2024 FSASC Quality & Risk Management Conference
April 4, 2024
Regulatory Update

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Objectives

- Update on the Risk Management Process
- Review of the top federal ASC tags
- Discuss two ASC survey case examples
- Agency Updates

Update on the Risk Management Survey Process

Pending Updates to the Survey Process

- Independent Risk Management Survey Process **Or**
- In conjunction with recertification/relicensure or complaint.
  - sampling of incident reports for review, and sampling for staff interviews and training file reviews are reduced
- More patient centered outcome-oriented survey process.

Entrance Conference

- Conduct meeting with the ASC Administration/Risk Manager/Risk Manager Designee.
- Present the Risk Management Entrance Checklist to facility Administration and explain the requested facility documents and information need to be provided as soon as possible.

Entrance Conference, cont.

- Introduce survey team members.
- Request additional information to address facility issues, complaints and risk management concerns as provided during the off-site preparation.

Tour

- The objective of this task is to observe the ASC where areas of concern have been identified to determine the compliance with the Risk Management regulations.
- Conduct **brief** observations and interviews related to the identified concerns during this tour.

Sample Selection and Information Gathering

- Sample Selection and size will depend.
- Information Gathering
  - Observations
  - Staff Interviews
  - Patient and Family Interviews
  - Patient Record Reviews
  - Facility Record/System Review
  - Personnel Records

Decision Making and Exit Conference

- The objective of this task is to integrate findings, review and analyze information collected from observations, interviews, and record reviews, and to determine whether the ASC is in compliance with the rules and regulations.
- The exit conference provides an opportunity for the surveyor to discuss areas of concern with the administrator and/or staff in charge.

Review of the top federal tags

ASC Top Federal Health Tags- CY 2021

Tag	Title	Regulatory Reference
Q0181	Administrations of Drugs	416.48(a)
Q0162	Form and Content of Records	416.47(b)
Q0241	Sanitary Environment	416.51(a)
Q0266	Discharge Order	416.52(c)(2)
Q0184 & Q0262	Verbal Orders & Admission and Pre-Surgical Assessment	416.48(a)(3) & 416.52(a)(2)

11

ASC Top Federal Health Tags- CY 2022

Tag	Title	Regulatory Reference
Q0181	Administrations of Drugs	416.48(a)
Q0241	Sanitary Environment	416.51(a)
Q0266	Discharge Order	416.52(c)(2)
Q0101	Physical Environment	416.44(a)(1)

12

ASC Top Federal Health Tags- CY 2023

Tag	Title	Regulatory Reference
Q0266	Discharge- Order	4126.52(c)(2)
Q0181	Administration of Drugs	416.48(a)
Q0101	Physical Environment	416.44(a)(1)
Q0162	Form and Content of Records	416.47(b)

Immediate Jeopardy Findings

ASC Case Example – Immediate Jeopardy

- June 7, 2023- Complaint (State and Federal)
- Conditions for Coverage: Q0040- Governing Body and Management And Q0060 Surgical Services
- The facility failed to ensure the endoscopy procedures were performed by licensed and qualified staff.
- During the procedure the patient was screaming in pain, asking the staff to stop. Staff continued with the procedure.
- Administrative staff were aware and failed to intervene to protect the patients.

15

ASC Case Example - Immediate Jeopardy

- August 22, 2023 – Complaint (State and Federal)
- Condition for Coverage Q0060 Surgical Services and Q0219 Patient Rights
- The facility failed to ensure surgical procedures were performed by qualified personnel in a safe manner.
- The facility failed to ensure that patients were informed of the unlicensed surgical technologists suturing surgical incision outside of their scope of practice.
- The facility failed to ensure that patients were fully informed of facility practices related to the closure of surgical wounds.

16

Agency Updates And Data

Adverse Incident Reporting- Reminders

395.0197 Internal risk management program.—

- (5) For purposes of reporting to the agency, the term “adverse incident” means an event over which health care personnel could exercise control, and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:
  - (a) Results in one of the following injuries:
    1. Death;
    2. Brain or spinal damage;
    3. Permanent disfigurement;
    4. Fracture or dislocation of bones or joints;
    5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;

Adverse Incident Reporting- Reminders.

6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

- (b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- (c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- (d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.

AHCA Incident Reporting System (AIRS) CY 2023

Number of Adverse Incidents

Year	Outcome Text Short	AMBULATORY SURGICAL CENTER Q1	Q2	Q3	Q4	Grand Total
2023	Death	2	2	4	4	12
	Limit Function				2	2
	Medically Unnecessary	1	1		2	4
	No Consent	4			1	5
	Remove Foreign Objects	1	2	1	2	6
	Surgical Repair	1	4	2	2	9
	Transfer	7	8	24	15	54
	Unrelated Surgery		1	4	2	7
	Wrong Patient Surgery		2		1	3
	Wrong Site Surgery	4	7	3	8	22
	Wrong Surgery	1	4	5	3	13
Grand Total		21	31	43	42	137

AHCA Incident Reporting System (AIRS) 2024 Q1

Number of Adverse Incidents

Year	Outcome Text Short	AMBULATO.. Q1	Grand Total
2024	Death	2	2
	Limit Function	1	1
	No Consent	1	1
	Surgical Repair	2	2
	Transfer	18	18
	Unrelated Surgery	1	1
	Wrong Site Surgery	1	1
	Wrong Surgery	1	1
Grand Total		27	27

Have Questions??

- Please contact the Office of Risk Management and Patient Safety directly at (850) 412-3731, or by email at **riskmgmtps@ahca.myflorida.com**
- **Office of Risk Management and Patient Safety (myflorida.com)**

Complaint Data

- CY 2022
  - Investigated: 46
  - Substantiated: 16
  - Common Substantiated Allegations: Life Safety, Quality of Care and QAPI
- CY 2023
  - Investigated: 40
  - Substantiated: 13
  - Common Substantiated Allegations: Falsification of Records, Unqualified Personnel, Adverse Incidents not reported timely, and QAPI.

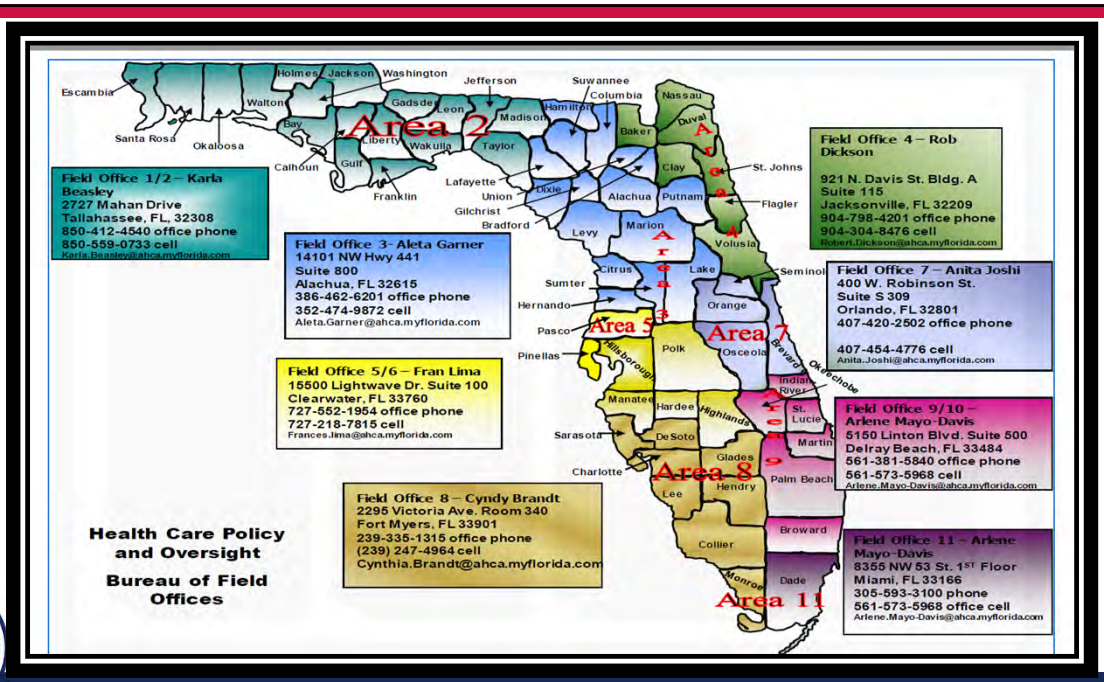
Patient Safety Culture Survey (PSCS) Program

- Section 395.1012, F.S. requires the Agency to collect PSCS data biennially from hospitals and ambulatory surgical centers
- Rule 59A-35.115, FAC providing specific requirements became effective January 26, 2023
- The initial reporting period will be **June 1 – August 31, 2025.**
- Additional information is available at: **https://ahca.myflorida.com/schs/commiteescouncils/indexpscs.shtml**

HB 7089- Health Care Expenses (Transparency)

- 395.301 Price transparency:
  - Facilities must post standard charges for shoppable services. (ASCs 1/1/2026, & Hospitals 7/1/2024)
  - Provide estimates in advance.
  - Establish an internal process for reviewing and responding to grievances from patients.
  - Must allow a patient to dispute charges that appear on the itemized statement or bill.
  - Respond to grievance within seven days.

25



26

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27

Risk Management Back to the Basics

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Why risk management?

- Manage the risk of harm to patients and staff by improving processes, training, and communication.

"If it's not safe, it's not care"

Institute for Healthcare Improvement

Regulations and Standards

- Code of Federal Regulations (CFR)
- Florida Statute and Florida Administrative Code

CMS Regulation

- 42 Code of Federal Regulations (CFR) 416
  - Medicare Conditions for Coverage, State Operations Manual, **Appendix L** – Guidance for Surveyors: Ambulatory Surgical Centers. July 21, 2023
    - 42 CFR 416.43 – Quality Assessment and Performance Improvement.

State Statutes and Rules for ASCs

- Florida Statute 395 and 408
- Florida Statute 395.0197
- Florida Administrative Code 59A-5
- Florida Administrative Code 59A-10
- Florida Administrative Code 59A-35

Florida Regulations: FS 408, Part II and FAC 59A-35

- 59A-35.115 Patient Safety Surveys
- Health Care Licensing
- Facility license required, must be displayed
- Change of Ownership
- Fees required
- Background screening
- Application process

CMS and AHCA Risk Management

- CMS Appendix L, §416.43
- State of Florida
  - Florida Statute 395.0197
  - Florida Administrative Codes
    - 59A-5
    - 59A-10
    - 59A-35.115

CMS Appendix L, QAPI section, Page 57 FSASC Risk Management, 7th edition, Page 45

- Last CMS update released July 21, 2023
- Regulation requires that an ASC's QAPI program must improve both outcomes and safety. Must
  - Be ongoing
  - Use quality indicators or performance measures, consider frequency of problems, prevalence, severity
  - Identify and reduce medical errors/adverse patient events

CFR §416.43 (a) QAPI Program Scope

- (1) include an ongoing program, demonstrates improvement, identification and reduction of medical errors.
- (2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control, and other aspects of performance that include care and services furnished in the ASC.

CMS §416.43(b) Program Data

- Program must incorporate quality indicator data, including patient care
- ASC must use the data collected to
  - Monitor the effectiveness and safety of its services and quality of its care
  - Identify opportunities that could lead to improvements and changes in its patient care.

CFR §416.43 (c) QAPI

- The ASC must set priorities for its performance improvement activities that
  - Focus on high risk, high volume, and problem-prone
  - Consider incidence, prevalence and severity of problems
  - Affect health outcomes, patient safety, quality of care

CMS examples: Quality metrics and infection control

§416.43(c) Program Activities

- Track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time
- Implement preventive strategies to target adverse events and ensure all staff is familiar with these strategies.

Interpretive Guidelines 416.43(c)

- Active data collection
- Data analysis
- Implement improvements/preventive strategies
- Sustaining improvements
- Staff training

CMS surveyor will:

- Ask to see examples of quality and adverse event data
- Ask who is responsible for data collection and analysis
- What education and training equips staff to conduct analysis of data
- Provide examples where data was used to identify opportunities for improvement
- How is staff trained on prevention of adverse events
- Ask staff what they know about QAPI and risk activities

§416.43(e)

- Governing body responsibilities. The governing body must ensure that the QAPI program…

  is designed to establish clearly the expectations that patient safety is a priority, not only by tracking of all adverse events, but also by the processes for analyzing and making changes in ASC operations to prevent future such events.

CMS surveyor will look for:

- All essential elements included in program
- How governing body is involved in the QAPI program
- Meeting minutes show governing body review of all elements
- Example of how program improved performance
- Resources, staff time allocated, staff involvement

Florida Administrative Code 59A-5.019 (2) Quality Assessment and Improvement

Each center shall have in place a systematic process to collect data on process outcomes, priority issues chosen for improvement, and the satisfaction of the patient. Processes measured shall include:

a) Appropriate surgical procedures;
b) Preparation of patient for the procedure;
c) Performance of the procedure and monitoring of the patient;
d) Provision of post-operative care;
e) Use of medications including administration and monitoring of effects;
f) Risk management activities;
g) Quality assessment/improvement activities including laboratory and radiology services;
h) Results of autopsies if needed.

59A-5.019(3) QAPI

- Each center shall have a process to assess data collected to determine:
  (a) The level and performance of existing activities and procedures,
  (b) Priorities for improvement, and
  (c) Actions to improve performance

QAPI "ongoing, high risk , high volume, problem prone"

AHCA surveyor will

- Interview the manager of QAPI and/or Risk Management about the QAPI program, action taken to correct problems identified, data collection, example of how QAPI findings and RM are integrated.
- Examine reports and minutes of meetings to determine if the ASC has documented the remedial action and its outcome.

State Statutes and Rules

- Florida Statute 395 and 408
- Florida Statute 395.0197
- Florida Administrative Code 59A-5
- Florida Administrative Code 59A-10
- Florida Administrative Code 59A-35.115

Florida Regulations

- Chapter 395, Part I, Florida Statute
  - Risk management: Chapter 395.0197
  - Duty to notify patients: Chapter 395.1051
  - Patient Safety: Chapter 395.1012
    - Patient Safety Surveys: Chapter 395.1012(4)
  - Other important sections of Chapter 395
    - Staff membership and clinical privileges: 395.0191
    - Peer review, disciplinary powers: 395.0193

395.0197(1) FS and 59A-5.003(11) FAC

- 395.0197(1) Every licensed facility shall, as part of its administrative functions, establish an internal risk management program that includes all of the following components.
- 59A-5.003(11) Each center licensed under chapter 395, FS, shall establish an internal risk management program pursuant to chapter 59A-10, FAC, as a part of its administrative function.

Definitions

- “Incident reporting” means a factual written statement about a particular incident detailing particulars as to time, location, all persons directly involved including functional titles, and the nature of event including description of injuries. The report shall contain a listing of witnesses to the event.

Definitions

- "Incident reporting system" means a series of systematized procedures for detecting, reporting, collating, analyzing, and summarizing incidents.
- "Internal risk management program" means the policies and procedures of a health care facility which constitute the internal risk management program as defined in Section 395.0197

Definitions

- "Investigation" or "investigate" means the identification, analysis and evaluation of an incident by a risk manager or his designee or by a representative of the Agency.

395.0197(1)(a) Investigation and Analysis

(1) Program must include

(a) Investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.

AHCA surveyor will

- Determine if the plan establishes incident categories
- Incidents and categories specific to the facility
- Review 6 monthly logs and 4 quarterly summary reports.

395.0197(1)(b) Develop Measures to Minimize Risk

(b)Development of appropriate measures to minimize risk

1. Education and training of all nonphysician personnel
   a. At initial orientation and
   b. At least one hour annually
2. Two people in recovery
3. Authorized persons only to assist or participate in surgical procedure
4. Procedure, protocols, systems to identify patients, planned procedure, correct site

AHCA surveyor will

- Review RM plan/program/policies for
  - Incident categories, trending logs and summary reports
  - Review past year's adverse incidents identified as risk reduction/process improvement opportunities
  - Interview RM or designee regarding role in risk reduction and risk prevention strategies
  - Verify strategies are systematic and implemented
  - What were results of actions to minimize risk?

Survey findings

- No evidence of development and implementation of risk reduction and risk prevention strategies.
- No evidence risk manager aware of QAPI activities, infection control surveillance, environment of care program.

395.0197(1)(b)(1) and 59A-10.0055(1)

- Education and training for all nonphysician **personnel** (including CRNAs, PRN, independent contractors) working in clinical areas and providing patient care
  - Initial orientation (within 30 days of employment)
  - Annually for one hour
- Personnel" for purposes of this rule means any employee or independent contractor of a facility or member of a facility's medical staff. 59A-10.002(26)

Personnel, 59A-10.002 (26)

- "Personnel" for purposes of this rule means any employee or independent contractor of a facility or member of a facility's medical staff.

AHCA surveyor will

- Review policies regarding education that includes incident reporting, Code 15 and annual incident reporting requirements
- Look at records to verify new and contracted personnel educated within 30 days and annually.
- Ask a few employees about their training and their role in patient safety: what occurrences, events, near misses to report; their role in patient safety; knowledge to report sexual abuse of a patient

395.0197(1)(b)(2) Recovery Room Staffing

- Staffing the recovery room, authorized staff member
- At least one other person in recovery room
- Exceptions: Live visual observation, electronic observation or “other reasonable measure taken to ensure patient privacy and protection”.

Note: (1) the second person is not specified and can be the patient’s responsible adult companion and (2) 59A-5.0085(3)(d) “A registered professional nurse shall be present in the recovery area at all times when a patient is present.”

AHCA surveyor will

- Review staff schedule for recovery room
- Review P&P re: 2-person requirement
- Tour the recovery room
- Interview staff regarding staffing patterns

395.0197(1)(b)(3) Investigation & Analysis

- Prohibition of unlicensed person assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment. Assistance or participation must be under direct and immediate supervision of a licensed physician. Cannot be an activity that may only be performed by a licensed health care practitioner.

AHCA surveyor will

- Interview surgical staff
- Identify any unlicensed staff participating in surgical procedures
- Review unlicensed staff competencies and competency assessments
- Review for documentation of direct and immediate supervision
- Review competencies for private or contracted scrub individuals

AHCA surveyor will

- Check staff for
  - Circulating nurses for every procedure no matter where it is performed: pre-op pain blocks, procedure room, operating room
  - CRNA cannot be administering anesthesia AND serve as circulating nurse
  - Recovery nurse whenever patient present
  - Licensed staff must be giving medications
    - Not techs
    - Not MA unless direct supervision by physician

395.0197(1)(b)(4) Ongoing

- Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, correct site to minimize risk of wrong patient, wrong surgical procedure, wrong site.

AHCA surveyor will

- Review adverse incidents
- Review plan/policy documents to address identity of patient/procedure
- Verify there is a system to prevent wrong patient, wrong procedure, wrong site
- Protocols monitored for quality program purposes
- Review development, implementation, and ongoing evaluation process to prevent occurrences

64B-8-9.007 Standards of Practice for Medical Doctors

64B-8-9.007 (b): The physician(s) *or physician assistant(s)* performing the procedure and another Florida licensed health care practitioner shall verbally and simultaneously confirm the patient's identification, the intended procedure and the correct surgical/procedure site prior to making any incision or initiating the procedure. The medical record shall specifically reflect when this confirmation procedure was completed and which personnel on the team confirmed each item.

Note: CMS states that only physicians can perform procedures in an ASC. Physicians include MD, DO, DPM, DDS, chiropractors. A PA, APRN or a scrub tech cannot perform procedures.

395.0197 (1)(c)Risk Management Program

(1) Program must include

(c) Analysis of patient grievances that relate to care and quality

"Patient grievance" means any complaint by a patient relating to patient care or the quality of medical services, except for those matters pertaining to the cost of care.

- Note: this definition is not the same used by CMS §416.50(d) or the American Society for Health Care Risk Management (ASHRM).

AHCA surveyor will

- Ask to see grievances relating to patient care and medical services
- Review analysis of grievance
- Check for evidence that resolution and corrective actions, when indicated, occurred
- Verify a plan to prevent further occurrences

395.0197 (1)(d) Patient Notification of Adverse Incidents

- (d) Informing patient when subject of an adverse incident. Such notice shall be given by an appropriately trained person designated by the licensed facility as soon as practicable to allow the patient an opportunity to minimize damage or injury.
- Note: 395.1051 also requires notification of patient and states this does not constitute an acknowledgement or admission of liability, nor can it be used as evidence.

AHCA surveyor will

- Review P&P on patient notification of adverse incident
- Review any training of person(s) conducting notification
- Review sample of incident reports for documentation of notification

Physician's Obligation to Report

- FS 456.0575: Practitioner
  - Every licensed health care practitioner shall inform each patient (or surrogate) in person about adverse incidents that result in serious harm to the patient.

395.0197(1)(e) Incident Reporting System

- (e) Development and implementation of reporting system based upon the affirmative duty of all health care providers and all agents and employees to report adverse incidents

59A-10.0055(2)(a)(b) Reporting System

- Reporting system shall include reporting within 3 calendar days to risk manager or designee
- Form to report shall contain
  - Patient's name, locating information, admission diagnosis, admission date, age and sex
  - Clear and concise description of incident including date, time, exact location and elements needed for annual report based on ICD-10-CM

AHCA surveyor will look for

- Policies and procedures
- Dates of events and dates of review
- Form contains fields for all information required
- Interview a sample of staff:
  - What is the reporting system?
  - What is the time frame for reporting?
  - Does staff know who are risk manager and designee?

59A-10.0055(2) (c)-(e) Reports

- Whether or not a physician was notified of incident and, if so, a brief statement of any medical treatment directives
- A list of all persons involved directly and witnesses along with locating information for each
- Name, signature, and position of person completing the report and date and time report completed.

395.0197 (2)Responsibility of Governing Board and Risk Manager

- RM program is responsibility of governing board, have risk manager responsible for implementation and oversight and who demonstrates competence through education or experience in all the following:

395.0197(2) Education or Experience

a) Applicable standards of health care risk management.
b) Applicable federal, state, and local health and safety laws and rules.
c) General risk management administration.
d) Patient care.
e) Medical care.
f) Personal and social care.
g) Accident prevention.
h) Departmental organization and management.
i) Community interrelationships.
j) Medical terminology.

59A-10.002(29) Risk Manager Designee

- "Risk Manager Designee" means any person appointed by the facility to work with the health care risk manager or to act as his representative in carrying out risk management activities. This appointment must be in writing.

AHCA surveyor will

- Verify there is a Risk Manager
- Review the job description re responsibilities
- Is there a RM designee? What are designee's responsibilities?
- What education or experience does the risk manager and the designee have?

Definitions in 59A-5 and 59A-10

- “General risk management administration” means the establishment, direction and evaluation of procedures, programs and other methods to reduce or minimize personal injury and financial losses. The term includes management of an incident reporting system and reporting of appropriate statistics.
- “Accident prevention” means those risk management techniques that seek to reduce the frequency and/or severity of incidents

Definitions in 59A-5 and 59A-10

- "Departmental organization and management" means the organizational structure, goals, objectives, philosophy, policies, procedures, and job descriptions which govern organizational operations of the health care risk management program as it functions within the licensed health care facility.
- "Community interrelationships" means community networks, liaisons and associations that are necessary to promote continuity of care or enhance the delivery of patient care and aid in the prevention and control of health care risks.

395.0197(4) RM Access to Records

- Person responsible for risk management shall have free access to all medical records.
- "Incident reports are part of the workpapers of the attorney defending … and are subject to discovery, but are not admissible as evidence in court."

397.0197(4) Continued: Development of Corrective Procedures

- Incident reports shall be used to develop categories of incidents which identify problem areas.
- Procedures shall be adjusted to correct the problem areas.

Chapter 395. 0197(5) and (7) FS and 59A-10.0065 F.A.C.: 15 Day Reports

- For purposes of reporting to the agency, the term "adverse incident" means an event over which health care personnel **could exercise control**…
- See page 10, FSASC RM white paper, 7th edition

AHCA surveyor will

- Ask about any Code 15 reports
- Timeliness of reporting within 15 days
- Review P&P about reporting Code 15 reports
- Review any re-admissions after being discharged
- Review records of any patients who expired in ASC
- Review records of transfers to higher level of care

395.0197(9) Sexual Misconduct

- RM shall investigate allegations
- Report every allegation to the administrator
- Notify the family or guardian of the victim of allegation
- Report to DOH every allegation of misconduct by a licensed practitioner

395.0197(10) Sexual Abuse Reporting

- Any witness or anyone possessing actual knowledge of act shall

(10) (a) Notify local police

(10) (b) Notify the risk manager and administrator

AHCA surveyor will

- Review any incident reports related to allegations of sexual misconduct
- Review P&P regarding investigation and reporting
- If allegation confirmed, what action was taken?
- Was family/guardian notified? DOH notified?
- Interview staff: do they know what to do if they hear allegation?

AHCA surveyor will

- Review any incident involving alleged sexual abuse
- Review P&P
- Ascertain if and when police were notified
- Determine if staff know what to do
- Ascertain knowledge of reporting requirements
- Is facility promoting safe culture and awareness?

59A-10.0055(3) RM review of incident reports

- The RM is responsible for
  - Reviewing all incident reports to identify trends or patterns
  - Develop recommendations for corrective actions, prevention education and training
- **Summary data** systematically maintained for **3** years

Note: retention of the incident reports is not specified

59A-10.055(3)(a) Summary Report to GB

- At least quarterly, RM shall provide a summary report to the governing body, which includes information about activities of RM

AHCA surveyor will

- Review report contents and who presents it
- Review GB agenda/minutes for RM reporting of summaries, safety issues, and reporting of current status of corrective actions and follow up

395.0197 Annual Report of Judgments

- (3) Each facility shall annually report to AHCA and DOH the name and judgments entered against each health care practitioner for which it assumes liability.
- (6) (a) Annual report summarizing incident reports.
  - Total number of adverse incidents
  - List of types of operations, procedures causing injuries
  - Types of injuries caused
  - Code number of licensee
  - Description of malpractice claims

395-0197(13) Agency Access to Records 59A-10.0055(13)

- AHCA has access to all records necessary to carry out review. Records are not available to the public except disciplinary proceedings by a licensing board if they occur.
- AHCA has access to all incident reporting and analysis, summary reports, evidence of corrective actions.

395.0197(9) Unlawful Coercion of Reporting Obligation

- Unlawful for any person to coerce, intimidate or preclude a risk manager from lawfully executing his or her reporting obligations.

Has you ever been afraid to report?

395.1012(1) Patient Safety Plan

- Each licensed facility must adopt a patient safety plan. A plan adopted to implement the requirements of 42 C.F.R. part 482.21 shall be deemed to comply with this requirement.

Note: 42 C.F.R. part 482.21 is QAPI for hospitals; same as 416.43 for surgery centers. See page 45+ in FSASC RM and Related Regulations white paper, 7th edition

AHCA surveyor will

- Review patient safety plan/QAPI plan
- Was plan implemented? If not, surveyor is to contact AHCA field office for further guidance.
  - Required evidence of QAPI activity
- Is information gathered used for QAPI and patient safety?

395.1012(2) Patient Safety Officer and Committee

- Each facility will
  - appoint a patient safety officer and a patient safety committee,
  - include at least one person who is neither employed by nor practicing in the facility,
  - purpose of promoting the health and safety of patients, reviewing and evaluating the quality of patient safety measures, assisting in the implementation of patient safety plan.

AHCA surveyor will

- Confirm appointment of patient safety officer and committee
- Confirm one member is not employed or contracted
- Interview patient safety officer regarding role and responsibility
- Review composition of committee
- Review committee agenda and minutes
- Review committee involvement in evaluation of measures implemented

FS 395.1012(4) and 59A-35.115 F.A.C. Patient Safety Surveys

- Conduct Patient Safety Culture Surveys (PSCS).
- Conduct within 2 years of effective date of rule
- And, thereafter, every 2 years
- Report data to AHCA between June 1 and August 31 every two years. First report of data due in 2025

Patient Safety Culture Survey

- Anonymous responses
- All “staff members”: physicians, advanced practice/allied health staff, all employed staff including PRN who have been staff member for at least 6 months.
- AHCA Form 3130-8016
- Data Submission via “data entry tool” uploaded
- AHCA to publish survey data findings. All or part?

PSCS Results Related to RM and QI

- Communication among team and ability to speak up
- Team members express ideas and make suggestions
- Have time, training, and help when needed
- Processes are changed to improve care
- Management provides resources

Patient Safety Culture Surveys Resources

- AHCA Patient Safety Culture Survey System User Guide
  - https://ahca.myflorida.com/content/download/22052/file/PSCS_System_Guide_2022.pdf
- AHRQ: Agency for Healthcare Research and Quality
  - https://www.ahrq.gov/sops/index.html

Summary

- CMS Appendix L
- 395, Part I, Florida Statutes,
  especially 395.0197 and 395.1012
- 59A-5 Florida Administrative Code
- 59A-10 Florida Administrative Code
- 59A-35.115 Florida Administrative Code

Q&A

sjones@aboutascs.com

Ambulatory Strategies Inc.

