reproductive risk only

Timeline
- Final version published Feb 2016
- Original enforcement date July 2018
- New Enforcement date Dec 2019

Risks
- Carcinogenicity (causing cancer in otherwise healthy cells)
- Cytotoxicity (toxic to cells)
- Fertility impairment or reproductive toxicity
- Genotoxicity (causing mutations)
- Organ toxicity
- Teratogenicity (causing mutations in embryos or fetuses)
<800> Ops Objectives

- Less time spent near source, less radiation received.
- Greater distance from source, less radiation received.
- Behind shielding from source, less radiation received.

A.L.A.R.A. AS LOW AS REASONABLY ACHIEVABLE

Hierarchy of Controls

- Elimination: Physically remove the hazard
- Substitution: Replace the hazard
- Engineering Controls: Isolate people from the hazard
- Administrative Controls: Change the way people work
- PPE: Protect the worker with Personal Protective Equipment
Antineoplastic HDs and all HD APIs must be unpacked in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.
HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. The manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.

- Compounding Antineoplastic HDs must be stored separately from non-HDs
- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator
- HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding
Engineering controls are required to protect the preparation from cross-contamination and microbial contamination

- A containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs
- The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed
- Supplement Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC
HDs must be administered safely using protective medical devices and techniques.

- Appropriate PPE must be worn when administering HDs.
- After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated HD waste at the site of drug administration.
- CSTDs must be used for administration of antineoplastic HDs when the dosage form allows.
- Techniques and ancillary devices that minimize the risk posed by open systems must be used when administering HDs through certain routes.
All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned.

- Entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection.
- All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination.
- The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials.
Personal Protective Equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues:
- Disposable PPE must not be re-used
- Reusable PPE must be decontaminated and cleaned after use
Products Policies & Procedures

Goals
- Patient Safety
- Worker Provider Safety
- Environmental Impact

Considerations
- Where will activity be performed?
- Who is permitted to perform activity? (Training & Complexity)
- PPE By Activity
- Hygiene
<USP800> Organizational

Identify and designate a qualified and trained person to oversee HD handling.

- Compliance with <800> and other applicable laws
- Ensuring competency of personnel
- Ensuring environmental control of compounding areas
- Communicating rational for risk-prevention policies
- Communicating risks that may compromise safety
- Reporting potentially hazardous situations
- Oversight of facility monitoring
- Preparation of reports of testing and sampling
- Acting on reports
Continuous Assessment of Risk

- **Level 1**: Antineoplastic agents requiring sterile compounding
- **Level 2**: Non Antineoplastic agents requiring sterile compounding
- **Level 3**: Final dosage forms with possible administration risks
- **Level 4**: Final dosage forms oral tablets and capsules

- **Drug**
- **Form**
- **Packaging**
- **Manipulation**
- **Documentation**
- **Annual Review**
Receive | Unpack | Store

<USP 800>

PPE Consideration
- Operations
- Incident
- Standard Gloves
  - Chemo Gloves
  - Respiratory
  - Neutral Negative Pressure Non Compounding Environment
  - Eye/face
  - Compounded Antineoplastic Stored Separately
  - Refrigerated HDs Require Separate Refrigerator
  - Non Sterile Compounding HDs Stored Separately

Engineering Controls
- Operations
Administer Part 2

<USP 800>

Administration

SubQ IM Injection From Vial

Prep From Vial

Admin from Prepared Syringe

Chemo Gloves

Gowns

Eye / Face If Not in Controlled Device

Respiratory If Not in Controlled Device

Controlled Environment

Withdraw & or Mixing N or IM From Vial or Ampule

Preparation Administration

Chemo Gloves

Gowns

Eye / Face If Possibility of Splash

Controlled Environment

Solution for Irrigation

Administration

Compounding

Chemo Gloves

Gowns

Eye / Face

Respiratory

Controlled Environment

Powder Solution For Inhalation

Administration

Compounding

Chemo Gloves

Gowns

Eye / Face If Possibility of Splash

Respiratory If Not in Controlled Device

Respiratory If Not in Controlled Device

Controlled Environment

Aerosol Administration

Chemo Gloves

Gowns

Eye / Face

Respiratory

Controlled Environment
Disposal & Cleaning

<USP 800>

- Disposal & Cleaning
  - Metabolites in Body Fluids: Chemo Gloves, Gowns, Eye / Face if Possibility of Splash, Respiratory If Inhalation Potential
  - Drug Contaminated Waste: Chemo Gloves, Gowns, Eye / Face if Possibility of Splash, Respiratory If Inhalation Potential

- Cleaning
  - Spills: Chemo Gloves, Gowns, Eye / Face, Respiratory
In Practice

- Spironolactone
- Depakote
- Methotrexate
- Dronedarone
- Dutasteride
- Fluconazole
- Paroxetine
- Warfarin
## Initial Assessment of Risk

**USP <800> Assessment of Risk Preparade For**
**DEMO Client**
1-Jun-19

The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list.

