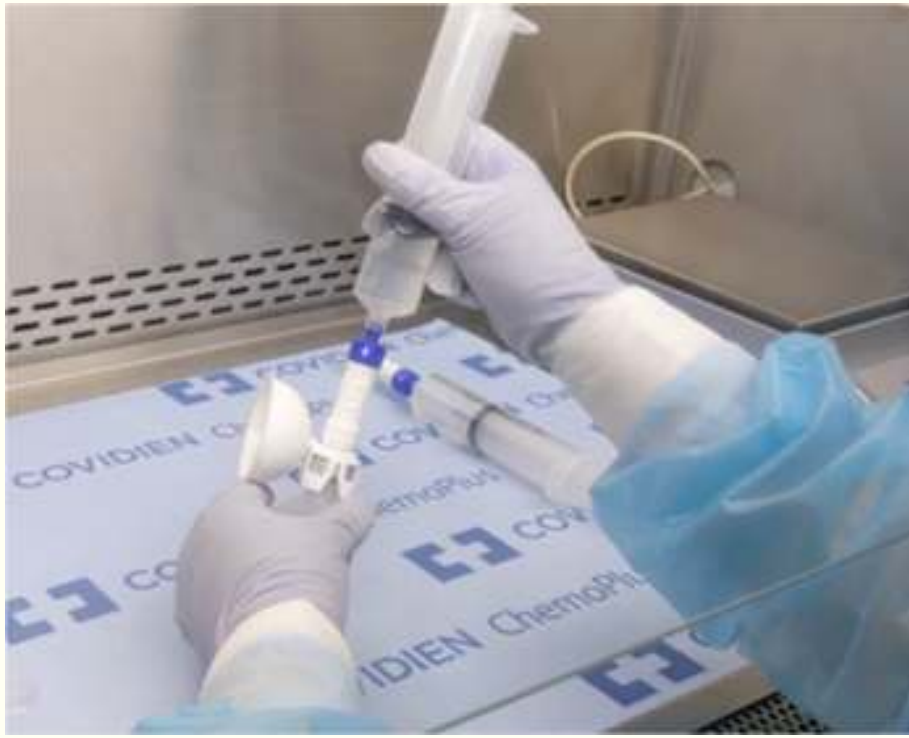
MEDICATION SAFETY: BEST PRACTICES IN STERILE COMPOUNDING



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Presenter Information

- Advanced Pharmacy Technician, Pharmacy Education
- Nationally Certified Pharmacy Technician
- Nationally certified by PTCB in Sterile Compounding, Technician Product Verification and Hazardous Drug Management.

Learning Objectives

1. Identify a safe compounding practice to minimize patient harm.
2. List a risk factor when compounding hazardous preparations.
3. Identify a quality assurance program used to promote medication safety.

ISMP STERILE COMPOUNDING SURVEY

ISMP Best Practices – July 2020 Survey

Compounding Pharmacy Practitioners, N=634

Purposes:

- Increase awareness of best practices
- Identify opportunities to improve safety
- Implementing safe pharmacy compounding practices
- Identify safety challenges

https://ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices

Compounding Technologies

- Barcode verification systems, 48%
- TPN compounding devices, 47%
- Remote supervision, 32%
- Gravimetric Verification, 25%
- Robots, 8%

https://ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices

Compounding Practices

- "Standard operating procedures are defined and always followed during the compounding process" – 56 % average, 62% technicians, 54% pharmacists.
- "Standard operating procedures are never, rarely, or sometimes defined and followed" – 10%
- Comments: short cuts are taken to improve efficiency and production numbers.

https://ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices

Compounding Practices

- 47% stated that they always “only prepare one CSP at a time.”
- A few respondents stated that the “kept partially used vials of medications and bags of diluents in the hood.”
- 49% of respondents reported that, “the dose volume information is always available on the label, so there is no need for calculations.”

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Errors in Sterile Compounding

- 74% of survey participants noted that within the 12 months, "at least one pharmacy sterile compounding error had occurred."
- Top 3 Errors reported include:
  - Incorrect dose or concentration (58%)
  - Incorrect base solution (51%)
  - Incorrect base solution volume (43%)

https://ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices

Errors Discussion

- Incorrect dose or concentration (58%)
- Incorrect base solution (51%)
- Incorrect base solution volume (43%)

https://ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices

Active Learning Question

Medication B has a concentration of 200 mg per mL.