We Bring the Pieces Together

Critical Points In Instrument Sterilization

Luci Perri, RN, MSN, MPH, CIC, FAPIC, CSPDT

Objectives

- Describe the requirements to safely transport contaminated instruments to the processing area
- Explain how to organize a sterile processing area to prevent crossover of clean and dirty
- Describe the required documentation in a sterile processing department/area

Spaulding's Classification

Critical: Enters sterile tissue or the vascular system	Sterilize
Semicritical: Contacts mucous membranes or non-intact skin	Sterilize or high-level disinfection
Noncritical: Contacts intact skin	Hospital grade EPA registered disinfectant

Guidelines and Standards

All reusable medical devices must be cleaned and maintained according to the **manufacturer's instructions** to prevent patient-to-patient transmission of infectious agents (CDC)

Items are pre-cleaned according to **manufacturer's instructions**, or if the manufacturer does not provide instructions, evidence-based guidelines prior to sterilization. (CMS ASC IC Worksheet)

Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care v2.3 September 2016. CDC. Division of Healthcare Quality Promotion. https://www.cdc.gov/infectioncontrol/pdf/outpatient/guide.pdf

Cleaning: Automatic

- All instruments must be cleaned in the completely open and disassembled (i.e., taken-apart) configuratic
- Clean all devices within a washer/disinfector using the equipment and detergent recommended by the manufacturer.
- Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.
- Rinse with distilled or deionized water to remove residual solution.

Parameters for Wrapped Instruments in Steam Sterilization

	Temperature	Exposure	Drying
Gravity Displacement	132°C (270°F)	15 Minutes	15 Minutes
Pre-Vacuum/Dynamic Air-Removal	132°C (270°F) 135°C (275°F)	4 Minutes 3 Minutes	15 Minutes 15 Minutes

MANUFACTURER'S INSTRUCTIONS

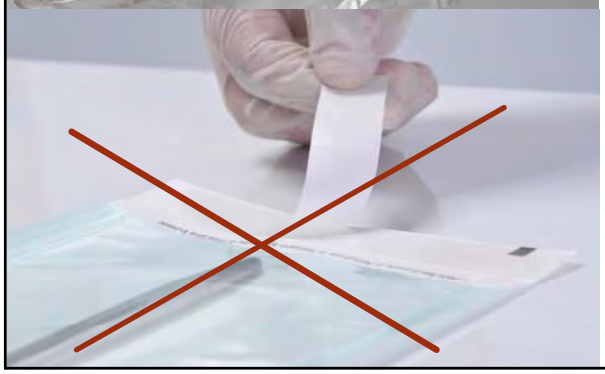
Point of Use Treatment

- Not a thorough cleaning
- Gross soil and debris removal
  - Blood, body fluids, surgical materials (orthopedic cement)

Instrument transport

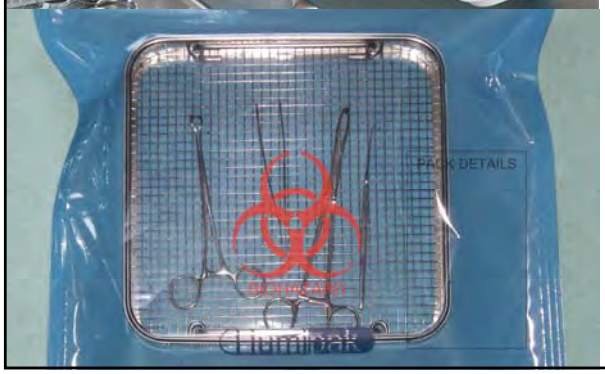
- OSHA BBP (29 CFR 1910.1030) Standard
- Needlestick Safety and Prevention Act (2001)

INSTRUMENT TRANSPORT



Instrument Transport

- Plastic bags
- Peel pouches



Instrument Transport Agents

Keep instruments moist	Best location to apply
• Wet towel • Surfactants • Enzymatic gel or spray • Self-seal pouch with an absorbent layer	• Procedure room? • Instrument cleaning area?

Instrument Processing PPE

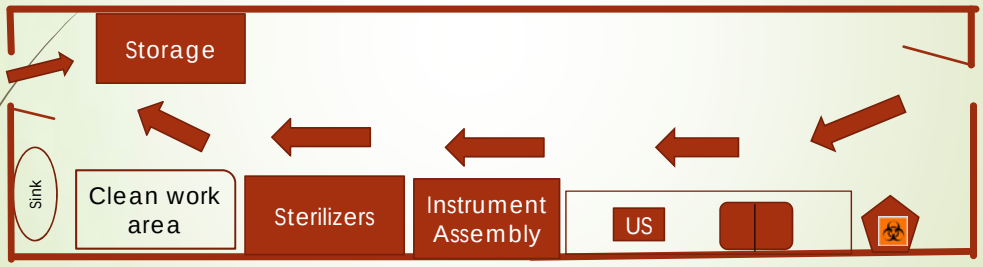
Heavy duty utility gloves	Impervious gown	Mask	Face shield	Goggles
• NOT exam or procedure gloves • MUST cover gown cuffs completely	• Won't allow water to penetrate to clothes	• Ideally, Level 3 (fluid resistant)	• If mask is Level 1 or 2	• ONLY if Level 3 mask worn

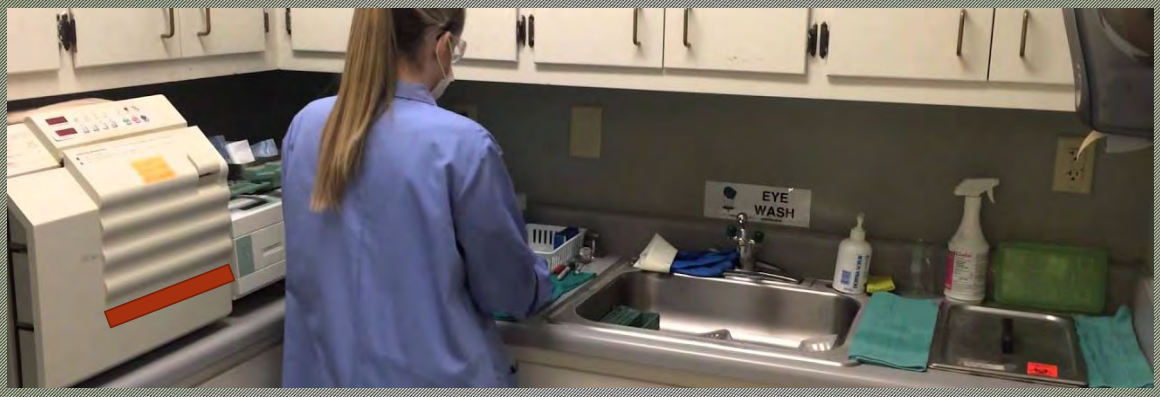
Traditional parts of an instrument sterilization area

- Receiving, cleaning and decontamination
- Prep and pack
- Sterilization
- Storage

Centers for Disease Control and Prevention. Guidelines for Infection Control in Dental Health-Care Settings — 2003. MMWR 2003;52(No. RR-17).
https://www.cdc.gov/mmwr/PDF/rr/rr5217.pdf

Workflow





Proximity

Instrument Processing Steps

Rinse #1

Manual or automated wash

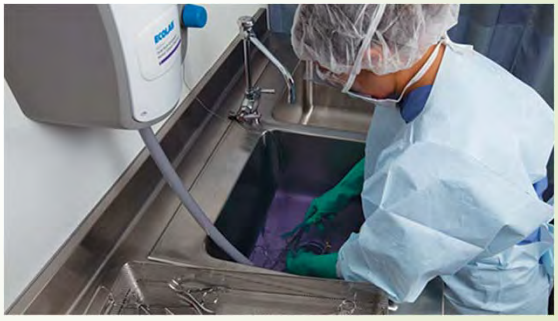
Rinse #2

Dry

Inspect

Package

Enzymatic soak



Automated Washers/Ultrasonics

Follow loading instructions

- Metal
- Types of instruments

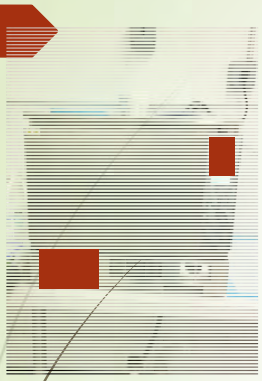
Ultrasonics washers

- MUST use basket

Ultrasonic Washers

Efficacy Testing

- Manufacturer's instructions
- Daily testing
- Document results



Instrument Washers

EFFICACY TESTING

- Manufacturer's IFU
  - Washer
  - Test
- Test daily when in use
- Document results

Visual Inspection

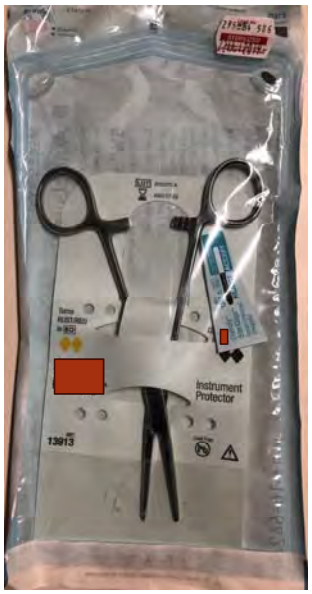
- **Flaws**
- **Damage**
- **Debris**
- **Detergent residue**
- **Completeness**
- **Instrument tape and plastic dipping material**
  - Inspect each time the instrument is processed
  - Check for wear according to the product IFU
    - Cracking
    - Peeling
  - Replace as often as needed

Sterilization monitoring

01 Chemical

02 Biological

03 Physical



CHEMICAL INDICATORS

Packaging Bloopers

Labeling

- Contents if not visible
- Date
- Load or cycle number
- Initials or other identifier of person packaging
- Where to write
  - Plastic side
  - Sterilization tape for wrapped sets

Biological indicators

- Match to sterilizer and cycles
- Correct incubator/reader
- Approved BI
- Frequency
  - Weekly minimum
  - Busy center runs BIs daily
  - Loads with implants requires a BI
- Document results of control and active

Sterilization

1

Manufacturer's instructions

- Sterilizer
- Instruments
- Packaging materials

2

What to do if those don't match?

Sterilization

- Follow manufacturer's instructions for preventive maintenance and routine maintenance (e.g. sterilizer cleaning)
  - Preventive maintenance should be documented
- Tabletop sterilizers
  - Distilled water
  - Cleaning frequency

Physical Monitoring to Verify Parameters

- Gauge
- Dial
- Electronic display
- Print out
- National guidelines: no printer = don't use

Sterilization Documentation

- Date
- Sterilizer number
- Specific contents
- Cycle parameters
- BI/spore test results

Takeaways

- Must measure diluted chemicals and water
- Transport according to OSHA BBP standard
- Appropriate PPE in decontamination
- Dirty to clean workflow
- Efficacy testing and documentation
- Labeling
- Follow IFUs
- Sterilization load documentation

QUESTIONS?

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Disclaimer

The information contained in this presentation is for informational purposes only and does not create an attorney-client relationship, or prohibit Johnson Pope Bokor Ruppel & Burns, LLP from representing clients in matters adverse to the audience members.

Topics

- Compliance programs & how they can help manage risks
- Risks related to health IT & contracts
- Data privacy, security, and HIPAA briefing

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Why does compliance matter?

- Failure to comply creates risk!
- Penalties and fines
- Criminal prosecution
- Licensure actions
- Patient trust
- Reputational harm
- Lawsuits $$$

Common Industry Compliance Issues

- Documentation errors/insufficient documentation
- Billing under another provider's NPI while credentialing is in process
- Failure to follow coding requirements (upcoding, unbundling, supervision, incident to)
- Lack of medical necessity (or documentation reflecting same)
- Non-compliant medical director compensation
- Impressible percentage-based compensation that do not meet an exception or safe harbor under applicable law
- Compliance issues caused by contractors/vendors

Compliance Refresher
Federal Regulatory Framework

- Federal Laws
  - False Claims Act
  - Anti-Kickback Statute
  - STARK Law
  - Beneficiary Inducement Statute

State Law Considerations

- Statutes and Rules Governing Physicians
  - Florida example:
    - Florida Medical Practice Act: Chapter 458, Florida Statutes
- State Fraud and Abuse Laws
  - Florida examples:
    - Florida Anti-Kickback Statute
    - Florida Patient Self-Referral Act
    - Florida Patient Brokering Act

Compliance Landscape for ASCs

- Florida Licensure Rules & Regulations
- CMS Requirements & Conditions of Participation
- Security, HIPAA, & Data Breaches
- Accreditation Requirements (AAAHC & JCAHO)
- Compliance Risks Related to Third Parties
- And more!

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Effective Compliance Program Requirements (Federal Sentencing Guidelines)

1. Implementing written policies, procedures, and standards of conduct
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected offenses and undertaking corrective action

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Compliance Program Benefits

- Reduces risk
- Helps protect the organization from violations of health care laws and regulations
- Keeps the workforce informed about compliance requirements that apply
- The adequacy and effectiveness of compliance programs is considered by the government when determining:
  - The appropriate form of any resolution or prosecution
  - Whether to apply penalties (and what amount)

https://www.justice.gov/criminal-fraud/page/file/937501/download

Considerations for ASC Compliance Programs

- All organizations should tailor their compliance programs and audits to their practice area
- Consider accreditation requirements, and build them into compliance program and compliance policies
- Identify third party relationships and how they can affect your compliance

Areas of Risk Related to Compliance

- Failure to train workforce members
- Contracts (or not having a contract)
- Failing to maintain appropriate documentation, or your third party's failure to do so
- Lack of policies, procedures, oversight, and auditing/monitoring

Third Party Management & Compliance

- Relationships with third parties can impact and pose risk to an organization's state of compliance
- Adequate diligence with third parties should be done to identify the need for, and risks posed by, third party relationships
- Contracts should specifically describe the services to be performed and the third party must actually be performing the work contracted and paid for
- Compensation should be commensurate with the work being provided in that industry and geographical region, fair market value, and commercially reasonable
- Ongoing third-party management is also important (such as updated due diligence, training, audits, and/or annual compliance certifications by the third party)
- DOJ has identified a company's third-party management practices as "a factor that prosecutors should assess to determine whether a compliance program is in fact able to "detect and prevent the particular types of misconduct most likely to occur in a particular corporation's line of business"
- Keeping workforce members well trained and engaged in compliance is key to ensuring compliance and managing third party risk and relationships

https://www.justice.gov/criminal-fraud/page/file/937501/download

Contract Compliance

Why does it matter?

- Helps ensure compliance with
  - Federal Fraud & Abuse Laws
  - State Fraud & Abuse Laws
  - New State Data Storage Laws
  - Third-Party Management & Requirements
  - HIPAA & State Privacy Law Requirements
  - Organizational Requirements
  - Patient Safety Risks & Each Party's Responsibility

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Examples of Contract Considerations

- Compliant compensation structures and language
- Excluded party language and considerations
- Ensuring BAAs require all current HIPAA required provisions and organizational requirements
- Indemnification and limitations of liability
- Identifying conflicts of interest
- Maintaining copies of contracts in an organized fashion
- Addressing state law requirements
- Managing risks related to third parties
- Insurance and other organizational requirements for third parties
- Pre-contracting diligence – how will this vendor impact your risk?

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The Importance of a BAA Example Press Release

- **No Business Associate Agreement? $31K Mistake – April 20, 2017**
- The Center for Children's Digestive Health (CCDH) has paid the U.S. Department of Health and Human Services (HHS) $31,000 to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and agreed to implement a corrective action plan. CCDH is a small, for-profit health care provider with a pediatric subspecialty practice that operates its practice in seven clinic locations in Illinois.
- In August 2015, the HHS Office for Civil Rights (OCR) initiated a compliance review of the Center for Children's Digestive Health (CCDH) following an initiation of an investigation of a business associate, FileFax, Inc., which stored records containing protected health information (PHI) for CCDH. While CCDH began disclosing PHI to Filefax in 2003, neither party could produce a signed Business Associate Agreement (BAA) prior to Oct. 12, 2015.
- Read the Resolution Agreement and Corrective Action Plan - PDF
- For more information on Business Associate Agreements, please visit https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html

https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/ccdh/index.html

Data Privacy & Security in 2024

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Common HIPAA Pitfalls

- Failure to provide access to PHI as required by HIPAA
- Texting PHI
- Improper handling or response to breaches/complaints
- Using PHI for publication, marketing, or research without following HIPAA requirements
- Clinical photography
- Non-compliant charges for medical records
- Following state law without checking HIPAA
- Inadvertently misdirecting or disclosing PHI to unauthorized parties
- Stolen records or devices
- Phishing and other cyber attacks
- Snooping in records
- Use of unsecure email
- Verbal disclosures
- Failure to execute a BAA with business associates

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Data Privacy & Security in 2024

- Increased risk this year
- More claims
- More penalties and fines
- More successful cyberattacks with exfiltration
- Risk of patient complaints
- Cyber insurance (more expensive or lack of)
- AI considerations

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Risk Areas to Consider in 2024

- How are you managing security risk, and how can you prove you are fulfilling the requirements under HIPAA?
- Are health IT systems part of your risk analysis with appropriate agreements and BAAs in place that adequately manage risk?
- Can you show implementation of a recognized cybersecurity framework (NIST)?
- Class actions and regulatory penalties – are you adequately covered by cyber insurance?
- How are you managing risks related to breaches caused by your third-party relationships?
- What steps are you taking to prevent workforce errors that cause breaches or jeopardize security?
- Do you have multi-factor authentication and encryption deployed?
- How are you ensuring that record requests from patients are fulfilled timely (and complete) as required by HIPAA?
- Are you charging patients for copies of records? If so, are your charges compliant with HIPAA?
- Are you ensuring that all patient information is being maintained in the U.S., its territories, or Canada? This applies to your third-party vendors as well!

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Data Privacy & Security Landscape

- HIPAA
- State Breach Laws (FIPA)
- New Florida Data Storage Requirements
- Contractual Requirements & Vendor Risks
- OCR Access Initiative
- Security & Cyberattacks
- OCR Penalties Related to Ransomware Attacks
- 21st Century Cures Act
- Enforcement Actions
- Class Action Lawsuits

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Change Healthcare Cyberattack

- Change Healthcare processes 15 billion health care transactions annually and touches 1 in every 3 patient records, according to a letter sent to the U.S. Department of Health and Human Services from the American Hospital Association
  - *See https://abc7.com/unitedhealth-group-recovering-from-significant-cyberattack-ceo/14546734/*
- Broad impact to patient care, pharmacy operations, and providers
- Threat actor identified as ALPHV/Blackcat
- March 13, 20224 OCR issued a "Dear Colleague" letter and press release providing that it had already opened an investigation of Change Healthcare and UHG that "will focus on whether a breach of protected health information occurred and Change Healthcare's and UHG's compliance with the HIPAA Rules."
  - https://www.hhs.gov/sites/default/files/cyberattack-change-healthcare.pdf

Successful Cyberattacks On the Rise

- Drastic increase in successful and "post-mortem" cyberattacks
  - OCR reported recently that 74% of large breaches in 2023 were hacking/IT events
- Can greatly impact operations, relationships, and patients
- Resulting in regulatory investigations being instituted quickly
- OCR has begun issuing penalties and fines to entities having data breaches caused by cyberattacks
- Class actions now typically follow

OCR Expects Entities to Maintain Safeguards to Protect Against Cyberattacks

"Our settlement highlights how ransomware attacks are increasingly common and targeting the health care system. This leaves hospitals and their patients vulnerable to data and security breaches." said OCR Director, Melanie Fontes Rainer. "In this ever-evolving space, it is critical that our health care system take steps to identify and address cybersecurity vulnerabilities along with proactively and regularly review risks, records, and update policies. These practices should happen regularly across an enterprise to prevent future attacks."

https://www.hhs.gov/about/news/2023/10/31/hhs-office-civil-rights-settles-ransomware-cyber-attack-investigation.html

OCR Recommendations

- Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and that they address breach/security incident obligations
- Integrate risk analysis and risk management into business processes and ensure that they are conducted regularly, especially when new technologies and business operations are planned
- Ensure audit controls are in place to record and examine information system activity
- Implement regular review of information system activity
- Utilize multi-factor authentication
- Encrypt PHI to guard against unauthorized access
- Incorporate lessons learned from previous incidents into the overall security management process
- Provide training specific to organization and job responsibilities and on regular basis and reinforce workforce members' critical role in protecting privacy and security

See OCR's press release here: https://www.hhs.gov/about/news/2024/02/21/hhs-office-civil-rights-settles-second-ever-ransomware-cyber-attack.html

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Cybersecurity Newsletter: HIPAA Security Rule Security Incident Procedures

(October 2022)

Includes items to consider including in security incident response procedures:

- Designating appropriate/qualified personnel to be members of incident response teams
- Communication plans and contact information for notifying security incident response team members, management, and others when a security incident occurs
- Processes to identify the scope of security incidents, and instructions for managing incidents
- Creating and maintaining a list of assets (computer systems and data) to prioritize when responding to a security incident
- Conducting a forensic analysis (to identify the extent/magnitude of security incidents)
- Reporting the security incident to appropriate internal and external entities (*e.g.*, the regulated entity's IT and legal departments, local FBI Cyber Taskforce Field Office, federal and state regulatory authorities, and other individuals or entities as required)
- Processes for collecting and maintaining evidence of the security incident (*e.g.*, log files, registry keys, and other artifacts) to determine what was accessed during the security incident
- Processes for conducting regular tests of the security incident response process

Recognizes that the nature of incidents vary, but having specific processes for different types of incidents (such as ransomware attacks) can help ensure proper awareness and appropriate/timely incident response

https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity-newsletter-october-2022/index.html

Risk Considerations for ASCs

- Contingency & Emergency Mode Operations –
  - How will you operate, treat patients, and access records in the event of a cyber attack?
- Security incident response procedures to timely contain, mitigate, and investigate security incidents and ensure timely fulfillment of breach notification obligations
- Security related to all systems and electronic devices
- Ongoing risk analysis
- Policies and procedures
- How can you show compliance and defend claims and regulatory actions resulting from a cyberattack, regulatory investigation, data breach, etc.?
- Are complaints and potential incidents timely managed, responded to, and documented? Do not ignore complaints!

Critical Security Focus Areas in 2024

- Periodic and complete HIPAA Risk Analysis
- Data back-up, emergency mode operations, and contingency plans
- Auditing and monitoring
- Maintenance and review of system logs
- Multi-factor authentication
- Workforce awareness
- Adequate cyber-insurance coverage
- Good contracts with vendors to manage vendor risk
- Ensuring patient information is maintained in the U.S., its territories, or Canada
- Identify AI risks and security considerations
- Third party (including health IT) diligence

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Other Regulatory Developments

- HHS Updated Website Compliance Guidance on March 18, 2024
  - https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html
- Recognized Cybersecurity Frameworks & Video from the OCR
- OCR has been issuing penalties related to cyber attacks
- Investigations are active and moving quickly
- FIPA revision to include “any information regarding an individual’s geolocation”
- Increase in class action lawsuits related to data breaches
- Florida law changes related to where patient information is maintained
- NIST AI standards, guidance, and security framework
- Regulatory requirements impact claim activity

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OCR Regulatory Activity & Focus Areas in 2024

- Risk Analysis Enforcement Initiative *NEW
  - Must be accurate and complete
  - OCR reported that most large breach investigations reveal a lack of a compliant risk analysis
- Ensuring Access to PHI
- Hacking/Ransomware
  - Security Rule/NIST CSF
- Website Compliance
- Finalizing Proposed Changes to Privacy Rule*

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AI Security Risk Considerations

- Contracting & BAAs
- Where is the AI running?
- If AI is used for clinical systems and documentation, how is it verified?
- Ensure providers still understand responsibilities
- Data integrity
- Patient safety considerations
- Impact to existing systems
- NIST guidance, technical standards, and risk management framework
- FDA Requirements (where applicable)
- AI does not replace professional responsibility, judgment, and decision making!

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Other OCR Resources

- Cyber Attack Checklist
  - *See* Office of Civil Rights, Dep't of Health & Human Servs., My Entity Just Experienced a Cyber-attack! What Do We Do Now? A Quick-Response Checklist from the HHS, Office for Civil Rights (OCR), (last visited Oct. 4, 2021), https://www.hhs.gov/sites/default/files/cyber-attack-checklist-06-2017.pdf
- Ransomware Guidance
  - *See* Office of Civil Rights, Dep't of Health & Human Servs., Fact Sheet: Ransomware and HIPAA (July 11, 2016), https://www.hhs.gov/sites/default/files/RansomwareFactSheet.pdf?language=es
- OCR Security Newsletter and Security Series
- Prior Resolution Agreements
- SRA Tool: Office of the National Coordinator for Health Information Technology (ONC), SRA Tool File (last visited Oct. 4, 2021), https://www.healthit.gov/sites/default/files/SRA-Tool-3.2.msi
- NIST's Implementing the HIPAA Security Rule: A Cybersecurity Resource Guide, available at: https://csrc.nist.gov/pubs/sp/800/66/r2/final
- OCR Common Cyber Attacks Video: http://youtube.com/watch?v=VnbBxxyZLc8
- OCR Risk Analysis Video: https://www.youtube.com/watch?v=hxfxhokzKEU

Recognized Security Practices Video

- Identifies RSPs:
  - Section 2(c)(15) of NIST Act (NIST Cybersecurity Framework)
  - Section 405(d) of Cybersecurity Act of 2015 (HICP cybersecurity practices)
  - "Other" programs that address cybersecurity recognized by statute or regulation
- Must demonstrate RSPs in place for previous 12 months (documentation key)
- Can be considered to *mitigate* civil monetary penalties and other limit exposure involving other remedies and audits
- Links to resources regarding the three frameworks are included at the conclusion of the presentation

See video presentation found on OCR's YouTube channel at: https://youtu.be/e2wG7jUiRjE

Recognized Security Practices Video

- Adopting recognized cybersecurity framework is still voluntary
- Entities under investigation or selected for an audit may be invited to submit data/information related to implemented recognized cybersecurity frameworks (data request)
- The data request may include examples of the type of evidence that may be provided
- Show actively in use (and for past 12 months) and fully implemented throughout the organization

See video presentation found on OCR's YouTube channel at: https://youtu.be/e2wG7jUiRjE

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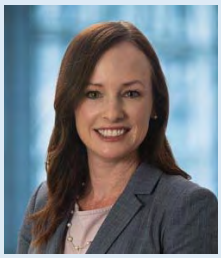

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Medication Management

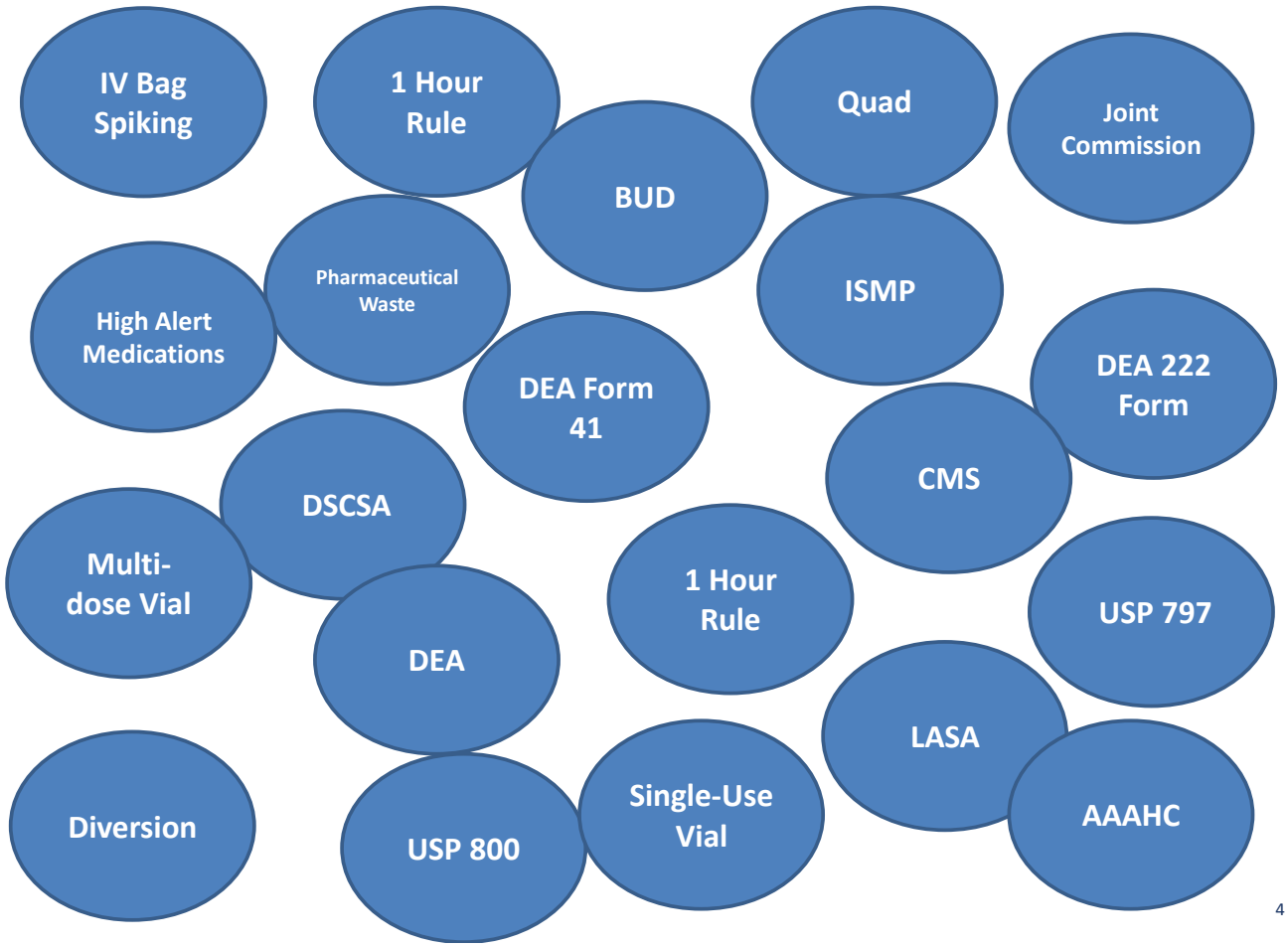
Pharmacy News & Essentials for ASC Leaders
2024