The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. If the information regarding a drug hazardous until more information is available.

### TABLE OF CONTENTS
- **ASSESSMENT OF RISK TABLE 1**
- **ASSESSMENT OF RISK TABLE 2**
- **ASSESSMENT OF RISK TABLE 3**

**HD BY FACILITY DEMO HOSPITAL**

### Executive Summary

Automated with RXTransparent

- **Manual**
- **Prone to Error**
- **Non-repeatable**
The RXTransparent platform has identified that there is new or updated information Hazardous Drug Transactions that affect your facilities. Please Login to the RXTransparent Analytics Platform for more information.

The following is a breakdown of the products affecting your organization and your last transaction volume by package size:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product</th>
<th>NDC</th>
<th>Strength</th>
<th>Package</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mylan Institutional LLC</td>
<td>METHOTREXATE SODIUM</td>
<td>67457-467-21</td>
<td>25mg/1mL</td>
<td>Methotrexate Sodium 25mg/1mL Solution for injection</td>
<td>10</td>
</tr>
</tbody>
</table>

Login to the RXTransparent Analytics platform or mobile app for more information about this drug shortage.

RXTransparent<USP>800
Phone: (646)783-3172
[www.rxtransparent.com](http://www.rxtransparent.com)
<table>
<thead>
<tr>
<th>Facility</th>
<th>Labeler</th>
<th>NDC</th>
<th>Product</th>
<th>Form</th>
<th>Strength</th>
<th>Package</th>
<th>AHFS Class</th>
<th>AdR</th>
<th>Link</th>
<th>Acknowledged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highlands</td>
<td>Allergan, Inc.</td>
<td>0023-9163-30</td>
<td>oxybutynin</td>
<td>Emulsion</td>
<td>5mg/mL</td>
<td>30 VIAL, SINGLE-USE in 1 TRAY (0023-9163-30)</td>
<td>92:44 Immunosuppressive agents</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>sanofi aventis U.S. LLC</td>
<td>0024-4142-10</td>
<td>dronedarone</td>
<td>Tablet, Film Coated</td>
<td>400mg/10</td>
<td>10 BLISTER PACK in 1 BOX (0024-4142-10)</td>
<td>24:04:04 Antibiotics</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.</td>
<td>0046-0872-21</td>
<td>estrogens, esterified</td>
<td>Cream</td>
<td>625mg/g</td>
<td>1 TUB, WITH APPLICATOR in 1 CARTON (0046-0872-21)</td>
<td>68:16:04 Estrogens</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>Roerig</td>
<td>0049-3920-83</td>
<td>nimodipine</td>
<td>Injection, Powder, Lyophilized For Solution</td>
<td>20mg/mL</td>
<td>12 VIAL, SINGLE-DOSAGE in 1 CARTON (0049-3920-83)</td>
<td>29:16:09:04 Mycological Antimycotics</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0168-75</td>
<td>warfarin</td>
<td>Tablet</td>
<td>4mg/1</td>
<td>10 BLISTER PACK in 1 CARTON (0056-0168-75)</td>
<td>20:12:04:08 coumarin derivatives</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0169-75</td>
<td>warfarin</td>
<td>Tablet</td>
<td>1mg/1</td>
<td>10 BLISTER PACK in 1 CARTON (0056-0169-75)</td>
<td>20:12:04:08 coumarin derivatives</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0170-75</td>
<td>warfarin</td>
<td>Tablet</td>
<td>2mg/1</td>
<td>10 BLISTER PACK in 1 CARTON (0056-0170-75)</td>
<td>20:12:04:08 coumarin derivatives</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Highlands</td>
<td>Bristol-Myers Squibb Pharma Company</td>
<td>0056-0172-75</td>
<td>warfarin</td>
<td>Tablet</td>
<td>5mg/1</td>
<td>10 BLISTER PACK in 1 CARTON (0056-0172-75)</td>
<td>20:12:04:08 coumarin derivatives</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
### Haz Drug Schedule On Demand

The assessment of risk must, at a minimum, consider the following:
- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

### Group 1: Antineoplastic drugs (AHFS Classification 10:00) [ASHP/AHFS DI 2016].

Note that many of these drugs may also pose a reproductive risk for susceptible populations (Table 2).