The weight of the patient is 220 lbs.

The dosage prescribed is 40mg per kilogram (kg).

How much, in mL, should the compounder draw up to achieve the dose of 40mg/kg?

Hint: Round up on the weight conversion

The weight of the patient is 220 lbs.
Convert to KG (220 / 2.2 = 100 kg, when rounded up!)

The dosage prescribed is 40mg per kilogram (kg).
100 kg x 40 mg = 4000 mg

How much, in mL, should the compounder draw up to achieve the dose of 40mg/kg? (conc. 200mg per mL)

4000 mg divided by 200 mg = 20 mL

SAFETY CHALLENGES & SUGGESTIONS

What is Quality Assurance?

The USP defines quality assurance (QA) as:

"A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards."

QA includes:

- Training, SOPs, cleaning procedures, storage, process validation procedures, etc.

What is Quality Control?

The USP defines quality control (QC) as:

"The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP."

QC includes:

- Verification of gravimetrics, reviewing appearance of final IV product, hazardous surface sampling, ISO classification certification.

No Visual Verification

- Unable to observe aseptic technique
- Pull back method still being utilized
- RPh cannot see drug volumes/syringes

Suggestions:

- Hourly rounds
- Gravimetrics
- Visual checks
- Observation sessions
- Camera technology

Safety Challenges & Suggestions

Variation in Practices:

- Workflow differences
- Not following SOPs
- No attention to detail

Suggestions:

- Create and update SOPs
- Educate changes to staff
- Standardize practices throughout the department

Excessive Workload

- Production numbers are increasing
- Turnaround time is unrealistic
- Overtime required to fully staff in a department

Suggestions:

- Track production statistics
- Use electronic health record reports
- Crosstrain staff members
- Split work assignments

Which of the following quality assurance procedures would promote medication safety?

A: Verification of gravimetrics
B: Process validation procedures
C: Performing ISO certification
D: Visual inspection of CSPs

~~Active Learning Question~~

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SAFE COMPOUNDING PRACTICES

Standard Operating Procedures (SOPs)

- **Identify changes in content**
- **Connect safety events to SOPs**
- **Review process: Include non-compounding staff**
- **Educate. Educate. Educate.**
- **Annually evaluate all SOPs**

Media-Fill Test Procedures

- **At least annually**
- **Low/Medium Risk Levels**
- **No interruptions**
- **Most challenging conditions**
- **Create a positive outcome**

Compounding Sterile Preparations

- **Safety Event Reporting**
  - **Knowledge of reporting**
  - **Recommendations accepted**
  - **Compounding staff represented**
  - **Staff looped into outcomes**

Compounding Sterile Preparations

Random Observation Sessions

- Identify shortcuts taken
- Question staff about BUDs
- Ask staff to outline procedures
- Document sessions:
  - Provide/develop score
  - Re-evaluate at set intervals

Safe Compounding Practices

Table 5. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

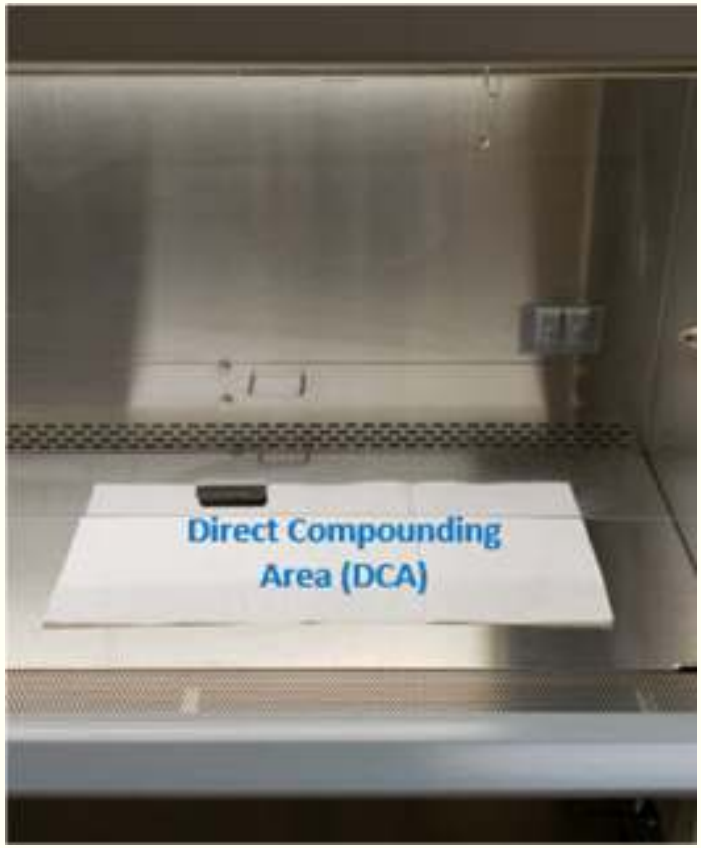
Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used, unless spills occur)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or cap-sules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes†
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up†	no	N/A