Michael O'Neal, D.Ph. BS Pharm, MBA
ASC Pharmacist Consultant

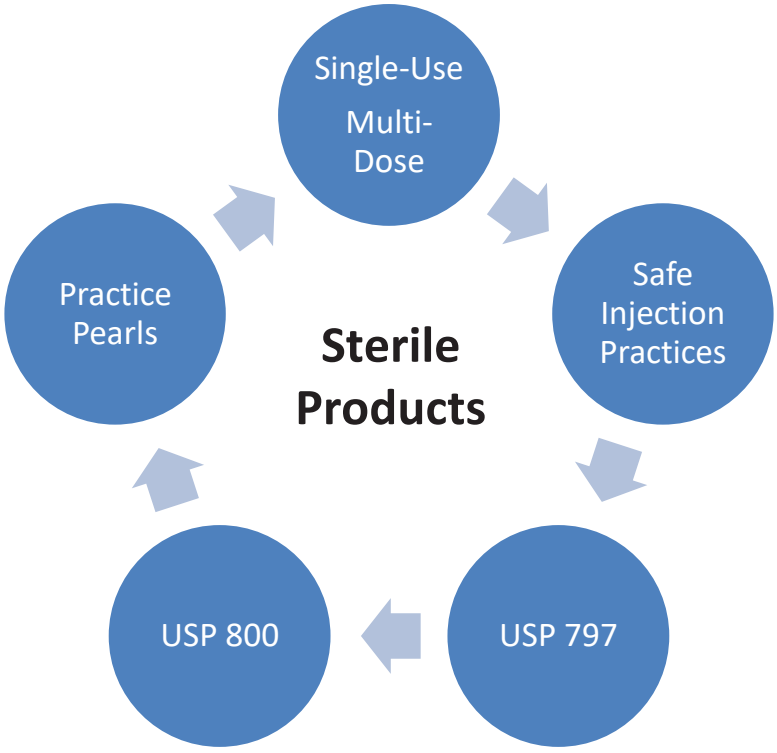
Learning Objectives

- Medication Management Updates - 2024
- Safety, Compliance and Best Practices
  - Accreditation, Regulations, Laws
- Highlights : Sterile products, USP 797/800, DEA, Emergency Management, Drug Shortages
- Practical, Informative, Interactive

Today's Topics



Sterile Products



Single-Use Vials

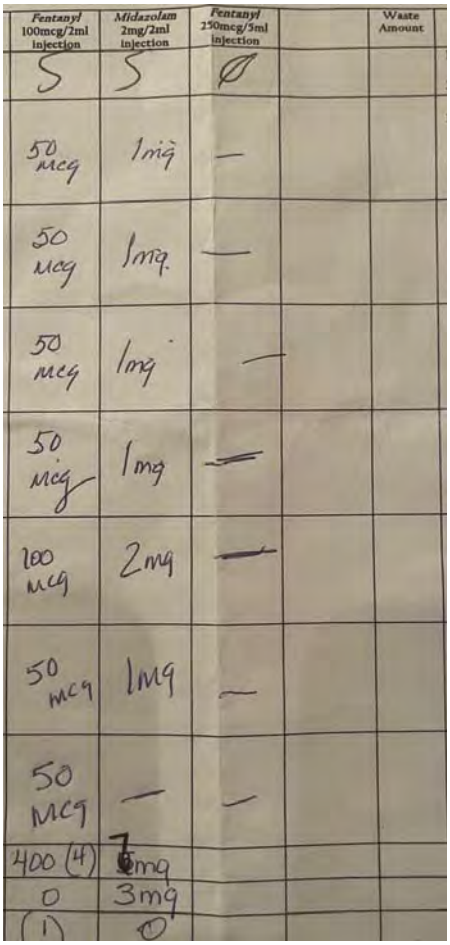
Multi-Dose Vials

Single-Use Vials

- No Preservatives
- **Never** use on more than 1 patient
- Discard after use on single patient
- Includes common Anesthesia Meds (midazolam, fentanyl, morphine, etc.)

Multi-Dose Vials

- Contains preservatives – no viral protection
- 28-day BUD outside of Procedural Areas
  - Aseptic Technique
  - Dated, Initialed
- ***Becomes Single-Dose when used within a patient treatment area*** (possible contamination)
- Waste it possible contamination!



Fentanyl 100mcg/2ml injection	Midazolam 2mg/2ml injection	Fentanyl 250mcg/5ml injection		Waste Amount
5	5	Ø		
50 mcg	1mg	—		
50 mcg	1mg	—		
50 mcg	1mg	—		
50 mcg	1mg	—		
100 mcg	2mg	—		
50 mcg	1mg	—		
50 mcg	—	—		
400 (4)	5mg			
0	3mg			
(1)	0			

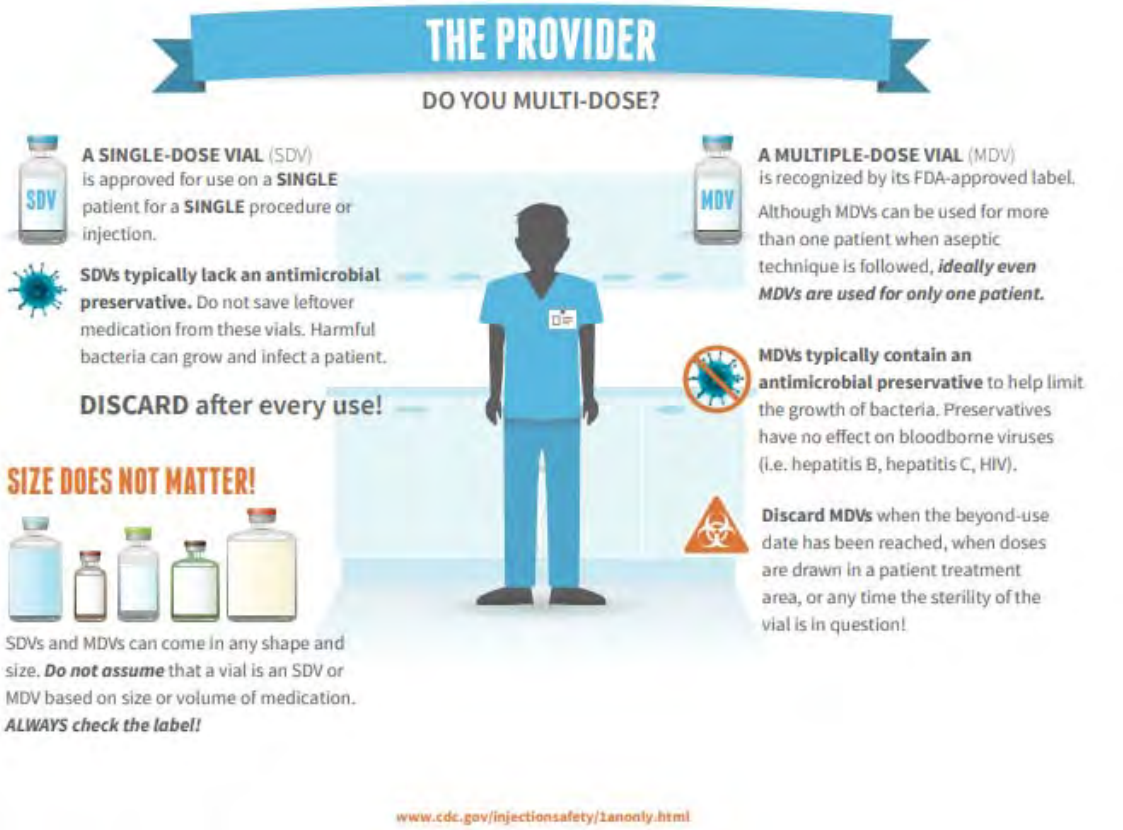
- Single-Use Vial
- Labeling / Storage
- Used in patient treatment area
- Anesthesia 'through-put'
- Drug Shortage implications
- Cost implications
- CDC / FDA / USP 797

Most controlled substances are single-use

CDC's Position — Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials

The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use. Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to healthcare providers. CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines (http://www.fda.gov/DrugShortageReport). CDC 's priority is protecting patients from harm. CDC routinely investigates and is apprised of infectious disease outbreaks involving single-dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant healthcare and legal expenses. Therefore, CDC continues to strongly support its current policies regarding single-dose/single-use vials. It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single-dose/single-use vials, as stated in United States Pharmacopeia General Chapter ‹797› Pharmaceutical Compounding – Sterile Preparations.

https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html



https://www.cdc.gov/injectionsafety/pdf/Injection-Safety-For-Healthcare-P.pdf

https://www.cdc.gov/injectionsafety/pdf/Injection-Safety-For-Healthcare-P.pdf

INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care*.

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare providers to safe injection practices. Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.

Injection Safety	Practice Performed?	If answer is No, document plan for remediation
Proper hand hygiene, using alcohol-based hand rub or soap and water, is performed prior to preparing and administering medications.	Yes No	
Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes No	
Single-dose or single-use medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes No	
Medication administration tubing and connectors are used for only one patient.	Yes No	
Multi-dose vials are dated by healthcare when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.	Yes No	
Multi-dose vials are dedicated to individual patients whenever possible.	Yes No	
Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). Note: If multi-dose vials enter the immediate patient treatment area, they should be dedicated for single-patient use and discarded immediately after use.	Yes No	

https://www.cdc.gov/injectionsafety/PDF/Safe-Injection-Checklist-P.pdf

STERILE PRODUCTS

What is 'USP'?

- **United States Pharmacopeia (USP)**
  - Established in 1820
  - Non-Profit / Non-governmental
  - Mission to "improve global health through public standards and related programs that help ensure QUALITY, SAFETY and BENEFIT of medications and foods"
  - Gold Standard for sterile and non-standard Pharmaceutical Compounding
  - USP 797 / USP 800 – Most applicable to ASCs
  - 797 Revisions finalized after delay on **11/1/22**
    - 1-year implementation period

www.usp.org

Resources

- USP <797> FAQs
- USP <797> Commentary
- USP General Chapter Education Courses
- Sign up for USP Healthcare Quality & Safety Updates

USP 797 Updates
November 1, 2022

⟨797⟩ Revisions

Immediate-Use CSPs

Requirements for Immediate-Use CSPs
Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
The preparation involves not more than 3 different sterile products.
Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.

www.usp.org

What is a 'sterile product' according to USP 797?

Pharmaceutical Compounding – Sterile Preparations

REVISIONS TO <797> | OFFICIAL STATUS NOTIFICATION | ACCESS <797> VIA COMPOUNDING COMPENDIUM

SIGN UP FOR COMPOUNDING UPDATES

Millions of medications are compounded each year in the US to meet the unique needs of patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Medications that are required to be sterile include those administered through injection, intravenous infusion (IV), intraocular (injection in the eye) or intrathecal (injection in the spine).

Understanding the risks inherent in sterile compounding and incorporating established standards are essential for patient safety. Compounded medications made without the guidance of standards may be sub-potent, super potent or contaminated, exposing patients to significant risk of adverse events or even death.

USP develops standards for preparing compounded sterile medications to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing.

3. What is the definition of sterile compounding?

For purposes of General Chapter <797>, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. However, administration and preparation per the manufacturer's approved labeling are out of the scope of the chapter as described in *1.2 Administration* and *1.4 Preparation Per Approved Labeling*, respectively.

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USP 797 / 800
Administration is now 'out of scope'

17. Is administration out of the scope of the chapter?

Yes. The intent of the chapter is to establish minimum standards for practitioners when compounding sterile products in order to minimize harm, including death, to human and animal patients. The scope of the chapter is intended to ensure a CSP maintains its integrity up until the time when administration begins. Standard precautions such as the Centers for Disease Control and Prevention's (CDC's) safe injection practices apply to administration (see *1.2 Administration*).

20. Is withdrawing a dose from a container of a conventionally manufactured sterile product or spiking an IV bag, without any further manipulation, for immediate administration to a patient considered compounding?

No, withdrawing a dose from a container or spiking an IV bag of a conventionally manufactured sterile product without any further manipulation is considered administration rather than compounding and is out of the scope of <797>. If the dose is further mixed with another product, it would be considered compounding and subject to the requirements of <797>.

21. Is spiking IV fluids (taking IV spikes and putting them into a bag; putting a set into an IV bag) considered compounding?

No, a facility's policies and procedures regarding spiking IV fluids is outside the scope of the chapter.

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Who does USP 797 / USP 800 apply to?

4. To whom do the standards in General Chapter <797> apply?

This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites. Any person entering a sterile compounding area, whether preparing a CSP or not, must meet the requirements in *3. Personal Hygiene and Garbing*.

Please note, compounding of sterile hazardous drugs (HDs) must additionally comply with General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*.

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It is *NOT* Compounding if…….

USP 797 – Section 1.3

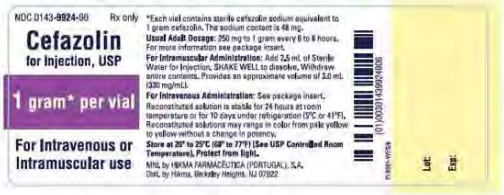
- **Aseptic technique** is used
- Processes are in place to **minimize contact w/ non-sterile surfaces**, **introduction of particulate matter/body fluids, and no mix-ups w/ other products or CSPs**
- **Physical & chemical compatibility** are evidence-based & confirmed
- The preparation involves **not more than 3 different sterile products**
- Unused, **single-use drugs** involved are discarded after preparation and **NEVER used on more than 1 patient**
- **Must be labeled** if administered by someone other than the preparer or preparer does not witness administration
  - 1) Drug names including diluent 2) Initials of preparer 3) 4-hour BUD

……it is also *NOT* compounding, when……

(USP 797 – Section 1.4)

Compounding ***does not*** include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided **(the Package Insert)** by the manufacturer and other directions from the manufacturer (supplemental information from manufacturer).

1. **The product is prepared for a single dose for an individual patient.**
2. **The package insert includes information for:**
   1. **Correct diluent to use**
   2. **Final strength/concentration of the product**
   3. **Container closure system (bag, syringe, etc.)**
   4. **Storage time**



https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1dc9de56-e259-4546-a1db-23119a8a088e&type=display

RECONSTITUTION

Preparation of Parenteral Solution

Parenteral drug products should be SHAKEN WELL when reconstituted, and inspected visually for particulate matter prior to administration. If particulate matter is evident in reconstituted fluids, the drug solutions should be discarded.

When reconstituted or diluted according to the instructions below, Cefazolin for Injection is stable for 24 hours at room temperature or for 10 days if stored under refrigeration (5°C or 41°F). Reconstituted solutions may range in color from pale yellow to yellow without a change in potency.

Single-Dose Vials

For IM injection, IV direct (bolus) injection or IV infusion, reconstitute with Sterile Water for Injection according to the following table. SHAKE WELL.

Vial Size	Amount of Diluent	Approximate Concentration	Approximate Available Volume
500 mg	2 mL	225 mg/mL	2.2 mL
1 gram	2.5 mL	330 mg/mL	3 mL

ADMINISTRATION

Intramuscular Administration

Reconstitute vials with Sterile Water for Injection according to the dilution table above. Shake well until dissolved. Cefazolin for Injection should be injected into a large muscle mass. Pain on injection is infrequent with Cefazolin for Injection.

Intravenous Administration

Direct (bolus) injection: Following reconstitution according to the above table, further dilute vials with approximately 5 mL Sterile Water for Injection. Inject the solution slowly over 3 to 5 minutes, directly or through tubing for patients receiving parenteral fluids (see list below).

Intermittent or continuous infusion: Dilute reconstituted Cefazolin for Injection in 50 to 100 mL of 1 of the following solutions:

- Sodium Chloride Injection, USP
- 5% or 10% Dextrose Injection, USP
- 5% Dextrose in Lactated Ringer's Injection, USP
- 5% Dextrose and 0.9% Sodium Chloride Injection, USP
- 5% Dextrose and 0.45% Sodium Chloride Injection, USP
- 5% Dextrose and 0.2% Sodium Chloride Injection, USP
- Lactated Ringer's Injection, USP
- Invert Sugar 5% or 10% in Sterile Water for Injection
- Ringer's Injection, USP
- 5% Sodium Bicarbonate Injection, USP

So what is 'in scope'?

- Repackaging of all Sterile Products

16. Does the chapter apply for repackaging of a conventionally manufactured sterile product?

Yes, repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements in this chapter.

- Preparation of more than 3 different sterile products

22. When compounding immediate-use CSPs, may more than three individual containers of a sterile product be used?

The immediate-use CSPs provision states that the preparation must not involve more than 3 different sterile products. Two or more of the same sterile components (product) may be used as long as there are not more than three different sterile components (products). For example, two vials of the same component (drug product) are reconstituted using two vials of *Sterile Water for Injection* (component products) and added to a single component product intravenous diluent bag such as NS or D5W. As another example, when the CSP requires combining 4 vials of the same component (drug product) into a single component product intravenous bag of diluent, only 2 different sterile components (products) are used to prepare the CSP. Both examples may be considered immediate- use as long as the criteria listed in *1.3 Immediate-Use CSPs* are met.

- Any deviation from the Package Insert

26. Is it considered compounding if the steps used to prepare a single dose of a conventionally manufactured product are different from the directions contained in the manufacturer's approved labeling?

Yes. Any compounding (e.g., mixing, reconstituting) that is not performed according to the manufacturer's approved labeling is considered sterile compounding and is subject to the requirements in the chapter.

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Naropin®

(ropivacaine HCl) Injection

Rx only

DESCRIPTION:

Naropin® Injection contains ropivacaine HCl which is a member of the amino amide class of local anesthetics. Naropin Injection is a sterile, isotonic solution that contains the enantiomerically pure drug substance, sodium chloride for isotonicity and water for injection. Sodium hydroxide and/or hydrochloric acid may be used for pH adjustment. It is administered parenterally.

Ropivacaine HCl is chemically described as S-(-)-1-propyl-2',6'-pipecoloxylidide hydrochloride monohydrate. The drug substance is a white crystalline powder, with the following structural formula:

At 25°C ropivacaine HCl has a solubility of 53.8 mg/mL in water, a distribution ratio between n-octanol and phosphate buffer at pH 7.4 of 14:1 and a pKa of 8.07 in 0.1 M KCl solution. The pKa of ropivacaine is approximately the same as bupivacaine (8.1) and is similar to that of mepivacaine (7.7). However, ropivacaine has an intermediate degree of lipid solubility compared to bupivacaine and mepivacaine.

Naropin Injection is preservative-free and is available in single dose containers in 2 (0.2%), 5 (0.5%), 7.5 (0.75%) and 10 mg/mL (1%) concentrations. The specific gravity of Naropin Injection solutions range from 1.002 to 1.005 at 25°C.

Solutions should be stored at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

The container closure is not made with natural rubber latex.

These products are intended for single dose and are free from preservatives. Any solution remaining from an opened container should be discarded promptly. In addition, continuous infusion bottles should not be left in place for more than 24 hours.

NAROPIN is a trademark of Fresenius Kabi USA, LLC.

USP 797 / Single-Use

24. Can a single-dose container be used to prepare doses for more than one patient when compounding an immediate-use CSP?

No. One of the conditions of the immediate-use CSP provision specifies that any unused starting components from a single-dose container must be discarded after preparation for the individual patient is complete. Single-dose containers must not be used for more than 1 patient when used for preparing immediate-use CSPs.

30. What is the difference between compounding and what is described in *1.4 Preparation Per Approved Labeling?*

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer if the product is prepared as a single dose for an individual patient and the approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time.

1-Hour → 4-Hour Rule

NEW

25. Why does the immediate-use CSP provision allow for administration to begin within 4 hours following the start of the preparation?

The immediate-use CSP provision was revised to allow up to 4 hours for beginning administration to balance the need for ensuring CSP quality with timely access to medication in a variety of healthcare settings. The allowance of up to 4 hours was based on the 4-to-6-hour lag phase of microbial growth, during which potential bacterial cells are adjusting to their environment and change very little, and they do not immediately start reproducing.[1] In the event bacterial cells were inadvertently introduced into a CSP during compounding, replication is unlikely and therefore there is a window of time in which a CSP can be held prior to administration.

[1] References:

- Daquigan N et al. Early recovery of *Salmonella* from food using a 6-hour non-selective pre-enrichment and reformulation of tetrathionate broth. *Front Microbiol*. 2016;7:2103.
- Jarvis, Basil. *Statistical Aspects of the Microbiological Examination of Foods, Third Edition*. Academic Press, 2016.
- Ryan, Kenneth et al. *Sherris Medical Microbiology, Sixth Edition*. McGraw-Hill Education, 2014.
- Wang J et al. A novel approach to predict the growth of *Staphylococcus aureus* on rice cake. *Front Microbiol*. 2017;8:1140.

38. Do facilities have to change their standard operating procedures (SOPs) and practices for immediate-use from 1 h to 4 h?

No, facilities may choose to maintain the 1-hour limit for administration of immediate-use CSPs, however increasing the time to 4 hours would be considered acceptable.

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4-Hour Rule Exceptions

- If the PI states otherwise

18. Does a conventionally manufactured sterile product prepared for administration to a single patient in accordance with manufacturer's approved labeling outside of ISO Class 5 conditions have to be administered within 4 hours of reconstitution or mixing if it meets all the conditions in *1.4 Preparation Per Approved Labeling*?

No. When all of the conditions in *1.4 Preparation Per Approved Labeling* are met, the storage information in the manufacturer's approved labeling may be followed.

- If center chooses to stay with 1-Hour rule

38. Do facilities have to change their standard operating procedures (SOPs) and practices for immediate-use from 1 h to 4 h?

No, facilities may choose to maintain the 1-hour limit for administration of immediate-use CSPs, however increasing the time to 4 hours would be considered acceptable.

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Sterile Products 'Designated 'Person'

10. Who can be the designated person(s)?

The designated person is one or more individuals assigned by the facility to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded sterile preparations (CSPs). Facilities must determine whether they have one or more designated person(s), select the designated person(s), and determine how to allocate responsibility if there is more than one designated person. The designated person(s) can delegate activities to an assigned trainer provided that is described in the organization's policies.

32. What qualifications must a designated person have?

This must be determined by the facility's SOPs. Some states and accreditation organizations have more specific guidance.

- One or more individuals – designate specific responsibilities if more than one
- Responsible and accountable for compounded sterile products (CSP) in facility
- Write in SOPs

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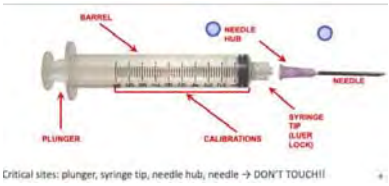
Competencies now required

41. What are the training and competency assessment requirements for personnel who only prepare immediate-use CSPs?

Training and competency assessment requirements are determined by the specific tasks performed and the facility's SOPs, and must include aseptic processes to minimize the potential for contact with nonsterile surface surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.

42. How often does the training and competency of personnel who perform immediate-use products need to be performed?

Section *1.3 Immediate-Use CSPs* requires that personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. No specific frequency is identified for training and competency of personnel who perform compounding of immediate-use CSPs.



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https://ashpadvantage.com/expert-insight/dos-and-donts-of-usp-chapter-797-personnel-training/

INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care.*

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare providers to safe injection practices. Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.

Injection Safety	Practice Performed?	If answer is No, document plan for remediation
Proper hand hygiene, using alcohol-based hand rub or soap and water, is performed prior to preparing and administering medications.	Yes No	
Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes No	
Single-dose or single-use medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes No	
Medication administration tubing and connectors are used for only one patient.	Yes No	
Multi-dose vials are dated by healthcare when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.	Yes No	
Multi-dose vials are dedicated to individual patients whenever possible.	Yes No	
Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). Note: If multi-dose vials enter the immediate patient treatment area, they should be dedicated for single-patient use and discarded immediately after use.	Yes No	

https://www.cdc.gov/injectionsafety/PDF/Safe-Injection-Checklist-P.pdf

New Ophthalmic Product Process
No more 28 day BUD

179. Are conventionally manufactured sterile topical ophthalmic products considered multiple-dose containers?

No, <659> *Packaging and Storage Requirements* defines multiple-dose containers as a container closure system that holds a sterile medication for parenteral administration (injection or infusion) that has met antimicrobial effectiveness testing requirements, or is excluded from such testing requirements by FDA regulation. Therefore, the requirement that multiple-dose containers not be used for more than 28 days unless otherwise specified on the labeling does not apply to conventionally manufactured sterile topical products.

- Eye drops and ointments may be used through the manufacturer's expiration date after being opened.
- If contamination is suspected, immediately discard. If the product is designated 'Single-Use' by the FDA, it can only be used on 1 patient.
- Always follow the **Package Insert** for BUD guidance.

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USP 797 Update FAQs

43. Is the use of dispensing pins allowed per <797>?

The chapter does not address the use of specific disposable supply items other than to say supplies in direct contact with the CSP must be sterile and depyrogenated. It is the responsibility of the facility to determine the appropriateness of specific items, including dispensing pins.

file:///C:/Users/User/Downloads/USP22_HQS_Compounding_797_FAQ_Document_V2a.pdf

USP 797 Immediate-Use Summary

- Compounding involves no more than 3 different sterile products
- If more than 3 products, must be compounded is ISO environment (compounding pharmacy)
- Aseptic Technique : Clean surface / Clean hands/ Alcohol swab & dry
- **1-hour to 4-hour rule - refer to package insert**
- Label if not administered or witnessed by the preparer
- Label must include name of drug/diluent, Initials of preparer, BUD time
- Avoid pre-drawing doses when possible

USP 800

(in accordance with USP 797)

Hazardous Drug Handling

https://www.prsrx.com/usp800track/

What are Hazardous Drugs?

- Carcinogenic
- Developmental Toxicity (including teratogenicity)
- Reproductive toxicity
- Genotoxic
- Organ toxicity at low doses

USP 800

KNOW YOUR EXPOSURE TO HAZARDOUS DRUGS

Help minimize your risk with the USP <800> HazRx® mobile app

What is the exposure?

usp.org

More than **8 million**

U.S. healthcare workers are exposed to hazardous drugs every year[1]

More than **12 billion**

doses of hazardous drugs are handled

Drugs are classified as **hazardous** when they possess any of **these characteristics**[1]:

- Impact or damage DNA/genes
- Cause cancer
- Contribute to infertility
- Impact a developing embryo or fetus
- Cause developmental abnormalities
- Cause organ damage
- Have a similar structure or function to drugs that are determined to

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

Who is at risk?

Anyone handling hazardous drugs is at risk of exposure[1]

- Pharmacists
- Pharmacy Technicians
- Nurses
- Physicians
- Surgeons
- Physician Assistants
- Respiratory Therapists
- Home Health Aides
- Nurses' Aides
- Housekeeping
- Janitorial Services
- Environmental Services
- Veterinarians
- Veterinarian Technicians
- Veterinarian Assistants

Where can exposure occur?