<table>
<thead>
<tr>
<th>AFHS Class</th>
<th>Drug</th>
<th>NDC</th>
<th>Strength</th>
<th>Package</th>
<th>Form</th>
<th>Risk of Exposure</th>
<th>SupplInfo</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00</td>
<td>tamoxifen</td>
<td>0589-2472-60</td>
<td>10mg/1</td>
<td>60 TABLET in 1 BOTTLE, PLASTIC (0589-2472-60)</td>
<td>TABLET</td>
<td>Low high IF manipulated</td>
<td>IARC Group 1 carcinogens; NTP**; FDA Pregnancy Category D</td>
</tr>
<tr>
<td>10:00</td>
<td>aromatase</td>
<td>16299-035-10</td>
<td>1mg/1</td>
<td>30 TABLET in 1 BOTTLE, PLASTIC (16299-035-10)</td>
<td>TABLET</td>
<td>Low high IF manipulated</td>
<td>FDA Pregnancy Category X</td>
</tr>
<tr>
<td>10:00</td>
<td>hydroxyurea</td>
<td>49884-724-01</td>
<td>500mg/1</td>
<td>300 CAPSULE in 1 BOTTLE (49884-724-01)</td>
<td>CAPSULE</td>
<td>Low high IF manipulated</td>
<td>Special warnings on handling bottles and capsules; FDA Pregnancy Category D</td>
</tr>
<tr>
<td>10:00</td>
<td>azacitidine</td>
<td>51999-600-33</td>
<td>1mg/1</td>
<td>30 TABLET in 1 BOTTLE (51999-600-33)</td>
<td>TABLET</td>
<td>Low high IF manipulated</td>
<td>FDA Pregnancy Category X</td>
</tr>
<tr>
<td>10:00</td>
<td>Megestrol</td>
<td>60432-176-08</td>
<td>40mg/mL</td>
<td>240 mL IN 1 BOTTLE, PLASTIC (60432-176-08)</td>
<td>SUSPENSION</td>
<td>HIGH</td>
<td>Nursing should be discontinued if megestrol is required; woman at risk of pregnancy should avoid exposure; FDA Pregnancy Category X</td>
</tr>
</tbody>
</table>
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General Q&A

Reminder: Qs submitted in advance get priority.
Federal/ State Split of Medicaid Rx Savings

Assume: Ms. Jones, a Medicaid managed care patient, gets a Rx at a FQHC.
The drug’s regular price is $40.
The 340B discount and the Medicaid rebate are both $10.
So the net price under both 340B and Medicaid is $30.

**OPTION ONE:**
- The FQHC buys the drug under 340B ($30)
- Medicaid reimburses the FQHC the regular price ($40)
- *The FQHC retains $10 in savings.*

**OPTION TWO:**
- The FQHC buys the drug under 340B ($30)
- Medicaid reimburses the FQHC the 340B price ($30)
- *“The state saves $10.”*

**OPTION THREE:**
- The FQHC buys the drug at regular price ($40)
- Medicaid reimburses the FQHC the regular price ($40)
- The state applies for the rebate ($10)
- *“The state saves $10.”*

But that’s not the end of the story!
Where do Medicaid savings go?

• When states get the savings, the majority of those savings go back to the Federal treasury.

• Medicaid costs are split between the Federal government and the states.
  • *The exact split varies, based on the state, the service, and the patient.*

• The Feds pay at least 50% - & as much as 90% - of total Medicaid costs.

• So 50 to 90% of Medicaid savings accrue to the Feds, rather than states.
Examples

When “the state gets the $10 savings”, only a fraction of those dollars stay in the state. For example:

Ms. Jones is a “traditional” Medicaid enrollee in a state like AK, CA, or VA, where the Feds pay 50% of costs for traditional enrollees:

Of her state’s $10 in Rx savings, $5 goes back to the Feds – so the state retains $5 in net savings.

Ms. Jones is a “traditional” Medicaid enrollee in a state like WV or MS, where the Feds pay around 75% of costs for traditional enrollees:

Of her state’s $10 in Rx savings, $7.50 goes back to the Feds – so the state retains $2.50 in net savings.

Ms. Jones is a Medicaid expansion enrollee, so the Feds pay 90% of her costs:

Of her state’s $10 in Rx savings, $9 goes back to the Feds – so the state retains $1 in net savings.

When the FQHC gets the $10 savings, the full $10 stays in the state and is invested in activities that expand access for underserved populations.
Other Questions?
Please do the 1-minute evaluation

https://www.surveymonkey.com/r/YJHSBXY