ISO Classes – Cleanroom Suites

ISO 5	ISO 7	ISO 8
BSCs CAI/CACIs LAWFs	Anteroom Buffer room	Anteroom (non-HD)

Direct Compounding Area

- Middle of BSC
- 6” from front/back
- 3” from sides
- Supplies should be stored outside of DCA
- Monitor for shadowing
- Only necessary supplies



Beyond-Use Dates

USP Chapter <797> guidelines (2008 version):

“the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.”

Beyond-Use Dates

- **Single-dose vial (SDV) = 6 hours**
- **Multi-dose vial (MDV) = 28 days, unless specified by mfg.**
- **Immediate use = 1 hour**

Risk Levels:

Low - ISO Class 5, less than 3 products, 2 entries

Medium - More than 3 products, complex manipulations

High - Non-sterile ingredients, Improperly garbed

Cleaning Procedures

Daily	Weekly	Monthly
PECs Countertops Floors	PECs	Walls Ceilings Storage

Storage of Medications

- **Review Databases**
  - **AHFS, Trissel's handbook on injectable drugs**
- **Use tall-man lettering**
  - **Examples: niCARdipine, LORazepam**
- **Identify medications**
  - **High-Alert, hazardous, protect from light**

Which of the following activities could be a potential risk factor when handling hazardous drugs (HDs)?

A: Donning 1 pair of chemotherapy gloves when cutting HD tablets
B: Donning 1 pair of chemotherapy gloves when handling a unit-dosed HD tablet.
C: Donning 2 pairs of chemotherapy gloves during an HD spill
D: None of the above

Active Learning Question

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COMPOUNDING HAZARDOUS MEDICATIONS

What is a Hazardous Drug (HD)?

Table One – Antineoplastic Drugs (1 or more of NIOSH criteria)	***Example:*** **Arsenic**
Table Two – Non-Antineoplastic Drugs (1 or more of NIOSH criteria)	***Example:*** **Tacrolimus**
Table Three – Non-Antineoplastic Drugs (Adverse reproductive effects)	***Example:*** **Ribavirin**

Compounding Hazardous Medications

Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings*

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Subcutaneous/ intra-muscular injection from a vial	Preparation (withdrawing from vial)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash[†]	no	N/A
Withdrawing and/or mixing intravenous or intramuscular solution from a vial or am-poule	Compounding	yes[‡]	yes	no	no	yes, BSC or CACI; use of CSTD rec-ommended
	Administration of prepared solution[¶]	yes	yes	yes; if liquid that could splash[†]	no	N/A; CSTD required per USP 800 if the dosage form allows

PPE recommendations

- **Bouffant cap/head and/or beard cover**
- **Face mask**
- **2 pairs of shoe covers**
- **2 protective gowns (one chemo-rated)**
- **2 pairs of rated (ASTM-6978) gloves**