Exposure can take place in any healthcare setting[1,6]

USP 800

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

USP 800

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

USP 800

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

1) Identify 'Point' Person to Oversee

2) Assessments / Build Plan

3) Develop center Hazardous Drug List

4) Assessments of Risk (AOR)

5) Implement

USP 800

5 Steps to Success

1) Identify 'Point' Person

Understanding of USP 800

Work with Consultant Pharmacist

Risks to Staff / Policy Plan

Risks of Non-Compliance

Assessing Compliance Risks

Policies / SOPs

Work with Staff to develop

Overall Compliance Plan

Employee Competencies

Annual Risk Assessments

Day to Day Oversight

2) Assessments

Exposure Risks / Processes : Receiving, Storage, Use, Disposal

Personnel Assessment

Who is exposed? How often exposed?

Safe Work Practices/Processes

Proper Use of PPE

Preparation/Administration/ Disposal

Policies / SOPs

3) Develop Haz Drug List

2016 CDC NIOSH List

Not EPA or OSHA List

NIOSH Hazardous Drug List / Formulary Cross Reference

Formulary Deletions if possible

Examples in each NIOSH Table

Table 1	• **Mitomycin (Mitosol™)** • Hydroxyurea • Megestrol • Methotrexate • Tamoxifen
Table 2	• Estradiol – Estrace™ • Carbamazepine – Tegretol™ • Phenytoin - Dilantin™ • Spironolactone
Table 3	• Oxytocin – Pitocin™ • Testosterone • Warfarin – Coumadin™

4) Create Assessment of Risks

Drug/Risk Group/Dose Form/Exposure Risk/Packaging/PPE

Inform Staff of Drugs/Risks

Review Annually
(during Formulary review)
Staff Competencies /Acknowledgement

Drug Name / Strength
Hazardous Group Packaging
Dose Form
Risk of Exposure
Storage
PPE

Documentation

5) Implementation

PPE Assessment

Gloves, Gowns, Disposal

Label

HD storage / Receiving & Storage Areas

Staff Competency

Storage and Use

Label as Hazardous Drug

Closed-System Transfer Devices (CSTD)

When applicable

Spill Kits

Waste bins

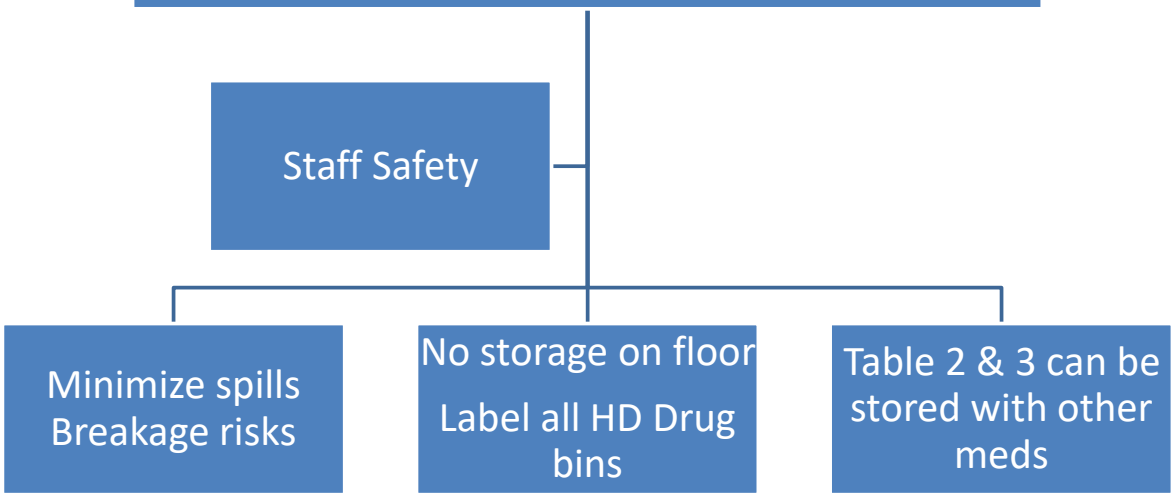
Assessment of Risk Example

USP 800 ASSESSMENTS OF RISK

Drug	Hazardous Grouping	Packaging	Form	Risk of Exposure	Storage	Single -Double Glove	Chemo Gown	Eye Protection	N-95
Bevacizumab (Avastin)	Group 1 / Antineoplastic	Prep from 503B Pharmacy	Syringe	Reproductive / Teratogenic	Individual bin / Leave in packaging from pharmacy until ready for use	Double	Yes	Yes if risk to eye exposure	No
Cytotec (misoprostol)	Group 3 / Reproductive	Bottle	Tablet	Fertility / Fetal	Bottle until dispense	Single	No	No	No
Estrace Cream	Group 2 / Non-Antineoplastic	Tube	Topical	Reproductive risk - Black Box warning - Cardivascular risk,	Indivudal bin	Single	No	No	No
Methylergonovine injection	Group 3 / Reproductive	Vial/Amp	Inject	Uterotonic effects	Individual bin	Single	No	No	No
Mitomycin Ophthalmic	Group 1 / Antineoplastic	Prep from 503B Pharmacy	Syringe	Mutagenic risk / Cancer	Individual bin / Leave in packaging from pharmacy until ready for use	Double	Yes	Yes if risk to eye exposure	No
Oxytocin Injection	Group 2 / Non-Antineoplastic	Unit of Use - Vial	Injection	Reproductive risk for women - potential spontaneous labor	Individual bin	Single	No	Yes if risk to eye exposure	No
Phenytoin Injection	Group 2 / Non-Antineoplastic	Unit of Use - Vial	Injection	Fertility risk	Individual bin				
Premarin Cream	Group 2 / Non-Antineoplastic	Tube	Topical	Reproductive risk - Black Box warning - Cardivascular risk,	Indivudal bin	Single	No	No	No

- Reviewed Annually as part of Formulary Review
- Imbed into Annual Competency Process
- Inform Staff of all exposure risks
- Staff acknowledgement
- Documentation

Hazardous Drug Storage



PPE Suggestions for Hazardous Drugs:

Receiving / Preparing / Handling / Administration / Spill Cleaning

Single Gloves: Table 2 Drugs	**Double Gloves:** Table 1 Drugs & Table 2 Drugs for contaminated Body fluids / Spills / Cleaning	**Chemo Gown:** Table 1 Drugs & Table 2 Drugs for contaminated Body fluids / Spills / Cleaning	**Eye Protection:** Table 1 &2 Drugs if potential for exposure	**Respiratory Protection:** Table 1 &2 Drugs if potential for exposure

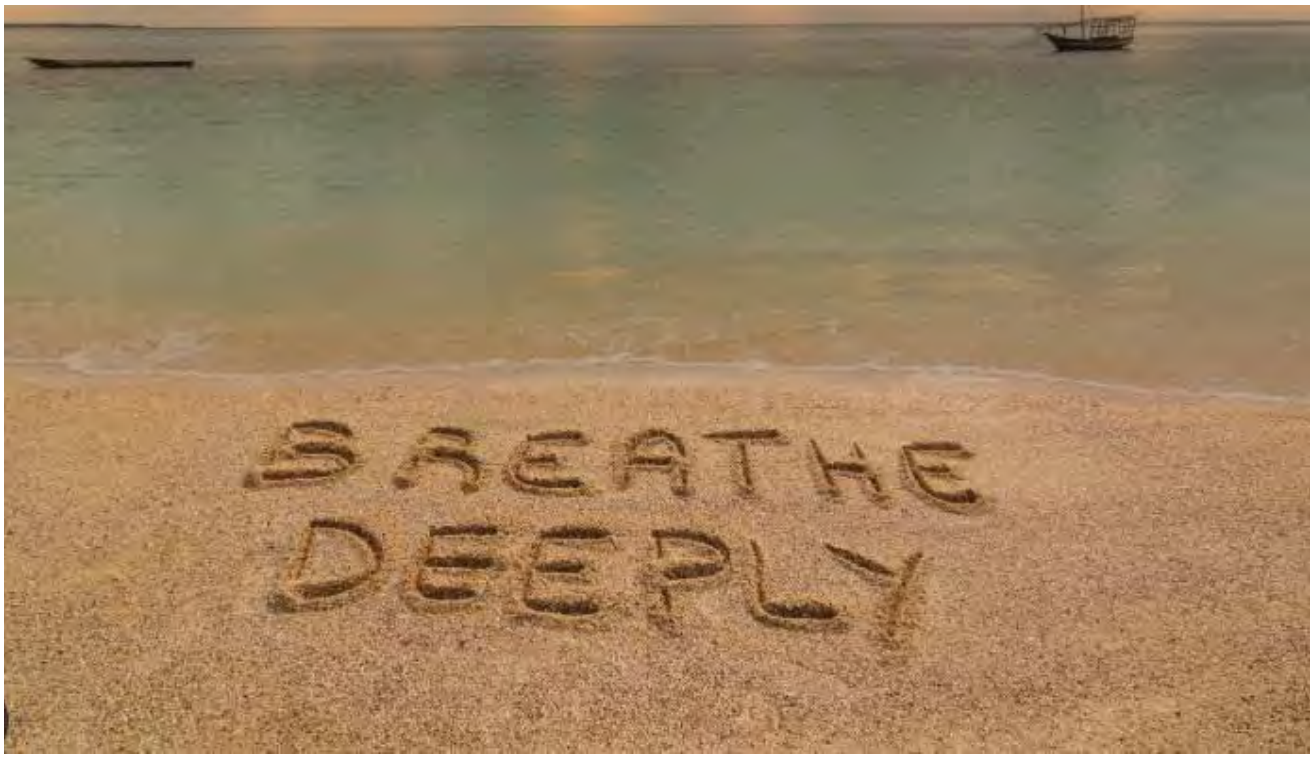
Work with your Consultant Pharmacist

Hazardous Drug -- ASC Impact

- All Table 1 Meds ***compounded by a Qualified Pharmacy***
  Table 1 drugs should not be stored in ASC prior to compounding * Final Finished Form assessment
- Table 2 /3 Meds – Not many used in ASC / Perform AOR / Educate & Inform / Label
- Assess Receiving/Storing processes. PPE availability, Waste containers, Spill Kit and process

Best Practice or Bad Practice?

Best Practice or Bad Practice?



Controlled Substances in the ASC

Controlled Substance Management

Controlled Substance Best Practices

- Closed-loop processes / Count sheets mirror cabinet order
- Clear/Concise documentation / Initial changes
- 2 licensed staff involved in each process
- Secure at ***ALL*** times
- Discovery / Disciplinary processes
- DEA 222 (C-IIs) & official invoice (C-III – C-V) transfers
- Third-Party verification / review (Pharmacist)

Controlled Substances in the ASC

- Annual assessment of controlled substance use at your ASC
- Biennial Inventory (recommend annually as Best Practice)
- Cameras over narcotic cabinets / Change lock codes regularly
- Knowledge of State Laws / Prescriber Law / E-Prescribing
- Prescribing from ASC versus Office-based
- Controlled Substance Monitoring Database (CSMD)
- Accrediting Body Guidance of Opioid Management (TJC)

DEA Registration process

- Medical School
- Graduation Year
- NPI
- State License #
- License Exp Date
- Name of facility / Medical Director
- Email contact- if they move
- Don't let expire!
- New DEA # for all changes to Medical Director
- CSOS breaks
- Must transfer narcotics via invoice and 222
- Initial count
- Keep paperwork on old DEA for 2 years

- Any Medical Director change prompts new DEA #
- Retire prior DEA license with initiation of new DEA
- Transfer controlled substances from old DEA to new DEA
- Perform Initial Inventory count

DEA Forms

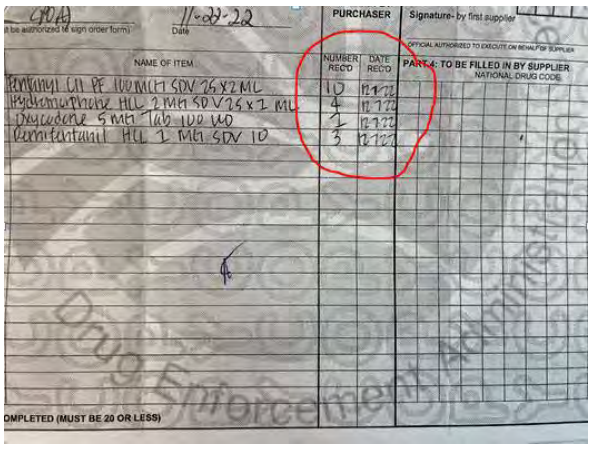
All available at www.deadiversion.usdoj.org

- **DEA Form 106**
  - Theft/Significant Loss
  - Complete once investigation complete
  - Also, report in writing (email) within ***one business day*** ****
  - Work with local DEA Field or Division Office
  - 45 days to complete after discovery of loss – gather all facts

- **DEA Form 41**
  - Destruction process **within facility**
  - Only for **stocked inventory** (not for waste associated with clinical use)
  - Only if waste is 'non-retrievable'
  - No flushing down sink/toilet

- **DEA Form 222**
  - Ordering / Transferring of C-II's ONLY
  - POA
    - Designated by facility in writing
    - Must be rescinded with changes

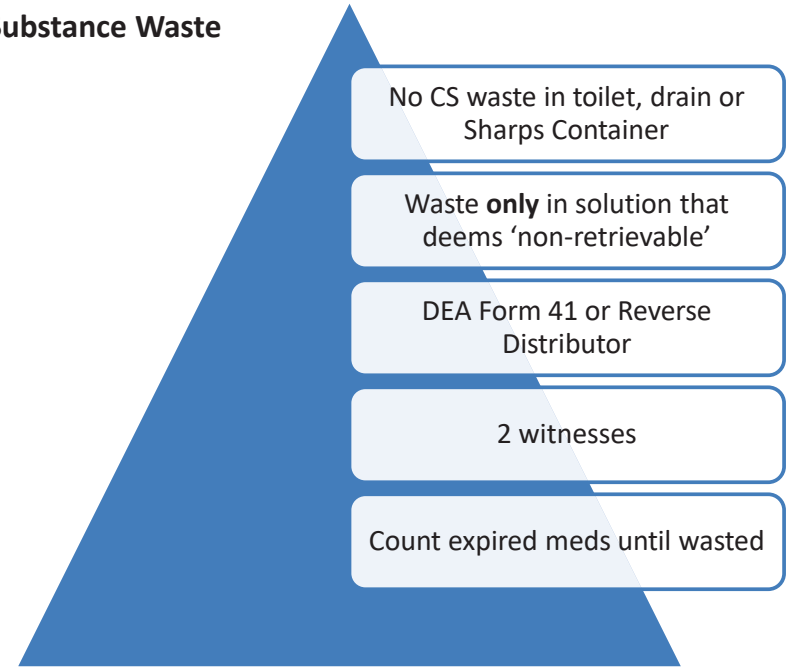
Close DEA 222/CSOS Process



Line #	# of Pkgs ordered	Size of Pkgs	Name of Item	National Drug Code	# of Pkgs Shipped	# of Packages Received	Date Received	Sub
1	2	PK	Fentanyl Citrate, Preservative Free 50 mcg / mL Injection Vial 2 mL CII	00409909422	2	2	2023-11-08	
2	1	BX	Oxycodone HCl / Acetaminophen 5 mg - 325 mg Tablet Blister Pack 100 Tablets CII	00406051262	1	1	2023-11-08	
4	1	CT	Hydromorphone HCl 1 mg / mL Injection Prefilled Syringe 1 mL CII	00409128331	1	1	2023-11-08	
5	1	BX	Oxycodone HCl 5 mg Tablet Blister Pack 100 Tablets CII	42858000110	1	1	2023-11-08	

- Complete Section 5 of 222 Form
- Electronically close CSOS
- Copies for DEA Investigator

Controlled Substance Waste



'Non-Retrievable' – " a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable or unusable for all practical purposes. 21 CFR 1300.05(b)

DEA Form 41
For Internal Waste

https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html

- Complete Form Fully
- Waste as 'irretrievable'
- File with narcotic documentation
- Save for 2 years – does not have to be submitted to DEA


Registrant Record of Controlled Substances Destroyed - DEA Form 41

Destruction of Controlled Substances

IMPORTANT NOTICE: Only those persons registered with and authorized by DEA to handle controlled substances may utilize/submit this form.

Registrant Record of Controlled Substances Destroyed - DEA Form 41 (PDF)

INSTRUCTIONS

Registrant Record of Controlled Substances Destroyed - DEA Form 41

Get Email Updates!

OMB APPROVAL NO. 1117-0007 Expiration Date 9/30/2017

U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION

REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED

FORM DEA-41

A. REGISTRANT INFORMATION

Registered Name:		DEA Registration Number:
Registered Address:		
City:	State:	Zip Code:
Telephone Number:		Contact Name:

B. ITEM DESTROYED

1. Inventory

	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
Examples	*16590-598-60*	*N/A*	*Kadian*	*60mg*	*Capsules*	*60*	*2*	*0*	*120 Capsules*
	0555-0767-02	*N/A*	*Adderall*	*5mg*	*Tablet*	*100*	*0*	*83*	*83 Tablets*
	9050	*B02120312*	*Codeine*	*N/A*	*Bulk*	*1.25 kg*	*N/A*	*N/A*	*1.25 kg*
1.									
2.									
3.									
4.									
5.									
6.									
7.									

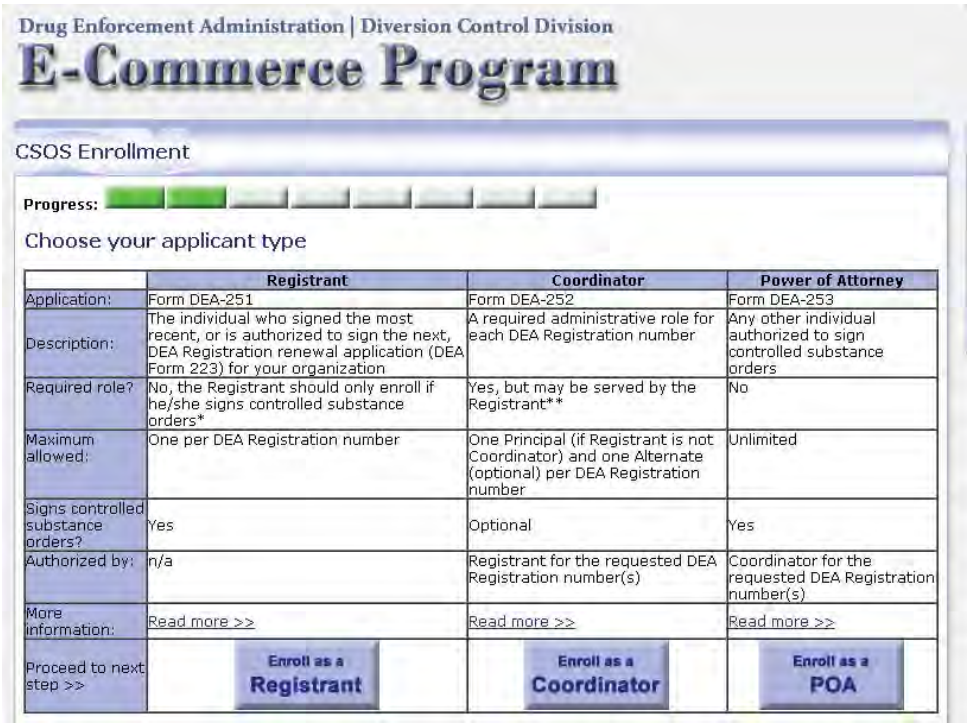
2. Collected Substances

	Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
Examples	*X*		*MBP1106, MBP1108 - MBP1110, MBP112*	*N/A*	*5*
		X	*CRL1007 - CRL1027*	*15 gallon*	*21*
		X	*CRL1201*	*5 gallon*	*1*
1.					
2.					
3.					
4.					
5.					
6.					
7.					

Form DEA-41 *See instructions on reverse (page 2) of form.*

Non-Retrievable waste examples

Controlled Substance Ordering System (CSOS)



Drug Enforcement Administration | Diversion Control Division

E-Commerce Program

CSOS Enrollment

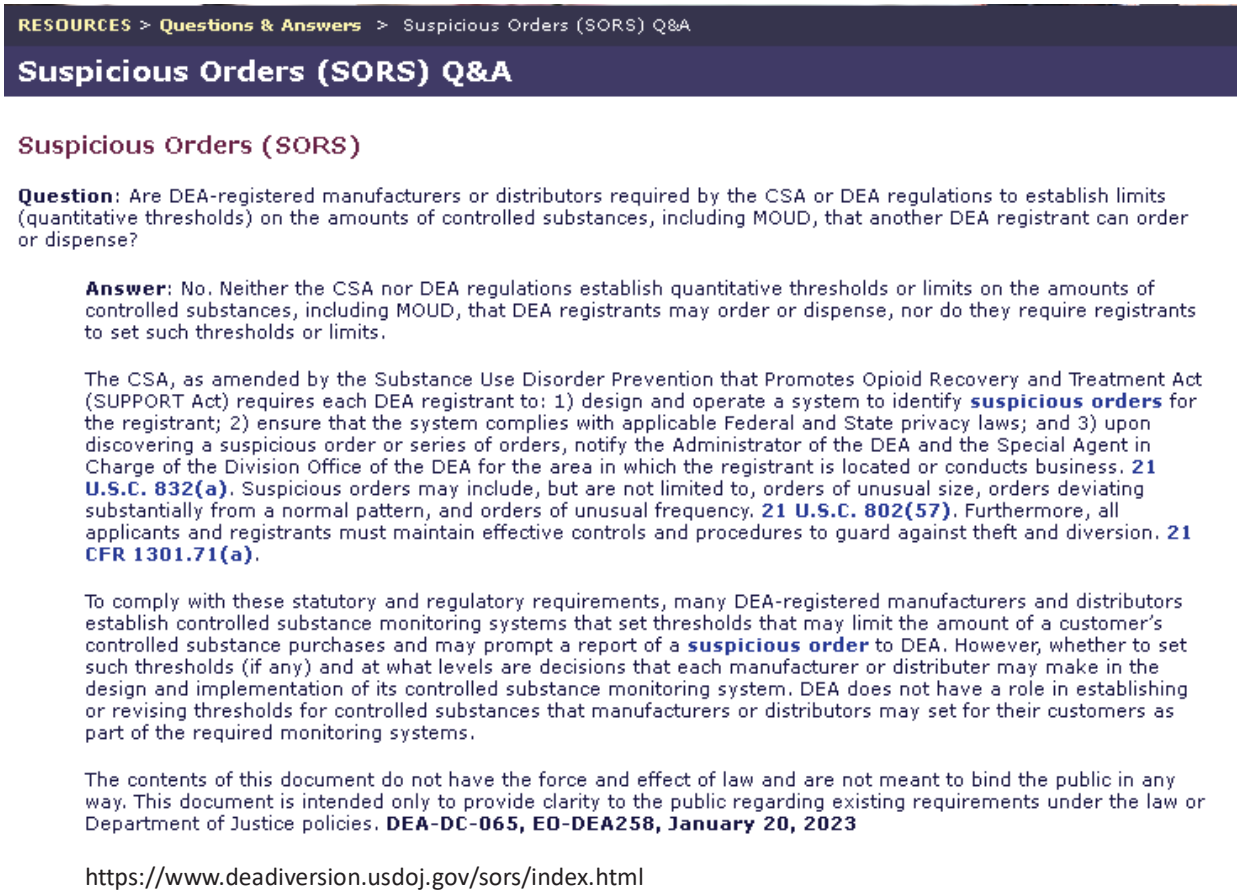
Progress:

Choose your applicant type

	Registrant	Coordinator	Power of Attorney
Application:	Form DEA-251	Form DEA-252	Form DEA-253
Description:	The individual who signed the most recent, or is authorized to sign the next, DEA Registration renewal application (DEA Form 223) for your organization	A required administrative role for each DEA Registration number	Any other individual authorized to sign controlled substance orders
Required role?	No, the Registrant should only enroll if he/she signs controlled substance orders*	Yes, but may be served by the Registrant**	No
Maximum allowed:	One per DEA Registration number	One Principal (if Registrant is not Coordinator) and one Alternate (optional) per DEA Registration number	Unlimited
Signs controlled substance orders?	Yes	Optional	Yes
Authorized by:	n/a	Registrant for the requested DEA Registration number(s)	Coordinator for the requested DEA Registration number(s)
More information:	Read more >>	Read more >>	Read more >>
Proceed to next step >>	Enroll as a Registrant	Enroll as a Coordinator	Enroll as a POA

- Quicker access to shortage meds
- POA in place for each staff member
- Efficiency

https://www.deaecom.gov/apprapps.html



RESOURCES > Questions & Answers > Suspicious Orders (SORS) Q&A

Suspicious Orders (SORS) Q&A

Suspicious Orders (SORS)

Question: Are DEA-registered manufacturers or distributors required by the CSA or DEA regulations to establish limits (quantitative thresholds) on the amounts of controlled substances, including MOUD, that another DEA registrant can order or dispense?

Answer: No. Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.

The CSA, as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify **suspicious orders** for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a suspicious order or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. **21 U.S.C. 832(a)**. Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. **21 U.S.C. 802(57)**. Furthermore, all applicants and registrants must maintain effective controls and procedures to guard against theft and diversion. **21 CFR 1301.71(a)**.

To comply with these statutory and regulatory requirements, many DEA-registered manufacturers and distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer's controlled substance purchases and may prompt a report of a **suspicious order** to DEA. However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributer may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies. **DEA-DC-065, EO-DEA258, January 20, 2023**

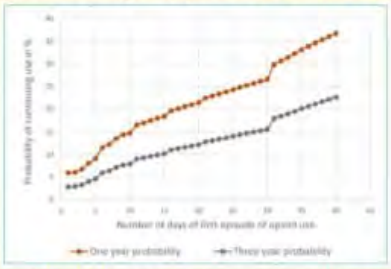
https://www.deadiversion.usdoj.gov/sors/index.html

Why are prescription limits a solution to the opioid crisis?

More and more studies confirm that initial duration and dosage matter in determining an individual's likelihood of being on opioids long-term. By setting appropriate limits on initial opioid prescriptions while maintaining individualized pain management care, Tennessee encourages prevention of long-term opioid use and abuse.

Risk of Addiction and Abuse Grows with Duration and Dosage

The likelihood of continuing to use opioids increases most dramatically after the 5th and 31st days on therapy; the filling of the second prescription of opioids; a 700 MME cumulative dose of opioids; and first prescriptions with 10- and 30-day supplies. (CDC, 2017)



One- and three-year probabilities of continued opioid use, by duration of first episode in days.

Each refill and week of opioid prescriptions is associated with a large increase in opioid misuse among opioid naive patients. Duration of the prescription rather than dosage is more strongly associated with ultimate misuse in the early postsurgical period. (BMJ, 2018)

Treatment with opioids is not superior to treatment with non-opioid medications in improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain. (JAMA, 2018)

New persistent opioid use can be considered one of the most common complications after elective surgery and is more common than previously reported. (JAMA Surgery, 2017)

www.tntogether.com

https://www.tn.gov/tnfacesofopioids.html

Situation

- New Center / New Staff
- High-Performing RN
- Became 'lead' for CRNA's and Box distribution
- No 2-person verification
- Distractions during process
- Editing logs
- Cameras

Findings / Learned

- Always 2 people involved in box refilling / verification
- Camera placement
- Local Law Enforcement
- DEA Notification / Visit
- State Infectious Disease Dept.
- Board of Nursing
- DEA Memorandum of Agreement

Best Practice or Bad Practice?

Patient MR Number	KETAMINE 1 x 5ml Total 5 ml	FENTANYL 4 x 2ml Total 8 ml	SUFENTANIL 4 x 1ml, 0 x 2ml Total 2 ml	ALFENTANIL 4 x 2ml Total 8 ml	MIDAZOLAM 2mg/2ml 4 x 2ml Total 8 ml	MORPHINE 10mg 1 x 1ml Total 1 ml	DILAUDID 1mg/ml 1 x 1ml Total 1 ml
Added:	____ ml	____ ml	____ ml	____ ml	____ ml	____ ml	____ ml
Total For Day:	5 ml	8 ml	2 ml	8 ml	8 ml	1 ml	1 ml
69119			15mcg				
69313		1ml					
69339			15mcg				
29818			20mcg				
68476			10mcg				
68904		1ml	20mcg				

Best Practice or Bad Practice?

https://www.securitymagazine.com/articles/87746-what-is-a-best-practice-and-should-you-deploy-them

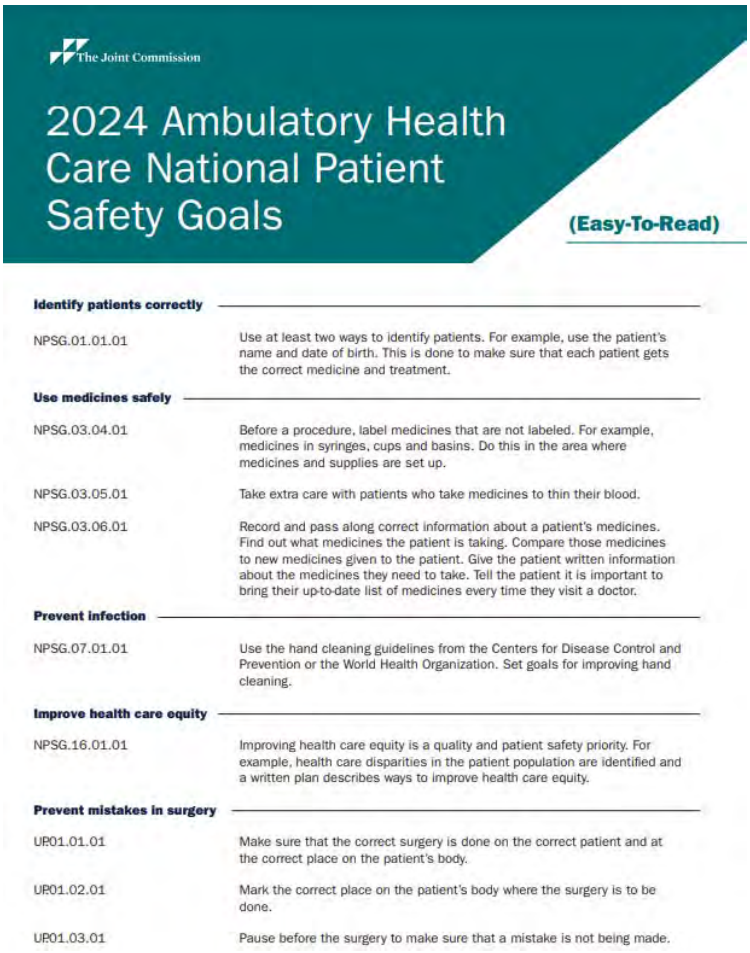
Medication Management Best Practices

High Alert / LASA Medications

- Assess/Update Annually
- Include Staff to build lists
- ISMP.org for lists (Develop center-specific)
- Label EVERY storage location (Carts/Boxes.etc)
- Individual Bins / Segregated Storage
- Practice Plans
- Staff Awareness
- POST LISTS !

Accreditation Bodies

- CMS
- State Regs
- TJC
- AAAHC
- AAAA



The Joint Commission

2024 Ambulatory Health Care National Patient Safety Goals

(Easy-To-Read)

Identify patients correctly

NPSG.01.01.01	Use at least two ways to identify patients. For example, use the patient's name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment.

Use medicines safely

NPSG.03.04.01	Before a procedure, label medicines that are not labeled. For example, medicines in syringes, cups and basins. Do this in the area where medicines and supplies are set up.
NPSG.03.05.01	Take extra care with patients who take medicines to thin their blood.
NPSG.03.06.01	Record and pass along correct information about a patient's medicines. Find out what medicines the patient is taking. Compare those medicines to new medicines given to the patient. Give the patient written information about the medicines they need to take. Tell the patient it is important to bring their up-to-date list of medicines every time they visit a doctor.

Prevent infection

NPSG.07.01.01	Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning.

Improve health care equity

NPSG.16.01.01	Improving health care equity is a quality and patient safety priority. For example, health care disparities in the patient population are identified and a written plan describes ways to improve health care equity.

Prevent mistakes in surgery

UP01.01.01	Make sure that the correct surgery is done on the correct patient and at the correct place on the patient's body.
UP01.02.01	Mark the correct place on the patient's body where the surgery is to be done.
UP01.03.01	Pause before the surgery to make sure that a mistake is not being made.

2024 TJC NPSG

- Patient Identifiers
- Labeling!!
- Anticoagulation Therapy
- Medication Lists
- Hand Cleaning
- Correct Surgery Site

https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2024/ahc-npsg-simple-2024.pdf

Top ASC Medication Management Findings

- Storage per manufacturer
- Medication Security
- Medication handling / waste
- Unauthorized medication access
- Labeling!
- Expired medication management
- Concentrated Electrolytes
- Patient's own medications / Samples
- Therapeutic Duplication of orders

https://www.wolterskluwer.com/en/expert-insights/ten-things-your-joint-commission-surveyor-is-looking-for

Common TJC Finding : Therapeutic Duplication

- Order Sets include clear indications for each PRN medication
- Nurse contacts Provider for clarification when duplications are identified
- PRN orders – Be specific with parameters
- Use specific pain scale parameters when dosing
- Clarify sequencing – " for n/v. If still n/v after 30 minutes, administer…"
- Scope of Practice – Nurse should not be determining dose without written plan

Clinical Emergency Management

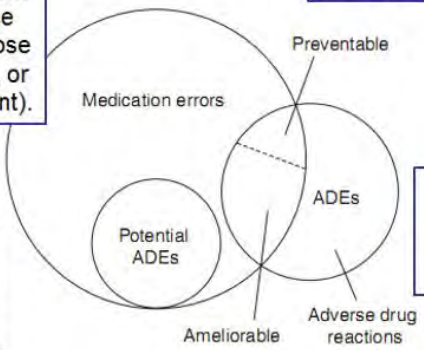
State requirements MHAUS.org (Malignant Hyperthermia) Medical Director & Anesthesia MEC Approval of changes Drill Annually	Ryanodex / Dantrolene Label Carts/Boxes for HA/LASA Pre-Mixed Infusions (Magnesium Dobutamine, KCL, Dopamine, etc.) Tubing Compatibility Pump Availability	All Clinical Scenarios: *Anaphylaxis* *Cardio-Pulmonary* *Methemoglobinemia* *Seizures* *Anesthetic Toxicity* Pediatric & Adult Preparation

Adverse Drug Event / Adverse Drug Reaction Management

ADE / ADR Definitions

Medication Error: An event that may cause or lead to inappropriate medication use or patient harm (for example: the wrong medication or dose prescribed, dispensed, or administered to a patient).

Adverse Drug Event (ADE): An injury due to a medication either from a medication error *or* ADR.



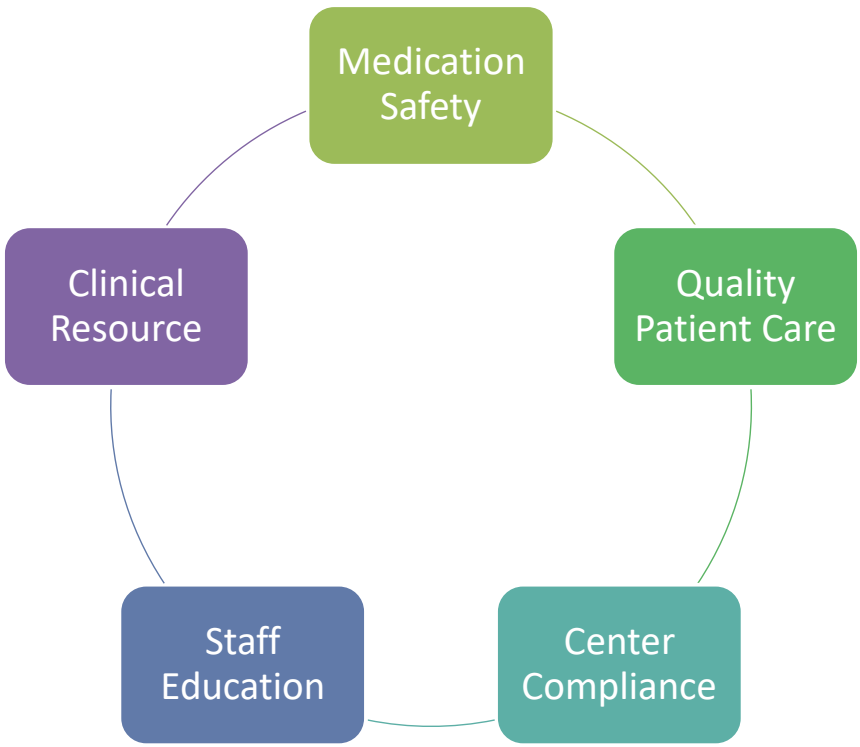
Adverse Drug Reaction (ADR): Non-preventable reactions due to side-effects or allergic reactions.

Near Miss/Near Hit/Close Call: An error discovered prior to reaching a patient.

Figure 1 Relationship between adverse drug events (ADEs), potential ADEs, and medication errors.

Morimoto, T, et al. Adverse Drug Events and Medication Errors: Detection and Classification Methods. *Qual Saf Health Care* 2004;13:306-314

Your Consultant Pharmacist



Consultant Pharmacist

- Contracted for services
- Competencies in TJC, AAAHC, QuadA, etc., CMS, State Laws, AORN, HIPPA
- Expert in Patient Safety, Compliance, and Quality Care
- Available for in-services to all staff-- i.e., Anesthesia, Nursing
- Creates 'closed-loop' survey and review processes
- Performs controlled-substance audits
- Provides regular center audits for Nurse Administrators and ASC Admin

SURGERY CENTER 2025 MEDICATION MANAGEMENT MONTHLY REVIEW												
(C) = COMPLIANCE (N) = NON-COMPLIANCE (BUD) = BEYOND-USE-DATE (AC) = ANESTHESIA CART	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
MEDICATION STORAGE												
Controlled Substance receiving documentation complete (signed/dated invoices & completed CSOS/DEA 222 forms)												
Medication storage areas are clean, organized, appropriately lit, correct temperatures & free of food and clutter												
Medications storage bins are clearly labeled with drug name, strength & concentration on shelves, boxes & carts												
High-Alert (HA), Look Alike/Sound Alike (LASA), & Hazardous medications labeled w/ lists posted & stored properly												
Neuromuscular blockers are stored in labeled (HA), lidded container (lidded not required in Anesthesia Cart)												
Expired medications are removed from inventory & quarantined until processed in a timely manner												
Medications are stored to ensure stability, sterility & safety as noted in Package Insert & from manufacturer												
Medications are behind locks and inaccessible by non-authorized persons as center policy allows												
Controlled medications are locked and inaccessible at all times by non-authorized individuals												
Emergency Carts are stocked, in date, sealed w/ break-away lock & and accompanied by updated Expiration Log												
Sanitation-Expiration Log in Medication Management Book is initialed by assigned staff for prior months												
Refrigerator/Freezer temps are in range of 36°F – 46°F & documented with NIST-certified, in-date thermometer												
MEDICATION PREPARATION												
Prepared medications are labeled with name, strength or concentration, initials and Beyond-Use Date (exp time)												
Single-use / Single-patient injectables are discarded after initial spike and used on only one patient												
Spiked Multi-dose injectable vials are labeled with BUD or discarded if used in a procedural area												
Open ophthalmic ointments and drops are dated with BUD *(28 days from opening unless sterility is compromised)*												
IV fluids removed from outer wrapper are labeled w/ BUD *(28 day- not written on bag)* & dated w/ BUD in warmer												
ANESTHESIA CARTS/BOXES												
Succinylcholine*(14 days)*, **Rocuronium***(60 days)*, **and Vasopressin***(12 months)* are dated w/ BUD on carts												
Opened eye ointments & drops are dated with BUD (*28 days***)** or discarded after each use												
Controlled medications are inaccessible at all times by non-authorized individuals												
Prepared medications are labeled with name, strength or concentration, initials and Beyond-Use Date (exp time)												
Injectable medications drawn in syringes or compounded are discarded after 1hr from prep time or after each case												
Spiked injectables, including narcotics, are discarded after each case and not used on more than one patient												

MEDICATION MANAGEMENT
SANITATION/EXPIRATION CHECK

The monthly procedure for the areas listed above is as follows:

- Check thoroughly for all expired drugs. Pull any expired drugs and place in the 'Expired Medication' bin. Expired meds should be reviewed for reordering
- All medications removed from their original containers should be labeled properly. If not, discard in a sharps container
- Clean and straighten any area that houses medications. This includes **labeling all medication storage bins/drawers/shelves** to prevent medication errors
- Review any medications that are no longer used in the center to ensure medications present are listed on the center's formulary and are currently used within the practice of the facility

YEAR:

AREA	ASSIGNED STAFF PERSON	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC
Procedure Room 1													
Narcotic Room													
Anesthesia Workroom													
Medication Refrigerator													
OR 1													
OR 2													
Emergency Cart													

Specific Beyond-Use Dates Out of Refrigeration

Succinylcholine
14 days

Cisatracurium
21 days

Rocuronium
60 days

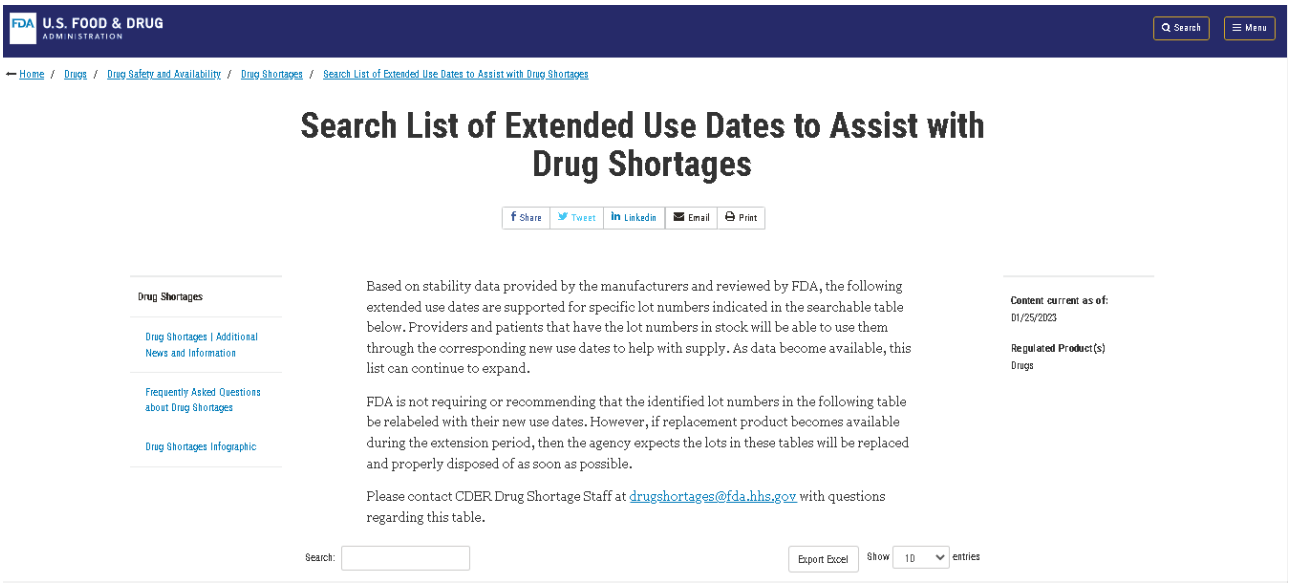
Atracurium
14 days

Vasopressin
12 months

Common TJC Finding – Storage per manufacturer

Temperature Monitoring
Refrigerators / Warmers / Rooms

- Perpetual monitoring/tracking system
- Documentation
- Audible alarm ON
- Process for excursions
  - Hold product
  - Contact manufacturer
  - Documentation in writing
- Thermometers In-Date
  - NIST-certified
- Staff awareness of process
- Monitor room temp if heat-producing equipment in med rooms



https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

FDA RESOURCE – EXTENDED EXPIRATION DATES

Product	Company	NDC Number	Lot Number	Expiration Date (Labeled)	Extended Use Date
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	16035DD	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	16090DD	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	16140DD	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	16145DD	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	16200DD	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	19060DD	1-Jul-2022	1-Jul-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	19095DD	1-Jul-2022	1-Jul-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	19135DD	1-Jul-2022	1-Jul-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	18075DD	1-Jun-2022	1-Jun-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	18145DD	1-Jun-2022	1-Jun-2023

Showing 1 to 10 of 169 entries

Previous 1 2 3 4 5 ... 17 Next

https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

Search List of Extended Use Dates to Assist with Drug Shortages | FDA

Product	Company	NDC Number	Lot Number	Expiration Date (Labeled)	Extended Use Date
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	18145DD	1-Jun-2022	1-Jun-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	18330DD	1-Jun-2022	1-Jun-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17100DD	1-May-2022	1-May-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17150DD	1-May-2022	1-May-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17210DD	1-May-2022	1-May-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17350DD	1-May-2022	1-May-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19058DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19060DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19061DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19062DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19063DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19223DK	1-Apr-2022	1-Apr-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0030921	28-Feb-2023	31-Aug-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0040921	28-Feb-2023	31-Aug-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0050921	28-Feb-2023	31-Aug-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0120621	30-Nov-2022	31-May-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0150621	30-Nov-2022	31-May-2023
Fludarabine phosphate injection, 50 mg/2 mL (25 mg/mL), single-dose vial,	Sagent Pharmaceuticals	25021-242-02	100020734	Jan-2023	Jul-2023
Heparin Sodium 25,000 units/250 mL (100 units/mL) in 5% Dextrose Injectio	Hospira, a Pfizer company	0409-7793-62	32303KL00	1-Aug-2023	1-Mar-2024
Heparin Sodium Injection, 25,000 units/250 mL (100 units/mL) in 5% Dextro	Hospira, a Pfizer company	0409-7793-62	33403KL00	1-Sep-2023	1-Apr-2024
Heparin Sodium Injection, 25,000 units/250 mL (100 units/mL) in 5% Dextro	Hospira, a Pfizer company	0409-7793-62	31201KL00	1-Jul-2023	1-Feb-2024
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	14293DK00	1-Feb-2022	1-Feb-2023
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	14422DK00	1-Feb-2022	1-Feb-2023
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	13140DK00	1-Jan-2022	1-Jan-2023
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	17377DK00	1-May-2022	1-May-2023

Extended Expiration List – Exportable

https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

Expiration Extensions

FDA Approval required MEC review/approval	Re-label all products with new expiration date Replace when product is available – FDA expectation	Keep documentation on file Minimize if possible

Labeling Requirements

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

- **Drug Name/Diluent/Strength**
- **Initials of preparer**
- Prep Time
- **BUD**

The Joint Commission

- **Medication Name/Strength**
- Date of Prep
- **BUD**
- 2 patient identifiers

USP <797>

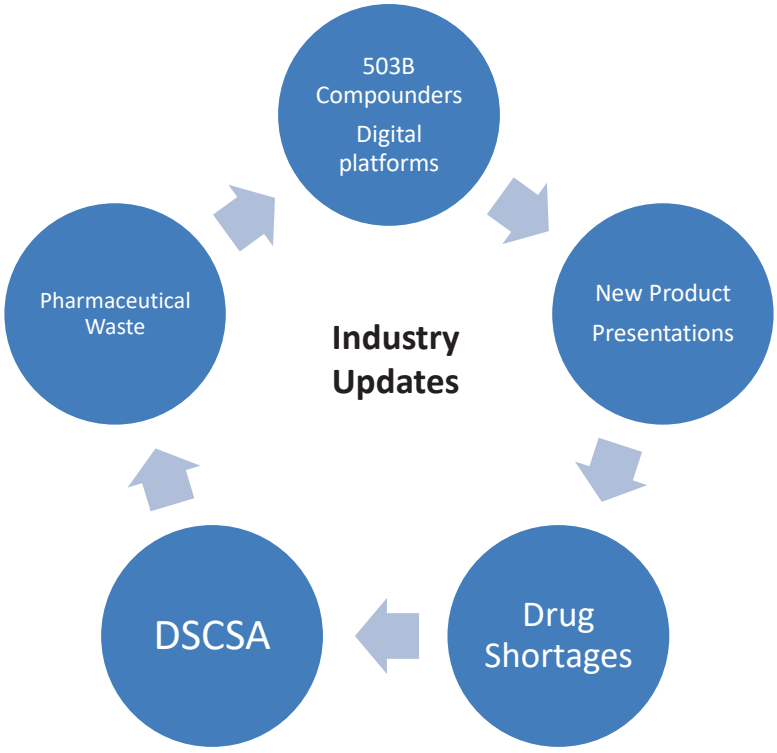
- **Medication(s) / Diluent(s) names**
- **Initials of preparer**
- **BUD (Packager Insert or 4 hours from prep initiation**

Best Practice or Bad Practice?

Other ASC Practice Pearls

- Replace Drug Information Books with each new Edition (ISMP)
- Review Policies / Write Policy when required
- 5 Rights – Patient/Drug/Dose/Route/Time
- Antimicrobial Stewardship

Industry Updates



NEW DRUG SOURCING OPTIONS

- Digital Pharmaceutical Sourcing
  - ‘Amazon’ – like
  - Shop multiple options in catalog
  - 503B listings
  - Price Bidding
  - Examples: Medigi™ / MedShorts™ / GraphiteRx™

503B Compounders

- Compound doses without prescription
- Syringe products / OR compliance
- Drug shortage strategy
- Short BUDs / Costly $$

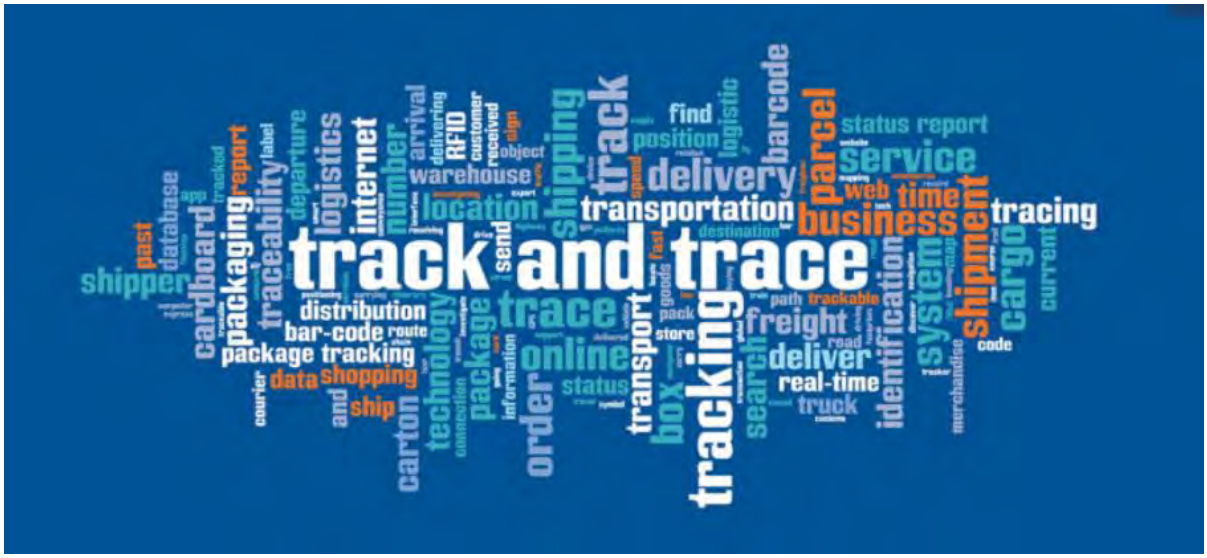
Pharmaceutical Waste in the ASC

https://www.danielshealth.com/knowledge-center/know-which-bin

- **Hazardous / Non-Hazardous**
- **Various bins for collection**
- **All pharmaceutical waste except controlled substances**
- **Consult with your Waste Vendor for assessment and strategy specific to your Formulary**
- **Sharps not acceptable source for Pharmaceutical Waste**
- **Lidded / Locked when possible**
- **P-listed and U-listed drugs managed specifically as dictated by State law and waste company**

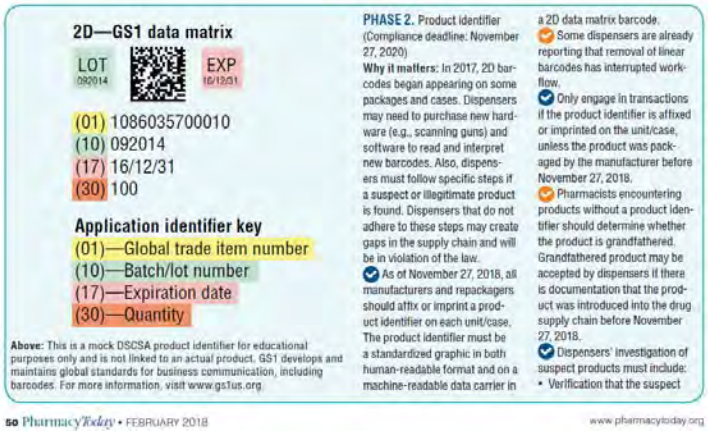
Pharmaceutical Waste Streams

Drug Supply Chain & Security Act



GO-LIVE- NOVEMBER 27, 2024

https://www.dcatvci.org/features/the-next-deadline-for-drug-supply-chain-security/



2D—GS1 data matrix

LOT 092014 EXP 16/12/31

(01) 1086035700010
(10) 092014
(17) 16/12/31
(30) 100

Application identifier key

(01)—Global trade item number
(10)—Batch/lot number
(17)—Expiration date
(30)—Quantity

Above: This is a mock DSCSA product identifier for educational purposes only and is not linked to an actual product. GS1 develops and maintains global standards for business communication, including barcodes. For more information, visit www.gs1us.org.

PHASE 2. Product identifier (Compliance deadline: November 27, 2020)

Why it matters: In 2017, 2D barcodes began appearing on some packages and cases. Dispensers may need to purchase new hardware (e.g., scanning guns) and software to read and interpret new barcodes. Also, dispensers must follow specific steps if a suspect or illegitimate product is found. Dispensers that do not adhere to these steps may create gaps in the supply chain and will be in violation of the law.

As of November 27, 2018, all manufacturers and repackagers should affix or imprint a product identifier on each unit/case. The product identifier must be a standardized graphic in both human-readable format and on a machine-readable data carrier in a 2D data matrix barcode.

Some dispensers are already reporting that removal of linear barcodes has interrupted workflow.

Only engage in transactions if the product identifier is affixed or imprinted on the unit/case, unless the product was packaged by the manufacturer before November 27, 2018.

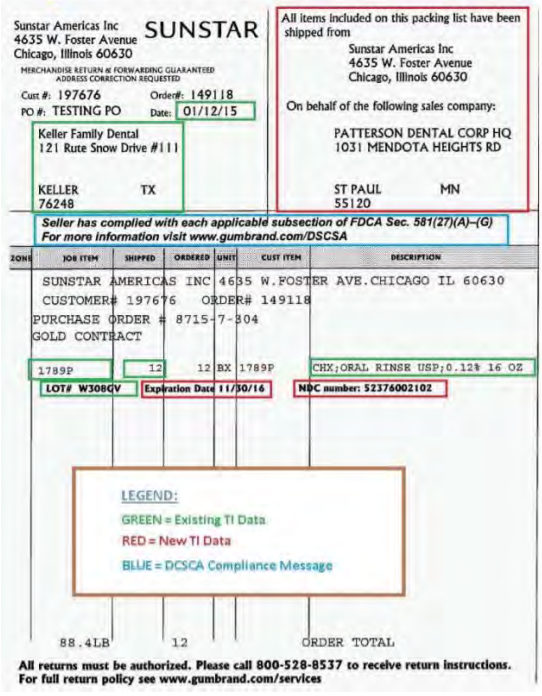
Pharmacists encountering products without a product identifier should determine whether the product is grandfathered. Grandfathered product may be accepted by dispensers if there is documentation that the product was introduced into the drug supply chain before November 27, 2018.