Cleanroom Suite Verbiage

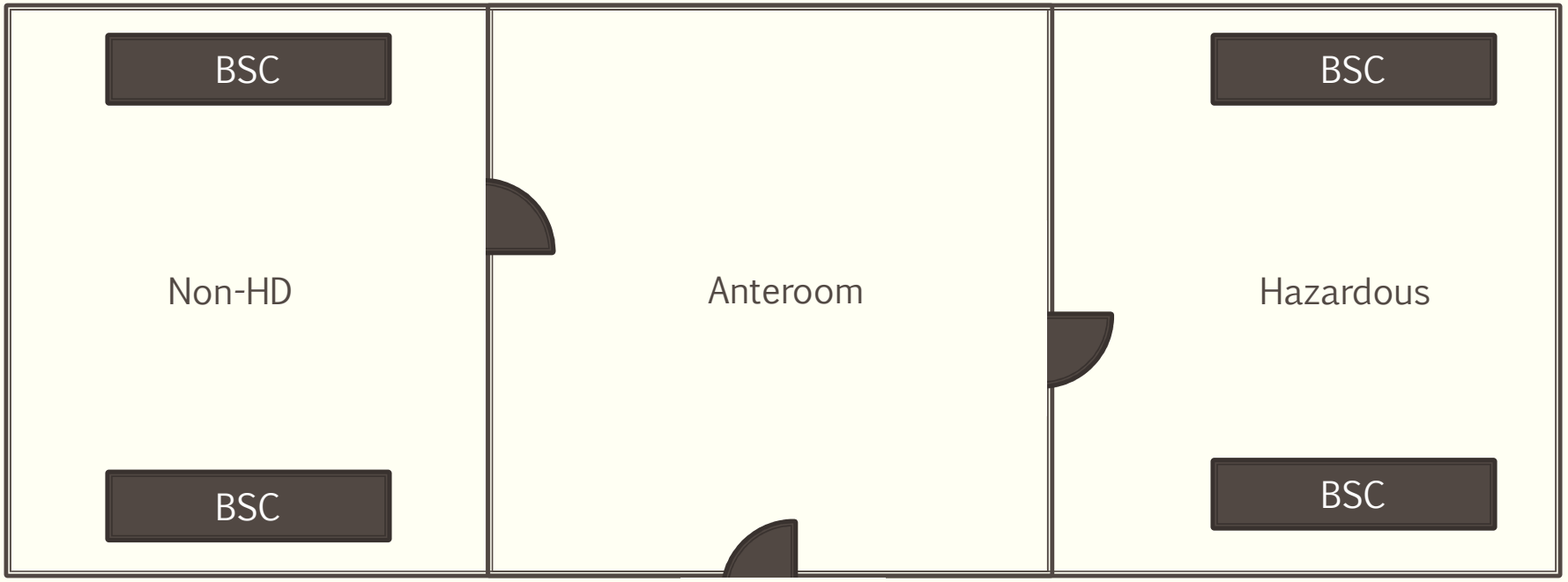
PEC = Primary Engineering Control

- BSC = Biological Safety Cabinet
- CACI = Compounding Aseptic Containment Isolator