Dispensers' investigation of suspect products must include:
• Verification that the suspect

50 PharmacyToday • FEBRUARY 2018 www.pharmacytoday.org

DSCSA – "T3"

Transaction Information (TI)
Transaction History (TH)
Transaction Statement (TS)



Sunstar Americas Inc
4635 W. Foster Avenue
Chicago, Illinois 60630
SUNSTAR

All items included on this packing list have been shipped from
Sunstar Americas Inc
4635 W. Foster Avenue
Chicago, Illinois 60630

On behalf of the following sales company:
PATTERSON DENTAL CORP HQ
1031 MENDOTA HEIGHTS RD
ST PAUL MN
55120

Cust #: 197676 Order#: 149118
PO #: TESTING PO Date: 01/12/15

Keller Family Dental
121 Rute Snow Drive #111
KELLER TX
76248

Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)–(G)
For more information visit www.gumbrand.com/DSCSA

ZONE	JOB ITEM	SHIPPED	ORDERED	UNIT	CUST ITEM	DESCRIPTION

SUNSTAR AMERICAS INC 4635 W.FOSTER AVE.CHICAGO IL 60630
CUSTOMER# 197676 ORDER# 149118
PURCHASE ORDER # 8715-7-304
GOLD CONTRACT

1789P 12 12 BX 1789P CHX;ORAL RINSE USP;0.12% 16 OZ
LOT# W308GV Expiration Date 11/30/16 NDC number: 52376002102

LEGEND:
GREEN = Existing TI Data
RED = New TI Data
BLUE = DSCSA Compliance Message

88.4LB 12 ORDER TOTAL

All returns must be authorized. Please call 800-528-8537 to receive return instructions.
For full return policy see www.gumbrand.com/services

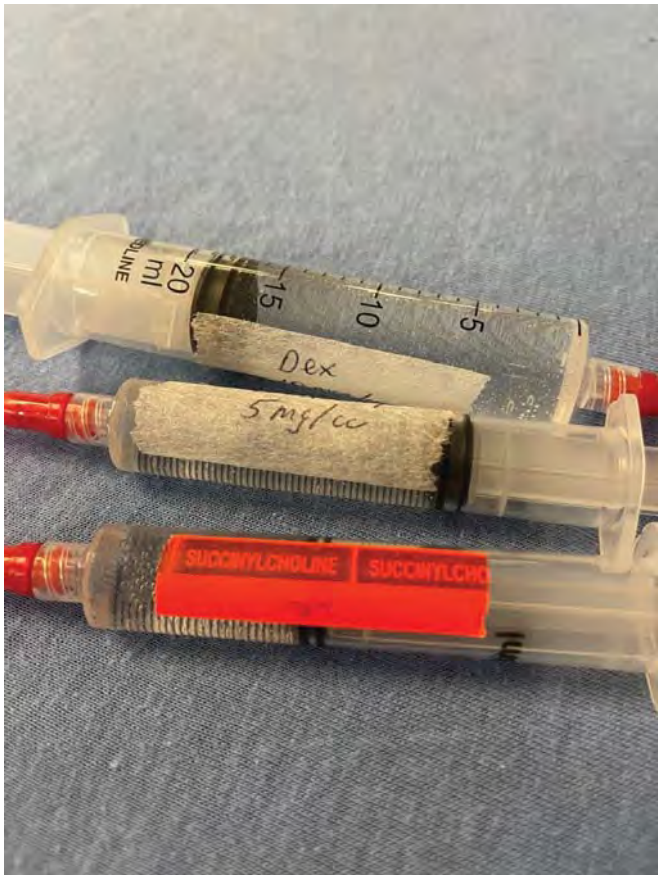
Pharmacy Today : February 2018 / www.pharmacytoday.org

- Policy / SOP
- Authorized Trading Partners
  - Licensure -- update annually through Board of Pharmacy
  - Validate prior to using
- Retention of T3 -- 6 years minimum
  - Wholesalers or Third-Party sources
  - Have contract to save data
- Validation / Verification
  - Process as receiving product
- Process for Suspect or Illegitimate Product
  - Recognition
  - Quarantine
  - Investigation
  - Notification
- T3 for borrowing / loaning or transfers to other facilities
  - Ownership / Possession
  - Specific patient needs versus inventory needs
- GLN required for your Ship-To location
- Work with your Consultant Pharmacist

DSCSA Summary

https://www.ipcrx.com/pharmacy-blog/pharmacy-services/dscsa-compliance-november-2023/

Best Practice or Bad Practice?



https://www.ismp.org/sites/default/files/attachments/2018-01/EntireAssessmentWorkbook.pdf

https://www.ismp.org/resources/medication-safety-self-assessmentr-perioperative-settings

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 7:

Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.

- Eliminate the storage of NMBs in areas of the hospital where they are not routinely needed.
- In patient care areas where they are needed (e.g., intensive care unit), place NMBs in a sealed box or, preferably, in a rapid sequence intubation (RSI) kit.
- Limit availability in automated dispensing cabinets (ADCs) to perioperative, labor and delivery, critical care, and emergency department (ED) settings; in these areas, store NMBs in a rapid sequence intubation (RSI) kit, or locked-lidded ADC pockets/drawers.
- Segregate NMBs from all other medications in the pharmacy by placing them in separate lidded containers in the refrigerator or other secure, isolated storage area.
- Place auxiliary labels on all storage bins and/or ADC pockets and drawers that contain NMBs as well as all final medication containers of NMBs (e.g., syringes, intravenous (IV) bags) that state: **"WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED"** or **"WARNING: PARALYZING AGENT – CAUSES RESPIRATORY ARREST"** or **"WARNING: CAUSES RESPIRATORY PARALYSIS – PATIENT MUST BE VENTILATED"** to clearly communicate that respiratory paralysis will occur and ventilation is required.*

Exception: The auxiliary label practice excludes anesthesia-prepared syringes of NMBs.

* Other acceptable alternatives to labeling storage bins and/or ADC pockets are to affix an auxiliary warning label (in addition to the manufacturer's warning on the caps and ferrules) directly on all vials and/or other containers stocked in storage locations, or by displaying a warning on the ADC screen, (e.g., "Patient must be intubated to receive this medication") that interrupts all attempts to remove a neuromuscular blocker via a patient's profile or on override. The warning should require the user to enter or select the purpose of the medication removal ("other" should not be a choice) and verify that the patient is (or will be) manually or mechanically ventilated.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 8:

a) Administer medication infusions via a programmable infusion pump utilizing dose error-reduction systems*.

b) Maintain a compliance rate of greater than 95% for the use of dose error-reduction systems.

c) Monitor compliance with use of smart pump dose error-reduction software on a monthly basis.

d) If your organization allows for the administration of an intravenous (IV) bolus or a loading dose from a continuous medication infusion, use a smart pump that allows programming of the bolus (or loading dose) and continuous infusion rate with separate limits for each.

- Allocate resources for ongoing maintenance, updating, and testing of the software and drug library for all smart infusion pumps.
- Ensure drug library content is consistent with the drug information and nomenclature (e.g., drug name, dosing units, dosing rate) in the electronic health record.
- Plan for the implementation of bi-directional (i.e., auto-programming† and auto-documentation‡) smart infusion pump interoperability with the electronic health record.

This *Best Practice* applies to all hospital settings, both inpatient and outpatient (e.g., magnetic resonance imaging [MRI] department, emergency department, outpatient infusion clinics), and to all situations in which medications are infused by the IV or epidural route, including anesthesia use and patient-controlled analgesia (PCA). The only exception is for small volume vesicant infusions (i.e., chemotherapy vesicants) which, when administered via the peripheral route, should only be infused by gravity and NOT by an infusion/syringe pump.

* Dose error-reduction systems (DERS): Refers to the integral computer software in smart infusion pumps intended to aid in prevention of infusion programming-related errors and warn users of potential over- or under-delivery of a medication or fluid by checking programmed doses/rates against facility configurable preset limits specific to a medication, fluid, and to a clinical application (e.g., epidural administration) and/or location (e.g., neonatal intensive care unit, medical/surgical unit).

† Auto-programming: Automatic programming of infusion parameters from the electronic health record system to the smart infusion pump (which are then verified, and the infusion is started manually by the practitioner) after use of the barcode medication administration system to associate the patient, fluid container (e.g., bag, bottle, syringe), and pump channel.

‡ Auto-documentation (also known as auto-charting or infusion documentation): Sending infusion information such as intake data, dose/rate changes, and infusion stop time, to the electronic health record system for manual clinician confirmation to enable accurate recording of this information to the patient's record after the infusion is started.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 9:

Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available. Have standardized protocols and/or coupled order sets in place that permit the emergency administration of all appropriate antidotes, reversal agents, and rescue agents used in the facility. Have directions for use/administration readily available in all clinical areas where the antidotes, reversal agents, and rescue agents are used.

- Identify which antidotes, reversal agents, and rescue agents can be administered immediately in emergency situations to prevent patient harm.
- Use this list to develop appropriate protocols or coupled order sets to ensure that the above *Best Practice* is met.

Rationale:

The goal of this *Best Practice* is to ensure that when an antidote, reversal agent, or rescue agent is known for a drug that has a high potential to cause an adverse reaction, or if a toxic dose is inadvertently administered, the agent is readily available and can be administered without delay. Some medications have a high potential to cause an adverse reaction even when the appropriate dose is administered (e.g., iron dextran). Adverse effects can also occur if an overdose of a medication is accidentally administered. In both cases, the reaction can be life-threatening, and sometimes immediate intervention is needed. For some drugs, an antidote, reversal agent, or rescue agent may exist to counteract the reaction. For example, naloxone counteracts the effects of opioids, flumazenil counteracts benzodiazepines, lipid emulsions counteract the cardiotoxic effects of local anesthetics, and uridine triacetate counteracts the toxic effects of fluorouracil.

ISMP has received reports of death and serious harm because there was a delay in the administration of the appropriate antidote, reversal agent, or rescue agent (e.g., **EPINEPH**rine for anaphylaxis). Known antidotes, reversal agents, and rescue agents must be routinely available and, in certain situations, stored in areas where these high-risk medications are administered. In addition, it is important to have standardized protocols or coupled order sets so qualified staff can treat the reaction/overdose without waiting for an order from the prescriber. Also, the directions for use should be available near where these agents are stored to avoid a delay or improper use and administration of the agent.

Best Practice 9 First Introduced:
2016-2017

Related *ISMP Medication Safety Alerts!*:
July 1, 2010; April 8, 2010; March 11, 2010; February 22, 2007; January 11, 2007; December 14, 2006; November 3, 1999; September 10, 1999.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 10 (ARCHIVED)

ARCHIVED Best Practice

See page 21

Eliminate all 1,000 mL bags of sterile water (labeled for "injection," "irrigation," or "inhalation") from all areas outside of the pharmacy.

BEST PRACTICE 11:

When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.

- Specifically, eliminate the use of proxy methods of verification for compounded sterile preparations of medications (e.g., the "syringe pull-back method," checking a label rather than the actual ingredients).
- Except in an emergency, perform this verification in all locations where compounded sterile preparations are made, including patient care units.
- Use technology to assist in the verification process (e.g., machine-readable coding [e.g., barcoding scanning, radio frequency identification] of ingredients, gravimetric verification, robotics, intravenous [IV] workflow software) to augment the manual processes. *When technology is in use, it is important that processes are in place to ensure it is maintained, the software is updated, and that the technology is always used in a manner that maximizes the medication safety features of these systems.*

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 13:

Eliminate injectable promethazine from the formulary.

- Remove injectable promethazine from all areas of the organization including the pharmacy.
- Classify injectable promethazine as a non-stocked, non-formulary medication.
- Implement a medical staff-approved automatic therapeutic substitution policy to convert all injectable promethazine orders to another antiemetic.
- Remove injectable promethazine from all medication order screens, and from all order sets and protocols.

This *Best Practice* includes not using intramuscular administration of promethazine because this can also cause tissue damage if accidentally injected intraarterially.

Rationale:

The goal of this *Best Practice* is to eliminate the risk of serious tissue injuries and amputations from the inadvertent arterial injection or intravenous (IV) extravasation of injectable promethazine. ISMP brought attention to this serious issue in August 2006 and conducted a survey to determine the prevalence of the issue. Of the nearly 1,000 responses to the survey, 1 in 5 reported awareness of such an occurrence in their facility during the prior 5 years. The US Food and Drug Administration (FDA) requires the manufacturer to include strong warnings about the risk of inadvertent intraarterial injection or perivascular extravasation of this drug in the package insert. Injectable promethazine has been included on the ***ISMP List of High-Alert Medications in Acute Care Settings*** (www.ismp.org/node/103) since 2007.

In 2009, ISMP recommended removal of injectable promethazine from an organization's formulary, if possible, and use of safer alternatives such as 5-HT 3 antagonists (e.g., ondansetron). However, these products were significantly higher in cost at the time. Since then, these alternative injectable antiemetics have become available as generic products and are significantly less costly. Thus, injectable promethazine has been used less frequently, and for safety, should now be removed from all formularies.

Best Practice 13 First Introduced:
2018-2019

Related *ISMP Medication Safety Alerts!*:

June 27, 2013; October 8, 2009; September 24, 2009; October 9, 2008; November 2, 2006; **August 10, 2006**.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 14:

Seek out and use information about medication safety risks and errors that have occurred in other organizations outside of your facility and take action to prevent similar errors.

- Appoint a single healthcare professional (preferably a medication safety officer) to be responsible for oversight of this entire activity in the hospital.
- Identify reputable resources (e.g., ISMP, The Joint Commission, ECRI, patient safety organizations, state agencies) to learn about risks and errors that have occurred externally.
- Establish a formal process for monthly review of medication risks and errors reported by external organizations, with a new or existing interdisciplinary team or committee responsible for medication safety. The process should include a review of the hospital's current medication use systems (both manual and automated) and other data such as internal medication safety reports to determine any potential risk points that would allow a similar risk or error to occur within the hospital.
- Determine appropriate actions to be taken to minimize the risk of these types of errors occurring in the hospital.
- Document the decisions reached and gain approval for required resources as necessary.
- Share the external stories of risk and errors with all staff, along with any changes that will be made in the hospital to minimize their occurrence, and then begin implementation.
- Once implemented, periodically monitor the actions selected to ensure they are still being implemented and are effective in achieving the desired risk reduction. Widely share the results and lessons learned within the facility.

BEST PRACTICE 15:

Verify and document a patient's opioid status (naïve versus tolerant*) and type of pain (acute versus chronic) before prescribing and dispensing extended-release and long-acting opioids.

- Default order entry systems to the lowest initial starting dose and frequency when initiating orders for extended-release and long-acting opioids.
- Alert practitioners when extended-release and long-acting opioid dose adjustments are required due to age, renal or liver impairment, or when patients are prescribed other sedating medications.
- Eliminate the prescribing of fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain.
- Eliminate the storage of fenta**NYL** patches in automated dispensing cabinets or as unit stock in clinical locations where acute pain is primarily treated (e.g., in the emergency department, operating room, postanesthesia care unit, procedural areas).

Fenta**NYL** patches are for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Extended-release formulations are for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

*** Opioid-tolerant patient:** Opioid tolerance is defined by the following markers: Patients receiving, for 1 week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fenta**NYL**/hour; 30 mg oral oxy**CODONE**/day; 8 mg oral **HYDRO**morphone/day; 25 mg oral oxy**MOR**phone/day; 60 mg oral **HYDRO**codone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.

Rationale:

The goal of this *Best Practice* is to support appropriate prescribing of extended-release and long-acting opioid medications and prevent death and serious patient harm from inappropriate use of these medications. A secondary goal is to specifically prevent the inappropriate use of fenta**NYL** patches to treat acute pain in patients who are opioid-naïve. *Fenta**NYL** patches were the highest-ranking drug involved in serious adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) from 2008 through 2010.* ISMP continues to receive reports, including fatalities, due to the prescribing, dispensing, and administration of fenta**NYL** patches to treat acute pain in opioid-naïve patients.

Best Practice 15 First Introduced: 2020-2021

Related *ISMP Medication Safety Alerts!*:

January 28, 2021; March 11, 2021; January 26, 2017; October 20, 2016; November 6, 2014; October 9, 2014; October 17, 2013; **May 30, 2013;** June 17, 2010; May 20, 2010; February 11, 2010; October 8, 2009; November 6, 2008; July 12, 2007; **June 28, 2007;** August 11, 2005; May 20, 2004; April 18, 2001.

NEW BEST PRACTICE 17:

NEW Best Practice

Safeguard against errors with oxytocin use.

a) **Require the use of standard order sets for prescribing oxytocin antepartum and/or postpartum that reflect a standardized clinical approach to labor induction/augmentation and control of postpartum bleeding.**

b) **Standardize to a single concentration/bag size for both antepartum and postpartum oxytocin infusions (e.g., 30 units in 500 mL Lactated Ringers).**

c) **Standardize how oxytocin doses, concentration, and rates are expressed. Communicate orders for oxytocin infusions in terms of the dose rate (e.g., milliunits/minute) and align with the smart infusion pump dose error-reduction system (DERS).**

d) **Provide oxytocin in a ready-to-use form. Boldly label both sides of the infusion bag to differentiate oxytocin bags from plain hydrating solutions and magnesium infusions.**

e) **Avoid bringing oxytocin infusion bags to the patient's bedside until it is prescribed and needed.**

Rationale:

The goal of this *Best Practice* is to prevent errors associated with oxytocin use. Intravenous (IV) oxytocin is used antepartum to induce labor in patients with a medical indication, to stimulate or reinforce labor in selected cases of uterine inertia, and as an adjunct in the management of an incomplete, inevitable, or elective abortion. Used postpartum, IV oxytocin is indicated to produce uterine contractions during expulsion of the placenta and to control postpartum bleeding or hemorrhage. However, improper administration of oxytocin can cause hyperstimulation of the uterus, which in turn can result in fetal distress, the need for an emergency cesarean section, or uterine rupture. A few maternal, fetal, and neonatal deaths have been reported because of oxytocin errors.

Since the mid-1990s, ISMP has been publishing safety alerts related to errors with oxytocin use. In February 2020, ISMP analyzed voluntary error reports submitted to the ***ISMP National Medication Errors Reporting Program*** *(ISMP MERP)* between 1999 and 2019. During that time, 52 reports involved oxytocin. About 10% of the reports described more than one oxytocin error that had occurred. About 44% of the reported events originated during dispensing, about a quarter (23%) originated during administration, and 13% during prescribing. A quarter (25%) of all events resulted in maternal, fetal, or neonatal harm. Analysis of these reports identified five event themes: prescribing errors, look-alike drug packaging and names, preparation challenges, administration-associated errors, and communication gaps; therefore, a *Best Practice* recommendation has been created for each of these five event themes.

Best Practice 17
First Introduced:
2022-2023

Related *ISMP Medication Safety Alerts!*:

January 28, 2021; November 5, 2020; **February 13, 2020**; January 30, 2020; July 26, 2018; April 19, 2018; August 9, 2012; September 9, 2010; June 3, 2010; June 18, 2009; September 11, 2008; June 15, 2006; March 23, 2006; November 3, 2005; October 20, 2005; July 14, 1999; June 30, 1999.

NEW BEST PRACTICE 19:

NEW Best Practice

Layer numerous strategies throughout the medication-use process to improve safety with high-alert medications.

a) **For each medication on the facility's high-alert medication list, outline a robust set of processes for managing risk, impacting as many steps of the medication-use process as feasible.**

b) **Ensure that the strategies address system vulnerabilities in each stage of the medication-use process (i.e., prescribing, dispensing, administering, and monitoring) and apply to prescribers, pharmacists, nurses, and other practitioners involved in the medication-use process.**

c) **Avoid reliance on low-leverage risk-reduction strategies (e.g., applying high-alert medication labels on pharmacy storage bins, providing education) to prevent errors, and instead bundle these with mid- and high-leverage strategies.**

d) **Limit the use of independent double checks to select high-alert medications with the greatest risk for error within the organization. (e.g., chemotherapy, opioid infusions, intravenous [IV] insulin, heparin infusions).**

e) **Regularly assess for risk in the systems and practices used to support the safe use of medications by using information from internal and external sources (e.g., The Joint Commission, ISMP).**

f) **Establish outcome and process measures to monitor safety and routinely collect data to determine the effectiveness of risk-reduction strategies.**

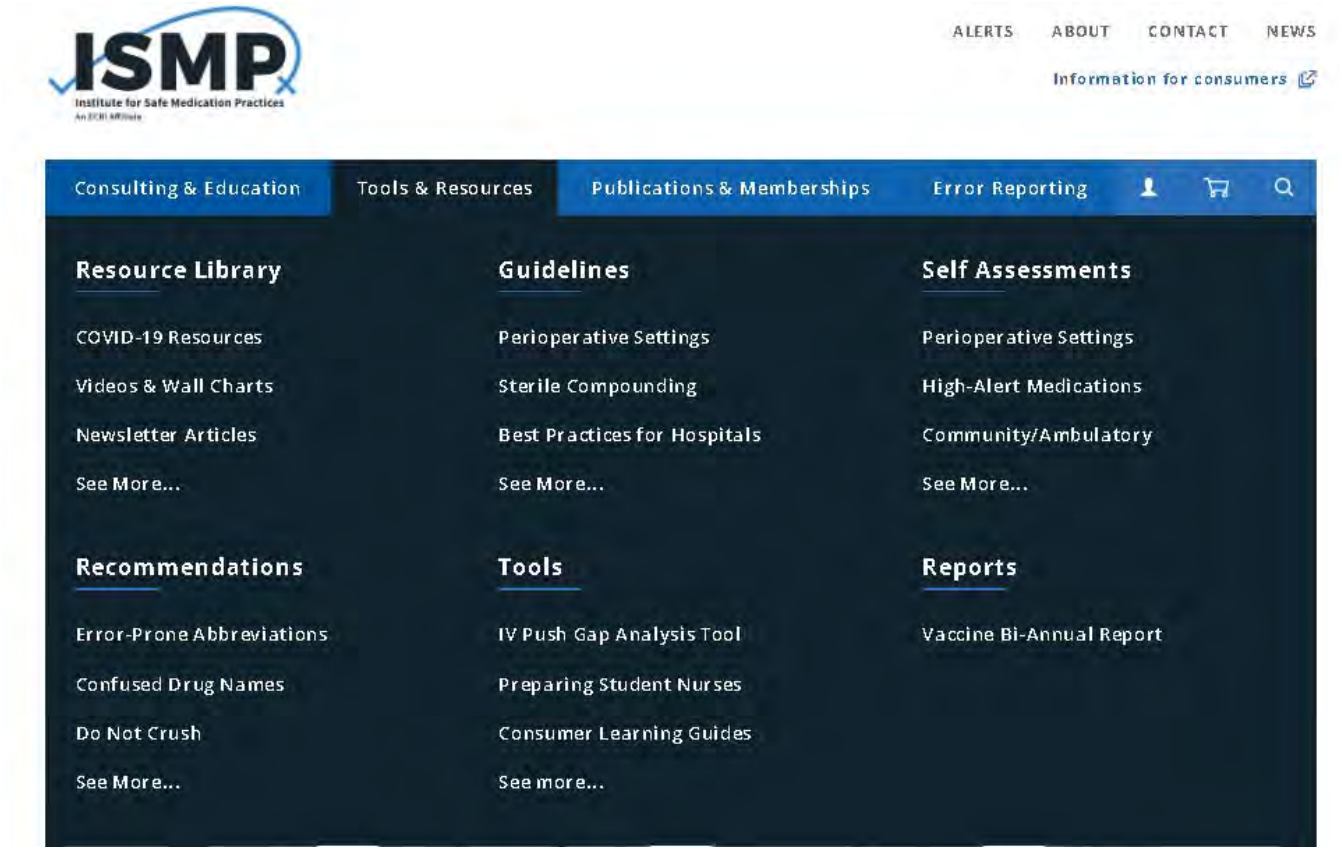
Rationale:

Events continue to happen in hospitals with medications that are on the hospital's list of high-alert medications. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. This is repeatedly borne out in the literature and by reports submitted to the ***ISMP National Medication Errors Reporting Program*** *(ISMP MERP)*. High-alert medications top the list of drugs involved in moderate to severe patient outcomes when an error happens. Most facilities have defined a list of high-alert medications, but some hospitals have neither a well-reasoned list of high-alert medications nor a robust set of processes for managing the high-alert medications on their list. Organizations' attempts to prevent errors may be limited to low-leverage risk-reduction strategies, rely on staff vigilance to keep patients safe, or focus on a single step or single practitioner in the medication-use process. The goal of this *Best Practice* is to engage hospitals to reassess their current list of high-alert medications, enact robust error-prevention strategies throughout the medication-use process, and monitor outcomes to reduce the risk of harm with these drugs.

Best Practice 19
First Introduced:
2022-2023

Related *ISMP Medication Safety Alerts!*:

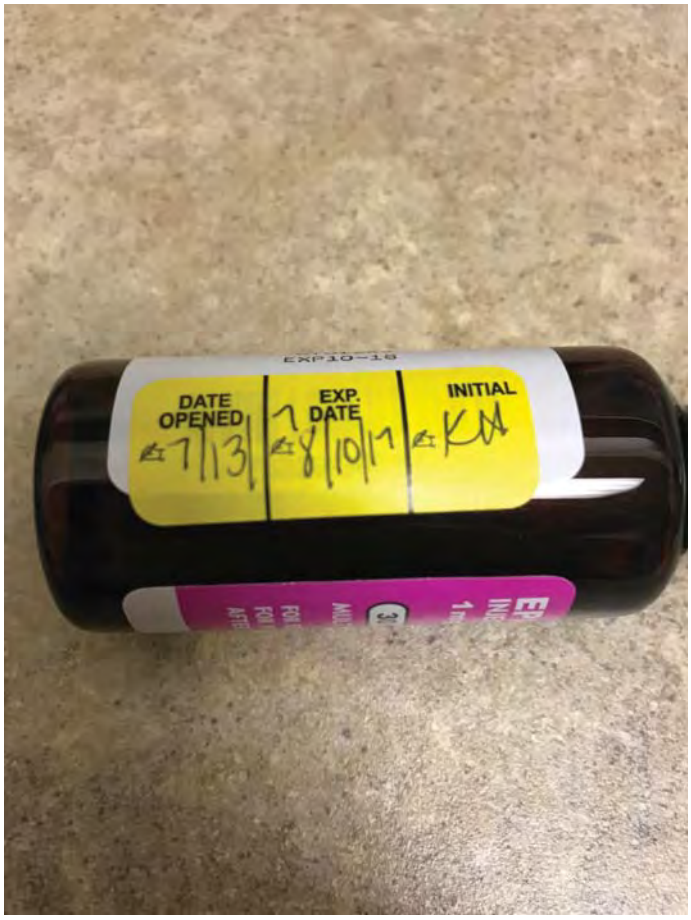
June 4; 2020; June 6; 2019; August 23; 2018; October 23; 2014; September 19; 2013; September 5; 2013; **April 4; 2013**; April 8; 2010; January 11; 2007



https://www.ismp.org/resources?field_resource_type_target_id%5B13%5D=13#resources--resources_list

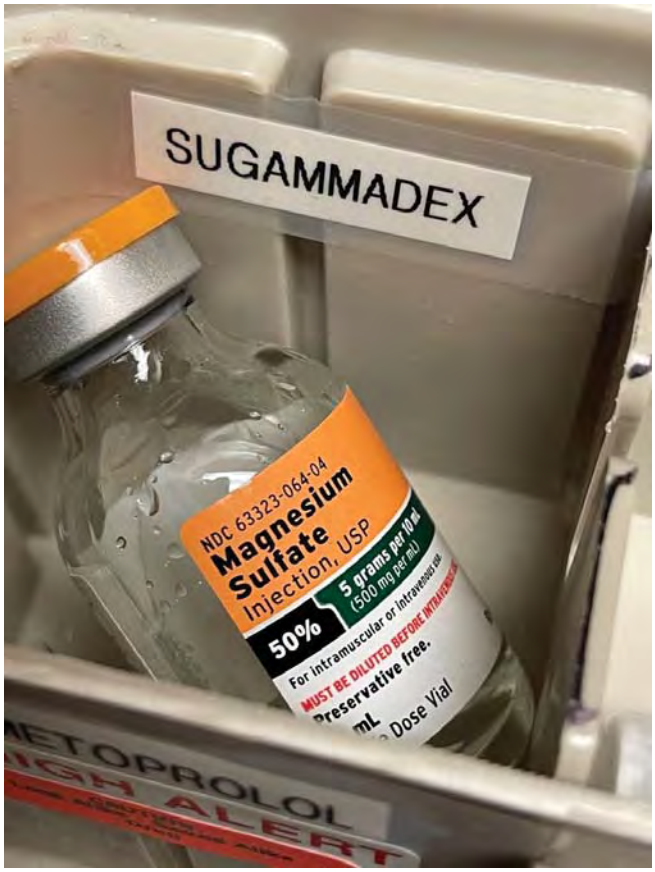
Best Practice or Bad Practice?

Best Practice or Bad Practice?

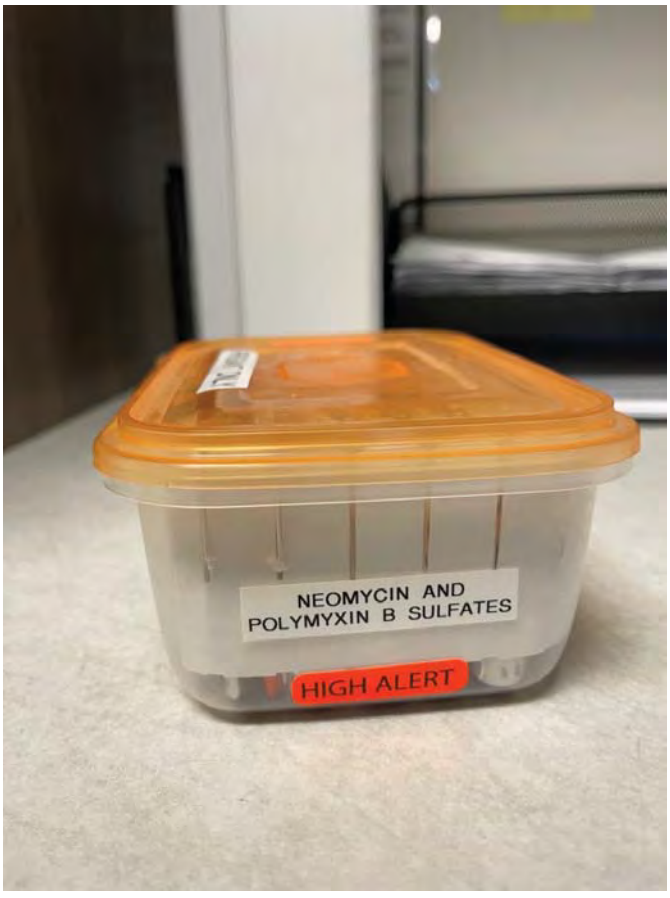


Best Practice or Bad Practice?

Best Practice or Bad Practice?



Best Practice or Bad Practice?



Midazolam 2mg/2ml injection	Fentanyl 100mcg/2ml Injection	Dilaudid 1 mg/ml Injection	Propofol 200mg/20ml injection	Propofol 500mg/50 mL	Wa Ar
5	5	5	10	2	
1	1		1		
			1		
	1	1	111	2	
1	2	1	5	2	
0	0	0	0	0	
4	3	4	5	0	

TRANSACTION WITNESSES:

Best Practice or Bad Practice?

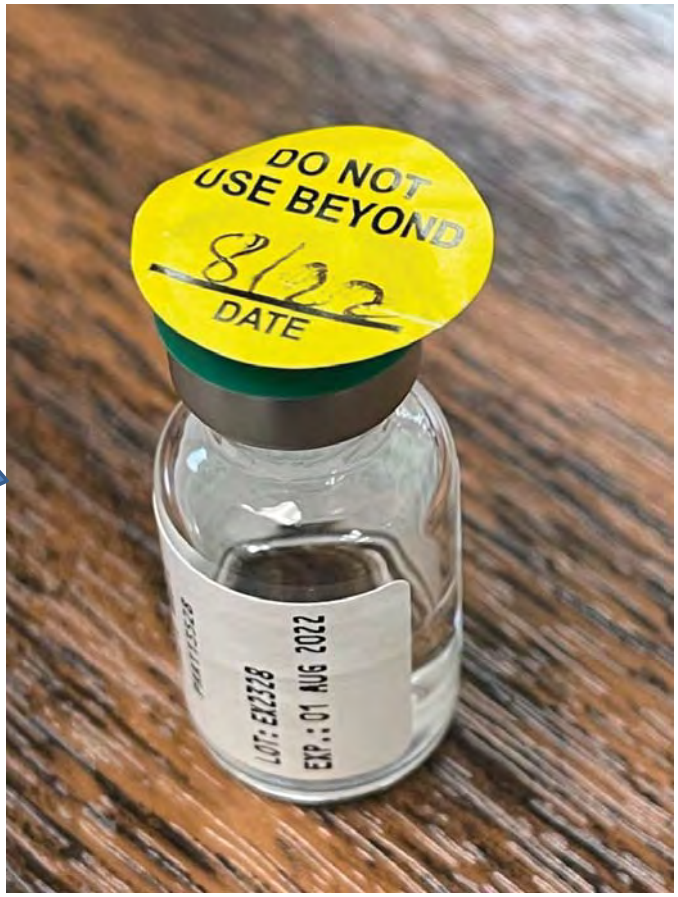
Best Practice or Bad Practice?

121

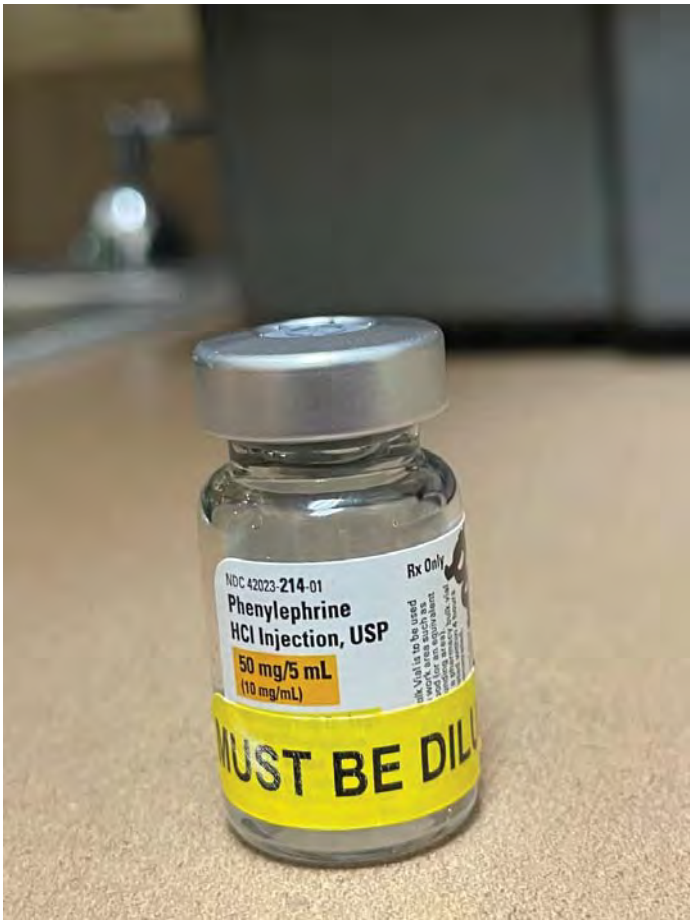
Best
Practice
or
Bad
Practice?

122

Best Practice or Bad Practice?

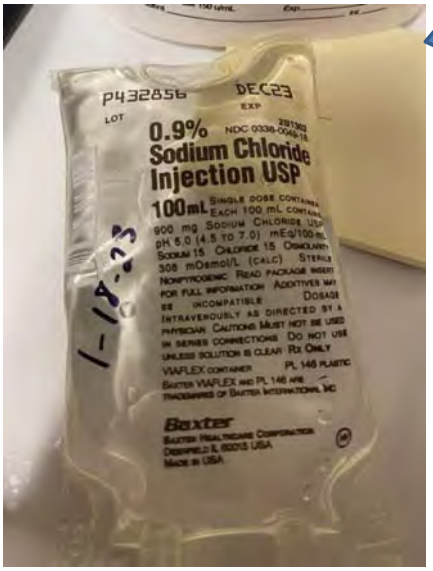


Best Practice or Bad Practice?



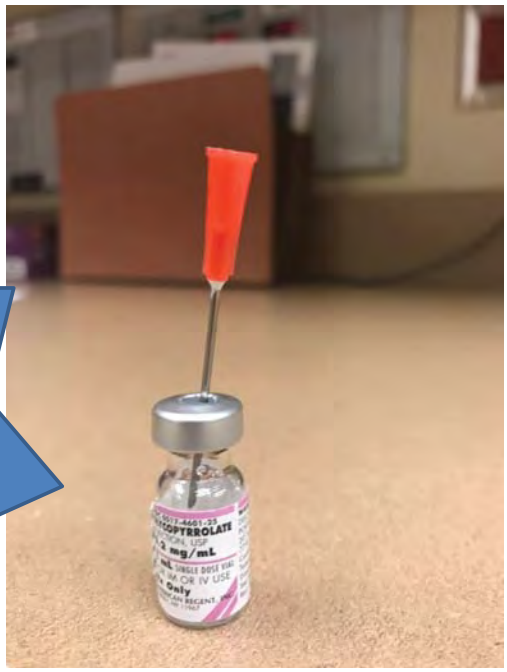
Best Practice or Bad Practice?

Best Practice or Bad Practice?



125

Best Practice or? Bad Practice



126

"ONE PERSON CAN MAKE A DIFFERENCE, AND EVERYONE SHOULD TRY."

– JOHN F. KENNEDY

Q/A : Open Discussion

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- Source: ASA Monitor, February 2023
- https://www.deaecom.gov/apprapps.html
- https://www.usp.org/compounding/general-chapter-797
- https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf
- https://www.deadiversion.usdoj.gov/sors/index.html
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- https://www.tn.gov/tnfacesofopioids.html
- https://www.deaecom.gov/apprapps.html
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Quality Measure Reporting Update for ASCs

Gina Throneberry, MBA, BSN, RN, CASC, CNOR
Director of Education and Clinical Affairs
Ambulatory Surgery Center Association (ASCA)

ASC Quality Reporting Program (ASCQR) Requirements

https://qualitynet.cms.gov/asc/ascqr/apu

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program payment determinations are now available from the Centers for Medicare & Medicaid Services (CMS). For 5,485 National Provider Identifiers (NPIs) that can to date be used to bill Medicare under the ASC payment system:

- 5,124, or **93.4%**, ASC facility NPIs will receive the full ASCQR payment update for CY 2024.

  96.4% received the full ASCQR payment update for 2023
  94.6% received the full ASCQR payment update for CY 2022.

- 361 ASCs, or **6.6%** did not meet all ASCQR Program requirements. These facility NPIs will receive a 2.0 percentage point reduction of the CY 2024 ASC annual payment update.

  3.6% (194 ASCs) did not meet all ASCQR Program requirements (2.0 percentage point reduction of the CY 2023 ASC annual payment update)
  5.4% (290 ASCs) did not meet all ASCQR Program requirements (2.0 percentage point reduction of the CY 2022 ASC annual payment update)

QualityNet

- Website address- https://qualitynet.cms.gov

- Two parts of QualityNet- “non-secure” and “secure”
  - Non-secure:
    - Subscribe to email updates and listserve: Each facility should have at least two people signed up for the QualityNet email notifications.
    - Download the Specifications Manual
    - Information about the measures, public reporting, data submission and other resources

CMS Ambulatory Surgical Center Quality Reporting Program

- Ambulatory Surgical Center Quality Reporting Specifications Manual

  - Verify you are using the correct version
  - 13.0 1Q24-4Q24

- Located @ https://qualitynet.cms.gov
- Scroll down and click “Ambulatory Surgical Centers” box
- Included in this manual:
  - Background and requirements
  - Measure information
  - Sampling specifications
  - Tools and resources

ASC Quality Reporting Program (ASCQR) Requirements

In 2024 there will be twelve measures **reported** for facilities to avoid a reduction in the following year's Medicare reimbursement.

Seven Web Based Measures:
- ASC-1
- ASC-2
- ASC-3
- ASC-4
- ASC-9
- ASC-13
- ASC-14

Four Claims Based Measures:
- ASC-12
- ASC-17
- ASC-18
- ASC-19

Reported through National Healthcare Safety Network (NHSN):
- ASC-20

ASC Quality Reporting Program (ASCQR) Requirements

** ASCs that have fewer than 240 Medicare claims (primary plus secondary payer) per year during a reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent reporting period for that subsequent payment determination year. This includes all program requirements, both claims-based measures and measure data entered via a web-based tool.

For example, an ASC with fewer than 240 Medicare claims in 2022 would not be required to submit 2023 data in 2024 which impacts the calendar year (CY) 2025 payment determination.

2024 Medicare Hospital Outpatient Prospective Payment System (OPPS/ASC) Final Rule

- Released on November 2, 2023

https://www.govinfo.gov/content/pkg/FR-2023-11-22/pdf/2023-24293.pdf

- ASC Quality Reporting Program begins on page 473 Section XV. *Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program*

2024 Medicare Hospital Outpatient Prospective Payment System (OPPS/ASC) Final Rule

- Quality Measures
  - Modification of the denominator for *ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*
  - Modification of the Survey Instrument Used for *ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
  - *Modification of ASC-20: COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)*
  - *Adoption of ASC-21: Risk Standardized Patient-Reported Outcome- Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting*

WEB BASED MEASURES

ASC Quality Reporting Program Measures

ASC-1: Patient Burn

ASC-2: Patient Fall

ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

ASC-4: All-Cause Hospital Transfer/Admission

- Web Based Reporting via HQR Secure Portal (https://hqr.cms.gov/hqrng/login)
- **These measures now apply to ALL ASC PATIENTS, not just Medicare Fee-For-Service patients.**

Data collection: January 1-December 31, 2023
Data submission: January 1-May 15, 2024

ASC Quality Reporting Program Measures

ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

- Web Based Reporting via HQR Secure Portal (https://hqr.cms.gov/hqrng/login)
- The numerator and denominator must be completed.
- If an ASC does not perform colonoscopies, select the box under the measure name and description that states, *"Please enter zeros for this measure as I have no data to submit."*
- CMS has modified the denominator to align with current clinical guidelines beginning with the CY 2024 reporting period / 2026 payment determination.

ASC Quality Reporting Program Measures

ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

- Numerator: Patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.
- Denominator: All patients aged ~~50~~ 45 to 75 years of age receiving screening colonoscopy without biopsy or polypectomy.

Data collection for this modification: January 1-December 31, 2024
Data submission for this modification: January 1-May 15, 2025

ASC Quality Reporting Program Measures

ASC-11 Cataracts- Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

- Assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery
- Administration of two visual function patient questionnaires- one completed by the patient prior to surgery and the other completed by the patient during the 90-day period after surgery
- **Voluntarily reported since 2015;**
- **In the CY 2023 OPPS/ASC final rule, it was finalized to change ASC-11 from mandatory to voluntary reporting beginning with the CY 2025 reporting period/CY 2027 payment determination.**
- Data submission via a CMS web-based tool

ASC Quality Reporting Program Measures

ASC-11 Cataracts- Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery: Modification of the Survey Instrument Used

- Beginning with the **voluntary** CY 2024 reporting period limit the survey instruments that an ASC may use to:

1. The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25):
   - 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision and peripheral vision)
2. The Visual Functioning Patient Questionnaire (VF-14):
   - most commonly used; 14 items relating to daily living activities and function such as reading, writing, seeing steps, stairs or curbs and operating a motor vehicle
3. The Visual Functioning Index Patient Questionnaire (VF-8R):
   - most concise; consists of questions related to reading, fine handwork, writing, playing board games and watching television

ASC Quality Reporting Program Measures

ASC-13: Normothermia Outcome

- Data submitted for ***a sampling*** that meets the denominator criteria
- Web Based Reporting via HQR Secure Portal (https://hqr.cms.gov/hqrng/login)
- The numerator and denominator must be completed.
- If an ASC does not perform procedures related to this measure, select the box under the measure name and description that states, *"Please enter zeros for this measure as I have no data to submit."*

Data collection: January 1-December 31, 2023
Data submission: January 1-May 15, 2024

ASC Quality Reporting Program Measures

ASC-14: Unplanned Anterior Vitrectomy

- Data submitted for ***all patients*** that meet the denominator criteria
- Web Based Reporting via HQR Secure Portal (https://hqr.cms.gov/hqrng/login)
- The numerator and denominator must be completed.
- If an ASC does not perform procedures related to this measure, select the box under the measure name and description that states, *"Please enter zeros for this measure as I have no data to submit."*

Data collection: January 1-December 31, 2023
Data submission: January 1-May 15, 2024

Key Points To Remember

- ASC-9, ASC-11 (presently voluntary) ASC-13 and ASC-14:
  - Active Security Official to access HQR Secure Portal
  - Recommended to have two security officials if possible
  - Sign in to HQR Secure Portal frequently (every 90 days) to keep the account “active”

CLAIMS BASED MEASURES

ASC Quality Reporting Program Measures

ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

- Data is pulled by CMS from the Medicare Fee for Service claims previously submitted by the hospital that the patient visits within seven days of the colonoscopy for January 1, 2016-December 31, 2018, and subsequent years.
- **No data submission** or reporting required from the ASC
- Claims Detail Reports (CDR) and Facility-Specific Reports (FSR) will be made available to facilities via the HQR Secure Portal prior to public reporting.
- Information regarding this measure and timelines for the CDRs and FSRs is located at https://qualitynet.cms.gov/asc/measures.
- Data is updated periodically on Care Compare.

ASC Quality Reporting Program Measures

ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures

- The measure outcome is all-cause, unplanned hospital visits (Emergency Department Visit, Observation Stays, Unplanned Inpatient Admission) within seven days of an orthopedic procedure performed at an ASC.
- Data is pulled by CMS from the Medicare Fee for Service claims previously submitted by the hospital that the patient visits within seven days of the orthopedic procedure.
- **No data submission** or reporting required from the ASC
- Claims Detail Reports (CDR) and Facility-Specific Reports (FSR) will be made available to facilities via the HQR Secure Portal prior to public reporting.
- Information regarding this measure and timelines for the CDRs and FSRs is located at https://qualitynet.cms.gov/asc/measures.
- Data is updated periodically on Care Compare.

ASC Quality Reporting Program Measures

ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures

- The measure outcome is all-cause, unplanned hospital visits (Emergency Department Visit, Observation Stays, Unplanned Inpatient Admission) within seven days of a urology procedure performed at an ASC.
- Data is pulled by CMS from the Medicare Fee for Service claims previously submitted by the hospital that the patient visits within seven days of the urology procedure.
- **No data submission** or reporting required from the ASC
- Claims Detail Reports (CDR) and Facility-Specific Reports (FSR) will be made available to facilities via the HQR Secure Portal prior to public reporting.
- Information regarding this measure and timelines for the CDRs and FSRs is located at https://qualitynet.cms.gov/asc/measures.
- Data is periodically updated on Care Compare.

ASC Quality Reporting Program Measures

ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers

- The measure outcome is all-cause, unplanned hospital visits (Emergency Department Visit, Observation Stays, Unplanned Inpatient Admission) within seven days of a general procedure performed at an ASC.
- Data is pulled by CMS from the Medicare Fee for Service claims previously submitted by the hospital that the patient visits within seven days of the general surgery procedure.
- **No data submission** or reporting required from the ASC
- Claims Detail Reports (CDR) and Facility-Specific Reports (FSR) will be made available to facilities via the HQR Secure Portal prior to public reporting.
- Information regarding this measure and timelines for the CDRs and FSRs is located at https://qualitynet.cms.gov/asc/measures.

OAS CAHPS SURVEY

ASC Quality Reporting Program Measures

ASC-15 (a-e) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey

- **Voluntary** reporting for CY 2024 reporting period.
- **Mandatory** reporting begins with CY 2025 reporting period/CY 2027 payment determination.
- The survey contains 34 questions.
  - Telephone version only contains 32 questions
  - The mail survey questionnaire contains two questions that ask if anyone helped the sample member complete the survey.

ASC Quality Reporting Program Measures

ASC-15 (a-e) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey

The five measures (ASC-15a-e) are collected via one Survey (OAS CAHPS):

- ASC-15a: About Facilities and Staff;
- ASC-15b: Communication About Procedure;
- ASC-15c: Preparation for Discharge and Recovery
- ASC-15d: Overall Rating of Facility; and
- ASC-15e: Recommendation of Facility

- **Official OAS CAHPS website https://oascahps.org/**

(This is the official website for news, training and information about the OAS CAHPS survey.)

ASC Quality Reporting Program Measures

ASC-15 (a-e) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey

- 22 questions related to the patient, the facility, communication, and patient reported outcomes
- 12 demographic questions
- ASCs may add up to 15 supplemental questions
  - (These could be questions the ASC develops specific to their facility or from an existing survey. All supplemental questions must be placed after the core OAS CAHPS Survey questions (Questions 1 through 24).

- Survey is currently available in English, Spanish, Chinese and Korean

- Need to have 200 completed surveys over a 12-month period

- Smaller ASCs that cannot collect 200 completed surveys over a 12-month reporting period will be required to survey all eligible patients (that is, no sampling).

ASC Quality Reporting Program Measures

ASC-15 (a-e) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey

Current administration methods:

- Mail-only;
- Telephone-only;
- Mixed modes:
  - Mail with telephone follow-up;
  - Web (electronic) with mail follow-up;
  - Web (electronic) with telephone follow-up

ASC Quality Reporting Program Measures

ASC-15 (a-e) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey

- A CMS-approved survey vendor will be required for survey administration. Currently 16 vendors listed on the website- https://oascahps.org
- CMS-approved vendor collects survey data for eligible patients at the ASCs monthly and reports that data to CMS on the ASC's behalf by the quarterly deadlines established for each data collection period.

***ASCA has created an OAS CAHPS Survey page with a list of approved vendors and the modes they offer as well as additional information about the survey. You can find it here: www.ascassociation.org/oas-cahps*

OAS CAHPS Participation Overview:
https://oascahps.org/OAS_Part_Overview.pdf

1. Register for login credentials on the OAS CAHPS website using this link: https://oascahps.org/For-Facilities/Register-for-Login-Credentials

2. Log onto the website using the login credentials created when completing Step 1 above. Then, complete the Facility CCN Registration Form available from your customized dashboard or click on this link: https://oascahps.org/For-Facilities/Facility-CCN-Registration.
   - *If unable to register, contact oascahps@rti.org or call 1-866-590-7468.*

3. Contract with a CMS-approved OAS CAHPS Survey vendor to conduct the survey. A list of approved survey vendors is available at the following link: https://oascahps.org/General-Information/Approved-Survey-Vendors.

4. On the OAS CAHPS website, authorize your contracted survey vendor to collect and submit OAS CAHPS Survey data. Detailed steps for completing the online Vendor Authorization Form are provided in the document linked here: https://oascahps.org/OAS_Vendor_Auth_Instructions.pdf.

OAS CAHPS Participation Overview:
https://oascahps.org/OAS_Part_Overview.pdf

5. Work with your approved vendor to determine a date each month by which the vendor will need the monthly patient information file for sampling and fielding the OAS CAHPS Survey.

6. By the agreed-upon date each month, compile and deliver to the survey vendor a complete and accurate list of patients (i.e., the monthly patient information file) and information that will enable the vendor to administer the OAS CAHPS Survey. An example patient file layout can be found at https://oascahps.org/Survey-Materials

7. Avoid influencing patients in any way about how to answer the OAS CAHPS Survey. For example, facilities may not hand out any information to patients about how to answer the survey. (Please refer to the section Communications with Patients About the OAS CAHPS Survey in Chapter III of the OAS CAHPS Survey Protocols and Guidelines Manual found at https://oascahps.org/Survey-Materials

OAS CAHPS Participation Overview:
https://oascahps.org/OAS_Part_Overview.pdf

8. On the OAS CAHPS website, review the survey data submission reports to ensure the data were submitted by your survey vendor on time and without errors. To access these reports, click on the “Data Submission Reports” link under the “For Facilities” menu tab after logging into the website.

9. On the OAS CAHPS website, review OAS CAHPS Survey results prior to public reporting. To access these reports, click on the “Survey Preview Report” link under the “For Facilities” menu tab after logging into the website.

10. Monitor the OAS CAHPS website for news and updates about the OAS CAHPS Survey throughout the year. Announcements can be found here: https://oascahps.org/General-Information/Announcements

OAS CAHPS Participation

Step 1: Register for login credentials on the OAS CAHPS website

Step 2: Log onto the website using the login credentials created when completing Step and complete the Facility CCN Registration

	2/27/2024	3/13/2024
Total Facility CCN Registrations	1585	1618

Step 3: Contract with a CMS-approved OAS CAHPS Survey vendor to conduct the survey.

Step 4: On the OAS CAHPS website, authorize your contracted survey vendor to collect and submit OAS CAHPS Survey data.

	2/27/2024	3/13/2024
Current Vendor Authorizations	1191	1208

** 521 facilities submitted data in Quarter 3 of 2023

ASC Quality Reporting Program Measures

ASC-15 (a-e) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey

- The designated OAS CAHPS Survey Administrator's roles and responsibilities are:
  - Designate another individual within the organization to serve as the backup OAS CAHPS Survey Administrator;
  - Remove access or approve the removal of access for users who are no longer authorized to access the private side of the web portal;
  - Serve as the main point of contact with the OAS CAHPS Survey Coordination Team; and
  - Notify the OAS CAHPS Survey Coordination Team if your role as the OAS CAHPS Survey Administrator will no longer be valid and identify a successor.

OAS CAHPS
https://oascahps.org/Survey-Materials

Protocols and Guidelines Manual (Version 8.1: Updated Feb 2024 (824 pages)
https://oascahps.org/Portals/0/SurveyMaterials/V8.1_OASCAHPS_ProtocolsGuidelinesManual.pdf

- Communications With Patients About the OAS CAHPS Survey- page 34 (PDF)
- Patient Eligibility Requirements- page 55 (PDF)
- Mail-Only Administration Procedures- page 91 (PDF)
- Telephone-Only Administration Procedures- page 105 (PDF)
- Mail with Telephone Follow-Up Survey Administration Procedures- page 117 (PDF)
- Web with Mail Follow-Up Administration Procedures- page 139 (PDF)
- Web with Telephone Follow-Up Administration Procedures- page 169 (PDF)
- Public Reporting- page 285 (PDF)

OAS CAHPS

Communications With Patients About the OAS CAHPS Survey

Information to patients about the survey can include the following messaging:

- The ASC is participating in the survey to learn more about the quality of health care that patients receive.
- Patients may be selected to participate in a survey about their experience at the ASC.
- Indicate the mode of the survey that the patient should anticipate receiving (telephone, mail or web).

OAS CAHPS

Communications With Patients About the OAS CAHPS Survey

It is not acceptable for ASCs to do any of the following:

- Provide a copy of the OAS CAHPS Survey questionnaire, cover letters or invitation letters/email messages to the patients.
- Ask any OAS CAHPS or similar questions of patients prior to administration of the survey or after discharge.
- Include words or phrases verbatim from the OAS CAHPS Survey in marketing or promotional materials.
- Attempt to influence their patients' answers to the OAS CAHPS Survey questions.
- Tell the patients the facility hopes or expects their patients will give them the best or highest rating or to respond in a certain way to the survey questions.

OAS CAHPS

Communications With Patients About the OAS CAHPS Survey

It is not acceptable for ASCs to do any of the following:

- Imply that the ASC or its staff will be rewarded for positive feedback from patients.
- Offer incentives of any kind to the patients for participating (or not) in the survey.
- Help the patient answer the survey questions, even if the patient asks for the provider's help.
- Ask patients why they gave a certain response or rating to any of the OAS CAHPS Survey questions.
- Include any messages or materials promoting the ASC or the services it provides in survey materials, including mail survey cover letters, questionnaires, telephone interview scripts, web survey instruments, and web survey letters or email messages.

OAS CAHPS

Patient Eligibility Requirements

A patient must meet all the 12 eligibility criteria below to be eligible for the OAS CAHPS survey.

1. Patients who had at least one eligible outpatient surgery/procedure during the sample month (including outpatient surgeries and procedures when the patient had an overnight stay for observation but was not admitted to the hospital as an inpatient);
2. Patients who were at least 18 years of age when they received their outpatient surgery or procedure;
3. Patients regardless of insurance or method of payment;
4. Patients whose outpatient surgery or procedure was given in an HOPD or ASC as defined by the project;

OAS CAHPS

Patient Eligibility Requirements

5. Patient's surgery or procedure meets project eligibility definitions, which are as follows:
   - 5a. A procedure is OAS CAHPS-eligible if it has a G-Code8 of G0104, G0105, G0121,or G0260, or
   - 5b. A surgery, diagnostic procedure, or other type of procedure is OAS CAHPS-eligible if it has a CPT-4 code in the 10004–69990 range, was performed in an outpatient surgery department or ambulatory surgery center, and if it has no accompanying modifier of 73 or 74 (discontinued procedure)10
   - 5c. Note that a facility may assign more than one code to a surgery or procedure. The presence of one eligible G-code or CPT code is all that is needed to make it OAS CAHPS-eligible.
6. Patients who have a domestic U.S.mailing address;
7. Patients who are not deceased;
8. Patients who do not reside in a nursing home;
9. Patients who were not discharged to hospice care following their surgery;

OAS CAHPS

Patient Eligibility Requirements

10. Patients who are not identified as prisoners;
11. Patients who did not request that the HOPDs or ASCs protect their identity (that is, not release their name and contact information to anyone other than facility personnel), hereafter referred to in this manual as "no publicity" patients; and
12. Some states have regulations and laws governing the release of patient information for patients with specific illnesses or conditions, and for other special patient populations, including patients with HIV/AIDS. It is the HOPD's or ASC's responsibility to identify any applicable state laws and regulations and exclude state-regulated patients from the survey as required by law or regulation.

OAS CAHPS

For all modes the **survey vendor** must:

- Initiate the survey for each monthly sample no later than 3 weeks (21 days) after the close of the sample month.
- Complete data collection six weeks (42 days) after the survey initiated.
- Submit data files to the OAS CAHPS Data Center on the second Wednesday of January, April, July and October.

Quarter and Year	Data Submission Deadline
2023 Quarter 3	January 10, 2024
2023 Quarter 4	April 10, 2024
2024 Quarter 1	July 10, 2024
2024 Quarter 2	October 09, 2024
2024 Quarter 3	January 08, 2025

OAS CAHPS

- The OAS CAHPS Survey Facility Preview Report provides ASCs with a preview of their own survey results from the voluntary reporting period approximately 2-3 weeks via the OAS CAHPS website before publicly reported. Beginning with the 2025 mandatory data collection the preview reports will be posted through the HQR secure portal.
- Data are publicly released for a facility when that facility has four consecutive quarter of data. Public reporting includes four rolling quarters of data.
- An ASC's payment determination will be based upon the successful ***submission*** of all required survey data and ***not*** their facility score.