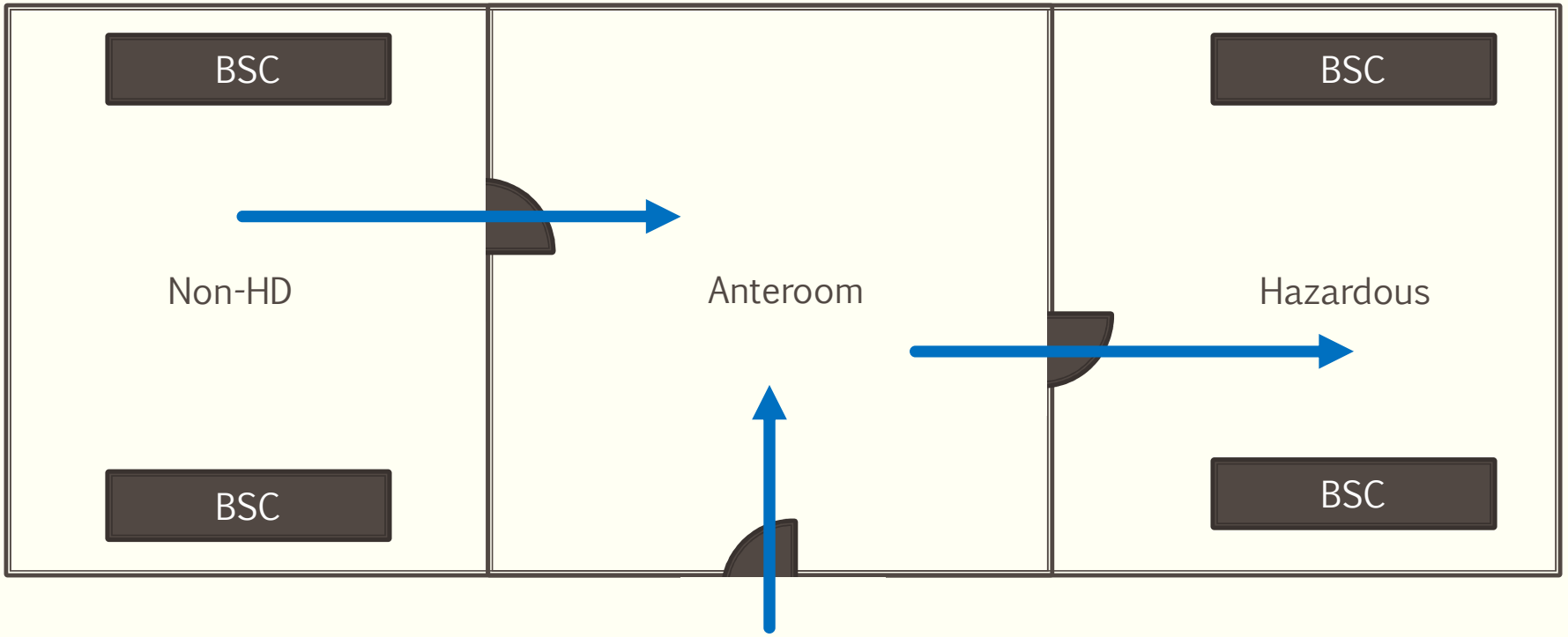
SEC = Secondary Engineering Control

- Buffer room = ISO 7, PECs are located
- Anteroom = ISO 7, garbing/handwashing

Ideal HD & Non-HD Configuration



Air Pressure Differentials



What is a CSTD?

- **Closed-system drug-transfer device – "a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system."**
- **Initial CSTD 1996, Europe**
- **Containment Supplemental Engineering Control**
- **Per USP Chapter <800>:**
  - **Compounding "should" - Administration "must"**

Compounding Hazardous Medications

Post-video Discussion

- **Vertical flow BSC**
- **Chemotherapy plastic-backed mat**
- **Swab critical sites**
- **Maintain in first-air**
- **Monitor for shadowing**
- **Maintain within DCA**

Degarbing/Doffing Recommendations

PEC	Buffer Room	Clean-side Anteroom	Dirty-side Anteroom
Outer Gloves	Outer Gown Outer Shoe Covers	Inner Gown Inner Gloves Wash hands	Shoe Covers Head cover Face Mask

Which of the following primary engineering controls pose an increased risk of exposure to hazardous medications?

A: Biological Safety Cabinet
B: Compounding Aseptic Containment Isolator
C: Vertical Laminar Airflow Workbench
D: All the above can be used

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Active Learning Question

Medication X is designated as a non-antineoplastic drug with potential adverse reproductive effects. Which of the following NIOSH tables is it classified under?

A: Table One
B: Table Two
C: Table Three
D: Table Five

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SUMMARY

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2. List a risk factor when compounding hazardous preparations.

3. Identify a quality assurance program used to promote medication safety.

QUESTIONS ????

CONTACT INFORMATION:
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References

- "**ISMP Survey Provides Insights into Pharmacy Sterile Compounding Systems and Practices**." *Institute For Safe Medication Practices*, 22 Oct. 2020, **ismp.org/resources/ismp-survey-provides-insights-pharmacy-sterile-compounding-systems-and-practices**.
- American Society of Health-System Pharmacists. **ASHP guidelines on handling hazardous drugs**. Am J Health-Syst Pharm. 2018; 75:1996- 2031.
- 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 (Supersedes 2014-138).
- **USP Chapter <797> and <800>** Healthcare quality & safety. (n.d.). Retrieved March 25, 2021, from https://www.usp.org/healthcare-quality-safety