ASC-20: COVID-19 VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data is reported via the National Healthcare Safety Network (NHSN)

NHSN/Secure Access Management Services (SAMS)

For the COVID 19 vaccination status measure, two things need to occur:

1. The facility must have an active NHSN account.
   AND
2. The facility must have a NHSN Facility Administrator with a current SAMS security profile.

****To avoid your account being locked out, you must log in to NHSN once every 60 days**

ASC Quality Reporting Program Measures

ASC-20 COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

- Numerator: ~~Cumulative number of HCP eligible to work in the ASC for at least one day during the reporting period and who received a complete vaccination course against COVID–19.~~
- Cumulative number of HCP eligible to work in the ASC for at least one day during the reporting period who received a complete vaccination course and are up to date with CDC recommended COVID– 19 vaccines.

- Denominator: ~~Number of All Core HCP eligible to work in the ASC for at least one day during the self-selected week, excluding persons with contraindications to COVID-19 vaccination.~~
- Number of HCP eligible to work in the ASC for at least one day during the reporting period, excluding persons with contraindications to COVID-19 vaccination as described by the CDC.

ASC Quality Reporting Program Measures

ASC-20 COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

– Required categories of HCP

1. Employee on facility payroll (regardless of clinical responsibility or patient contact)
2. Licensed independent practitioners, e.g., physicians (MDs, DO), advance practice nurses and physician assistants who are affiliated with the facility who do not receive a direct paycheck from the facility
3. Adult students/trainees and volunteers who do not receive a direct paycheck from the facility
4. Other contract personnel

ASC Quality Reporting Program Measures

ASC-20 COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

- Begin reporting data beginning January 1, 2022, for the CY 2024 payment determination
- Report the measure through the CDC NHSN web-base surveillance system
- Collect the numerator and denominator for **at least one, self-selected week during each month of the reporting quarter** and submit the data before the **quarterly** deadline (The week selected needs to begin and end in that month you intend to submit. Select the second or third week of the month to avoid entering data for the wrong month.)
- The CDC would calculate a single quarterly rate for each ASC by taking the average from the three submission periods for that quarter. CMS would publicly report each quarterly rate as calculated by the CDC.
- Data collection forms, instructions, resources and FAQs are available at https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html

Upcoming ASC-20 Reporting Deadlines

The ASC can report any month in the quarter through 11:59pm Pacific Time of that quarterly deadline.

Quarterly Data Submission	Deadline
Quarter 4 2023 (October 1 – December 31, 2023)	May 15, 2024
Quarter 1 2024 (January 1 – March 31, 2024)	August 15, 2024
Quarter 2 2024 (April 1 – June 30, 2024)	November 15, 2024
Quarter 3 2024 (July 1 – September 30, 2024)	February 15, 2025

ASC-20 COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

Definition of "Up To Date"

- Always use the NHSN surveillance definition corresponding to the reporting week that you are reporting data for.

https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf

- Changes in Reporting Definitions:
  - Reporting Period: Quarter 4 of 2023 (Sept 25, 2023 – Dec 31, 2023)
  - Reporting Period: Quarter 1 of 2024 (January 1, 2024- March 31, 2024)

COVID-19 Vaccination Reporting https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html

Facilities can submit COVID-19 vaccination data to NHSN in three ways:

1. Directly into the data entry screens of the COVID-19 vaccination module
2. Through .CSV Data Import of the Person-Level COVID-19 vaccination form
3. As of September 2023, by the Person-Level COVID-19 vaccination form

1. Directly into the data entry screens of the COVID-19 vaccination module:

- Data Tracking Worksheet for COVID-19 Vaccination Among Healthcare Personnel (October 2022 thru June 25, 2023)- Excel spreadsheet (Retired)
  - Tracking Worksheet
  - Reporting Summary
- **The October 2022 version of the Excel Data Tracking Worksheet is the latest version however it is no longer being maintained by NHSN.**

COVID-19 Vaccination Reporting https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html

2. Through .CSV upload of the Person-Level COVID-19 vaccination form

New .CSV templates and example files are listed at the abovementioned website.

3. Person-Level COVID-19 vaccination form

- Helps users organize and manage their facility's data
- The application calculates and enters the weekly totals for you.
- The application determines who is up to date based on vaccination dates and reporting week. *It applies the up-to-date definition for the facility.*

  – *Healthcare Personnel Safety Person-Level Vaccination Form: General Training- Sept 2023*
  https://www.cdc.gov/nhsn/pdfs/hps/covidvax/hps-nhsn-person-level-vaccination-sep-2023-508.pdf

  – *Updates to Weekly COVID-10 Vaccination Data Reporting Healthcare Personnel Safety Component- Jan 2024*
  https://www.cdc.gov/nhsn/pdfs/hps/covidvax/hps-component-covid19-updates-january-2024-508.pdf

ASC Quality Reporting Program Measures Final

ASC-21 Risk Standardized Patient-Reported Outcome- Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting

- This measures reports the facility-level risk-standardized improvement rate in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for 12 months prior to the date of the procedure and in Medicare FFS Part A and B during the procedure.

- This measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed at ASCs and does not include any inpatient procedures.

ASC Quality Reporting Program Measures Final

ASC-21 Risk Standardized Patient-Reported Outcome- Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting

- Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning:
  - For THA recipients: The Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR)
  - For TKA recipients: The Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR)
- Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery).
- Improvement scores are risk-adjusted to account for differences in patient case-mix.

ASC Quality Reporting Program Measures Final

ASC-21 Risk Standardized Patient-Reported Outcome- Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting

- The THA/TKA PRO-PM uses four sources of data for the calculation of the measure:
  1. PRO data (one of the two joint-specific PRO instruments and one of the two additional PRO instruments for pre-operative mental health score: (1) Patient-Reported Outcomes Measurement Information System-Global Mental Health subscale or (2) the Veterans RAND 12-Item Health Survey Mental Health subscale
  2. claims data
  3. Medicare enrollment and beneficiary data; and
  4. U.S. Census Bureau survey data

ASC Quality Reporting Program Measures Final

ASC-21 Risk Standardized Patient-Reported Outcome- Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting

- The first voluntary reporting period would begin CY 2025 for eligible outpatient procedures between January 1, 2025, through December 31, 2025; the second voluntary reporting period would begin with the CY 2026 reporting period for eligible outpatient procedures between January 1, 2026, and December 31, 2026; and the third voluntary reporting period would begin with CY 2027 for eligible procedures between January 1, 2027- December 31, 2027.

- Mandatory reporting would begin with CY 2028 reporting period for CY 2031 payment determination for eligible outpatient procedures occurring January 1, 2028, through December 31, 2028. *(This three-year gap is because of the delay when the procedure occurs, when the results and reported (greater than 1-year post-op) and payment determination.)*

ASC-20 COVID-19 Vaccination Coverage Among Health Care Personnel (HCP)

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program provides a Web-Based Measure Status Listing that allows facilities to check their data submission status for web-based measures in the program.

- https://www.qualityreportingcenter.com/en/ascqr-program/data-dashboard/ccn/
- COVID-19 Lookup (CY 2025 Medicare Payment Update): enter your ASC's CCN to see your facility's submission status.

Please note that currently this page is only being updated monthly, so if you just submitted your data, it might not yet be displayed there.

Data last updated on:
NHSN Submission: March 18, 2024

ASC Lookup Tools

https://www.qualityreportingcenter.com/en/ascqr-program/data-dashboard/ccn/

- Web-Based Status Listing (PY 2024)

Provides a quick way to determine if your facility has completed data submission for ASC-9, ASC-11 (voluntary), ASC-13, ASC-14 and ASC-20.

Enter your facility's CMS Certification Number (CCN) or National Provider Identifier (NPI).

Data last updated on:
Web Based Measures Submission: May 16, 2023
NHSN Submission: March 18, 2024

Care Compare

- There are seven measures publicly reported (ASC-9, ASC-11, ASC-12, ASC-13, ASC-14, ASC-17, ASC-18 and ASC-20).

- https://www.medicare.gov/care-compare/
- Click "Hospitals" icon
- Click "Visit the ASC data on CMS.gov"
- Can view data by facility, state and nationally

2023 Measures Under Consideration (MUC) List

- The Screening for Social Determinants of Health (SDOH) is a process measure that assesses the total number of patients, who were 18 years or older on the date of service, screened for social risk factors (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety). Recommended to move forward.
- The Screen Positive Rate for Social Determinants of Health (SDOH) is a process measure that provides information on the percent of patients who were screened for all five health-related social needs (HRSNs), and who screened positive for one or more of the above. Not recommended to move forward.
- Facility Commitment to Health Equity: is a structural measure that assesses facility commitment to health equity using a group of equity-focused organizational competencies (part of strategic plan, data collection, data analysis, quality improvement and leadership engagement). Recommended to move forward.

2023 Measures Under Consideration (MUC) List

- Other measures on the MUC list to take note of *(not currently proposed for ASC Quality Reporting Program, but it is possible that they could be in the future):*
  - Hospital Harm-Falls with Injury
  - Hospital Patient Experience of Care-addition of questions regarding restfulness (environment),care coordination among staff, information given by staff regarding symptoms to watch for after discharge
  - Patient understanding of key information related to recovery after an Outpatient Procedure
  - Patient Safety Structural Measure-an attestation-based measure that assesses whether hospitals demonstrate having a structure and culture that prioritizes patient safety
  - Age Friendly Hospital Measure- assesses hospital commitment to improving care for patients 65 years of age or older receiving services in the hospital, operating room, or emergency department

Questions?

- For ASC Quality Reporting Program Questions: https://cmsqualitysupport.servicenowservices.com/qnet_qa?id=ask_a_question
- NHSN: Instead of using nhsn@cdc.gov, nhsntrain@cdc.gov, and nhsndua@cdc.gov, NHSN-ServiceNow should be used to submit questions to the NHSN Help Desk. https://www.cdc.gov/nhsn/about-nhsn/helpdesk.html
- RTI International (OAS CAHPS): Contact oascahps@rti.org or call 1-866-590-7468

Contact Information

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To Code or Not to Code (15)

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Adverse Incident Reporting

The term “adverse incident” means an event over which health care personnel could exercise **control** and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which results in one of the following injuries:

Code 15 Reporting

- Death
- Brain or spinal damage
- The performance of a surgical procedure on the wrong patient
- The performance of a wrong surgical procedure
- The performance of a wrong-site surgical procedure
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition

Code 15 Reporting, continued

- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient **and** documented through the informed-consent process
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure

Annual Report

Code 15 Reports **PLUS**

- Permanent disfigurement
- Fracture or dislocation of bones or joints
- A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility
- Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent
- Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident

Reporting

Within 15 calendar days (Code 15):

"Any of the above incidents, whether occurring in the licensed facility or arising from health care prior to admission in the licensed facility, shall be reported by the facility to the agency within 15 calendar days after its occurrence."

Annual reporting:

After December 31 and by April 1

Case 1

- Block of ankle
  - Patient to have block prior to surgery
  - Site marked by anesthesiologist
  - Anesthesiologist went to medication room to draw medication
  - Anesthesiologist returned and inserted needle. Patient said, “Why are you injecting my right ankle?”
  - Anesthesiologist realized wrong ankle.
  - No medication injected.

Case 2

- Patient and husband came into lobby and walked to registration. Patient signed in and staff member said something about patient returning for second surgery. Husband said, “Yes, maybe the doctor will do the correct side this time.”
- Registration staff informed administrator of comment.
- Discussed with surgeon who said, based on image on the date of the previous surgery and patient’s comments in pre-op, he decided left instead of right side was needed that previous admission.

Case 2, continued

- What was written on the consent form? Was consent changed to do other side? No. Why not?
- What is documented in the medical record regarding patient assessment?
- Were films taken the day of previous injection prior to time of procedure?
- Did operating room staff know during that first surgery that site was not as scheduled or consented? Why not?
- What role does the nurse and radiology tech have in correct site for injection?
- Does the site get marked in pre-operative area? If not, when does it occur?

Case 3

- Patient had a plan of care that listed the procedures the physician planned to perform. This was part of the H&P and went to the surgery center via electronic transmission.
- The pain practice scheduler went online to ASCs scheduling system and scheduled procedure #3.
- The patient was admitted. The circulator confirmed the procedure by asking the patient, so did the anesthesia provider.
- The doctor did the surgery that was written on the consent, the white board of the OR, and verified by circulator and anesthesia provider.

Case 3, continued

- Patient went to doctor for follow up and that is when doctor noted he had performed procedure #3 when he had ordered procedure #2.
- What processes were involved?
  - Scheduling
  - Review of H&P by ASC staff. H&P and plan said procedure #2 to occur
  - Clarity with patient about procedure and site
  - Persons involved in time out in operating room
  - Memory re-call, previous steps or fresh look at documentation?
- Since #3 was also planned later, was this a wrong procedure?

Case 4

- Patient was nearly blind before surgery.
- At end of surgery day, RN reports that a lens in the OR is “extra” and should have been removed from the O.R. when 5th case cancelled.
- 23.5 diopter planned for patient # 6. Diopter of 22.0 implanted was for patient # 5.
- Staff alerts physician who has already left for the day.
- Next day, patient returns to doctor’s office. Is delighted that vision is great. Patient DID NOT NEED to return to surgery for replacement lens.

Case 5

- Patient had cataract surgery.
- At follow up visit next day, patient vision much worse than expected.
- Office records show 25.0 diopter. Office assistant wrote 20.5 on the lens sheet that goes to the ASC.
- ASC pulled 20.5 and doctor implanted 20.5
- Physician did not replace lens. Patient fitted for glasses to correct vision. Why?

Case 6

- Early afternoon, tech tells RN manager that scope washer repairman arrived. Huh? What for?
- 16 lower GI cases performed that morning.
- From 4th case onward, processing not performed correctly. 4th patient was Hepatitis C positive.
- CDC: "If symptoms occur, the average time is 6–7 weeks after exposure, but this can range from 2 weeks to 6 months. However, many people infected with the Hepatitis C virus do not develop symptoms."
- Called med mal carrier and held discussions.
- Patients 5 – 16 were contacted. ASC paid for testing immediately, at 2 weeks, at 8 weeks, at 6 months, at one year. No patients were Hep C positive.

Case 7

- Patient is terminal cancer patient with renal failure and many other co-morbidities.
- Patient has pain procedure.
- Patient admitted to hospital within 30 hours after procedure.
- Patient expires.

Case 8

- Patient has pain procedure.
- Day after, patient has kidney dialysis.
- Two days after dialysis patient dies.

Case 9

- Patient (33-years-old) had abdominoplasty and breast implants.
- Two days after surgery, boyfriend goes to awaken her and finds her unresponsive in bed.
- EMS transports to hospital emergency department where she is pronounced dead.
- ER record: patient had aspirated. Awaiting toxicology.
- Boyfriend's statements: Patient had lots of pain. He left bed to sleep on sofa due to her snoring. She had taken meds from medicine cabinet in addition to pain meds prescribed by surgeon.

Case 10

- 24-year-old male had hand surgery to repair crushed bones
- Codes on the OR table. 911 called.
- Transported to hospital – less than 15 minutes away.
- Resuscitation unsuccessful.
- History of illegal drug use. At hospital, patient's friend said he had used drugs prior to arriving at ASC.

Documenting the Event

- Record only the direct medical care. Write only the facts.
- Do not write conclusions, opinions, admissions or accusations.
- Not part of the medical record and nothing in medical record that states an incident report was completed.
- No copies made of the incident report

Analysis of the Event

- Record analysis separate from the incident report facts.
- Make review part of quality and peer review process.
- Attempt to determine and understand the cause
- Perform Root Cause Analysis
- Blame free environment to encourage reporting and thoughtful, open-minded analysis
- “Over which healthcare could exercise control”

Root Cause Analysis or Roots of Causes

- System or process approach – not a blame game
- Determination of human and other factors
- Determination of related processes and systems
- Analysis of underlying cause and effect systems through a series of ***why*** questions
- Identification of risks and their potential contributions
- Determination of potential improvement in processes or systems

Action

- Action plan for improvement or correction for each root cause or contributing factor.
- At minimum, a suggested corrective action, a date of implementation, a team appointed to carry out the action, how and when each action will be evaluated, and the date of evaluation.
- Did the action fix the problem? (QAPI)

AHCA Reporting

- AHCA asks for root cause analysis? Are your required to submit RCA?
- Do you file report when you are not sure of cause or if there was control over it?
- Do you file report when you learn of an event that occurred weeks or months ago?
- How can AHCA know of an event?

Resources

- Patientsafety.va.gov
  - FMEA example
- AHRQ.gov: Agency for Health Care Quality
- Joint Commission
  - Universal protocol
  - Root cause analysis and template
- ASHRM

Questions

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Agenda

- This presentation covers:
  - Key Employment Laws
  - The responsibilities of supervisors and managers through various phases with employment process.
  - Practical Ways to Avoid Workplace Liability
  - Q & A

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A Motto to Live By…

- "Without Human Resources, there is no bottom line…"

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AI Will Not Prevent or Replace HR Issues

- Employee relations issues are as old as work itself
- The type of issues may change, but basic human nature does not
  - Types of discrimination and protected conduct continue to evolve
  - Changing attitudes toward presents new challenges
    - Remote work, even where physical presence is required
- Increased emphasis on employee rights and ability to move between employers

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Basic Keys to Avoiding Liability

- "Top Down" and widespread commitment to creating a respectful workplace that provides equal employment opportunities for all.
- Understanding and complying with applicable laws that prohibit discrimination, harassment and retaliation.
- Laws are intended to ensure individuals are not discriminated against or harassed in the workplace based on any protected categories
- Take the laws and your internal policies seriously. The laws and policies strictly prohibit and do not tolerate unlawful discrimination or harassment or retaliation

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Types of Behavior at Issue

- Discrimination based on membership in protected class
- Harassment
- Retaliation because someone engaged in or complained of discrimination or harassment
- “Bullying”
- Workplace violence
- Leave/Absence/Attendance issues

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Key Employment Laws

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Quick Summary of Relevant Laws

- **Title VII of the Civil Rights Act of 1964** (Title VII), which prohibits discrimination based on race, color, religion, sex (including gender, pregnancy, sexual orientation, and gender identity), marital status and national origin
- the **Age Discrimination in Employment Act** (ADEA), which prohibits discrimination against individuals aged 40 and over based on their age
- the **Americans with Disabilities Act** (ADA), which prohibits discrimination based on **disability**
- **Section 1981 of the Civil Rights Act of 1866**, which prohibits discrimination based on race, color, and ethnicity
- the **Equal Pay Act** (EPA), which prohibits sex-based wage discrimination against men or women performing substantially equal work in the same establishment
- the **Genetic Information Nondiscrimination Act** (GINA), which prohibits discrimination based on genetic information
- the **Uniformed Services Employment and Reemployment Rights Act** (USERRA), which prohibits discrimination based on past, current, or prospective service in the uniformed services
- **Florida Civil Rights Act – overlaps with Title VII, ADEA, ADA**

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Additional Legal Protections for Employees

- Leave laws (FMLA, ADA)
  - Mental health, Long COVID, pregnancy
  - Medical leave, parental leave, sick leave
- Whistleblower protections (SOX, Florida Private Employers Whistleblower Act)
- Health & Safety (OSHA)

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Employer Liability for Discrimination and Harassment and Retaliation

An employee's discriminatory or harassing or retaliatory actions may be imputed to employer in certain circumstances and lead to getting sued.

An employer is **strictly liable** for discrimination and retaliation by supervisors if it results in a tangible employment action (such as termination or demotion).

An employer may be held liable even without any tangible employment action if the employee can prove **hostile work environment** harassment.

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Potential Liability if Violations

- Back pay and interest
- Reinstatement
- Front pay
- Compensatory damages (capped under Federal law, no cap under Florida law)
- Punitive damages (capped under Federal law and Florida law)
- Liquidated damages
- Attorney's fees

Does not include cost of defense (and typically employer cannot recover attorneys' fees if wins)

KEY TAKE AWAY – Lawsuits Are Expensive

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Policies

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Do you have a Discrimination/No Harassment policy

- Example: **EQUAL EMPLOYMENT OPPORTUNITY/ NO DISCRIMINATION/ NO HARASSMENT POLICY**
- Does it mirror federal and state law requirements?
- How do employees have access to it?

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Example

Equal Opportunity Employer

It is the Company's policy to provide equal employment opportunity in all aspects of the employer-employee relationship and all privileges and conditions of employment. The Company may not unlawfully discriminate on the basis of race, color, religion, sex (including pregnancy, childbirth, or related medical condition), national origin, ancestry, age, physical or mental disability, legally protected medical condition, or veteran status or any other basis made unlawful by applicable federal, state or local law, ordinance or regulation. The Company also makes reasonable accommodations for disabled employees who request an accommodation for qualifying medical conditions, unless undue hardship would result.

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TAKE AWAYS

Employers are required to provide equal employment opportunities throughout employment life cycle:

- Recruitment; Interviewing and Selection; Hiring.
- Compensation.
- Informal Coaching and Feedback.
- Formal Performance Appraisals.
- Career Progression and Development (Promotion/Training).
- Work Environment Culture.
- Terminations.
- "Post" Termination.

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What Is Discrimination?

Taking some employment action that has the purpose or effect of treating an employee (or group of employees) differently than a similarly situated employee (or group of employees) based on a protected characteristic (typically a material tangible difference)

- Unfair treatment
- Compensation
- Promotion
- Retention
- Termination
- Discipline
- Leave management

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What Is Discrimination? (cont.)

Discriminatory misconduct can sometimes be overt, such as the use of racial slurs, but it can also be subtle or even concealed.

Examples include:

- An African-American employee is repeatedly passed up for a promotion even though he is clearly the most qualified.
- A manager does not hire a female applicant because he is concerned she will get pregnant and take a leave of absence.
- A manager makes an assumption that an older worker wants to retire and therefore selects him for a position elimination.

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What is Harassment?

Harassment is a type of discrimination. It is often referred to as a "hostile work environment."

Harassment defined as:

- unwelcome conduct based on one's protected class where enduring the offensive conduct becomes a term or condition of employment; or
- the conduct is so severe or pervasive that it creates an environment that a reasonable person would consider to be intimidating, hostile, or abusive.

Sexual Harassment also includes *Quid pro quo* harassment and applies where a supervisor seeks sexual favors either:

- In return for a job benefit (for example, a promotion or raise).
- To avoid a job detriment (for example, a demotion or pay cut).

Harasser's intent irrelevant

Remember, one instance of severe conduct can be enough.

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Who Can Be a Harasser?

- Supervisors.
- Co-workers.
- Customers.
- Clients/vendors.
- Individuals or groups doing business with the company or on the premises.
- Men can harass women.
- Women can harass men.
- Men can harass men.
- Women can harass women.
- Minority can harass another minority (same race or not)

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Harassment Not Limited to the Workplace

Harassment (sexual or other type) can occur outside the workplace, for example during:

- Annual sales meetings or conferences.
- Business trips.
- Holiday parties.
- Sporting events.

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What Is Retaliation?

- Taking some employment action that has the purpose or effect of treating an employee differently because they engaged in protected activity
  - Refusal/failure to hire
  - Unfair treatment (such as isolating, unfavorable assignments)
  - Compensation
  - Promotion
  - Retention
  - Termination
  - Discipline
  - Leave management

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TAKE AWAYS

Do not have a practice or culture of tolerating harassment of any kind at the workplace, including sexual harassment [or bullying].

Foster a work environment where everyone is treated with dignity and respect.

This means being an employer that does not allow conduct that:

- Has the purpose or effect of creating an intimidating, hostile, or offensive work environment or otherwise adversely affects an individual's employment opportunities.
- Explicitly or implicitly requires sexual conduct in exchange for some employment benefit.

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Example of Complaint Policy

Complaint Procedure

Every employee has a right to redress for unlawful discrimination or harassment. Employees are encouraged to report any incidents of discrimination or harassment forbidden by this policy immediately so that complaints can be quickly and fairly resolved.

If an employee believes he/she is being or has been unlawfully discriminated against or harassed on the job or believes the comments, gestures or actions of any employee, including members of management, supervisors and co-workers, as well as by any person doing business with or for [name of employer], to be offensive, or of a nature to impair the employee's working ability or emotional well-being, the employee should use the following procedure:

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Example Complaint Policy (cont.)

Complaint Procedure

A complaint, in writing, should be made to any Manager or the President or COO as soon as possible after any incident believed to be prohibited is conducted.

The complaint should include the details of the incident or incidents, the names of the individuals involved and the names of any witnesses.

All allegations of unlawful discrimination or harassment will be thoroughly and objectively investigated. This investigation will be completed with as much confidentiality as is possible and a determination regarding the allegations will be made and communicated as soon as practicable.

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Example Policy (cont.)

Complaint Procedure

If the Company determines that inappropriate conduct has occurred, [name of employer] will take effective remedial action. Any employee determined by [name of employer] to be responsible for such conduct will be subject to appropriate disciplinary action, up to and including termination of employment. Appropriate action will also be taken to deter any future such conduct. Whatever action is taken will be communicated to the employee who initiated the complaint. [Name of employer] may not retaliate against any employee for making a complaint and does not tolerate retaliation by management employees or co-workers.

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Why does this matter?

- Having a policy prohibiting discrimination and harassment, a complaint procedure, and a mechanism to remedy the problem creates a defense for employers.
  - This is known as the *Faragher* defense
  - Why is this defense important?
    - It recognizes that bad behavior will occur at the workplace. The employer's response determines liability.

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TAKE AWAYS

- Complaints should be reported immediately so that the company has an opportunity to address the situation.
- Employees have various avenues of reporting conduct that they feel is harassing, including informing either:
  - direct supervisor,
  - the supervisor of your direct supervisor,
  - to Human Resource's personnel or
  - the President

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TAKE AWAYS (cont.)

As an employer you must take every complaint seriously and:

- Conduct a prompt and thorough investigation.
- Address inappropriate behavior.
- Take disciplinary action when appropriate.
- Deal with confidentiality issues.

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Best Practices

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Guidelines for Leaders

- Be consistent in how you manage employees!
  - Treat similarly situated employees similarly.
  - If the employee can show he or she has been treated differently than other employees in similar circumstances, the risk of liability increases.
  - Legitimate reasons for differences in treatment (i.e., prior discipline, historical performance issues, length of service, etc.) must be clear, compelling, and **documented.**

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Guidelines for Leaders

- Foster an open environment.
- Know your policies and apply them consistently (i.e. no favoritism).
- Seek involvement of HR early on.
  - Immediately report harassment or discrimination to HR.
  - Medical, disability, leave-related issues.
  - Documented Discipline or Corrective Action.
- Do not ignore problems and act promptly.
- Above all else: Create respect by respecting others as professionals.

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Establishing Performance Expectations

Performance Reviews

- Don’t be afraid to be truthful. If there are problems, discuss them. A cautious, inaccurate review is worse than no review.
- Be as objective as possible. Avoid speculation and commentary about non-work-related reasons for performance problems.
- Make sure the words you use accurately describe performance.

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Establishing Performance Expectations

Potential Concerns with Performance Reviews

- Rating employees within a narrow band or range which dilutes differences in performance among employees.
- Recency trap: rating employees based on the past few weeks rather than over the entirety of the appraisal period.
- Annual review process lacks substance.
- Saving all feedback for the annual review.
- "Grade inflation" (i.e. better reviews and comp than warranted).
- Favoritism.

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Best Practices - Performance Management

- Based on behavior and performance, not personalities.
- Nothing requires a company to accept poor quality/poor quantity of work from any employee.
- Be reasonable, flexible and patient, but do not accept persistent poor performance.
- Failure to manage low performers can lead to morale problems with high performers ("group project" mentality).

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Best Practices - Performance Management

- Define the performance deficiency.
- Refer to specifics or a pattern of conduct.
- Be constructive.
- Explain the big picture -- how this conduct impacts coworkers/organization.
- Don't avoid taking action.
- ***Timeliness is key.***

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Best Practices - Corrective Action

- Spell out the consequences if the employee does not improve.
- Offer assistance (additional training, etc.).
- Make the employee responsible.
- Be cautious of potential consistency issues.
- Note previous discussions, the direction for the future and, whenever possible, get the employee's agreement.

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Risks of Termination

- Evaluation of Risk Factors
  - High level employees (high earners)
  - Employees in protected classes
    - age, sex, race, disability, etc.
  - Long-service employees with "good" records

"Don't think of it as getting fired. Think of it as finally being recognized for your incompetence."

- Managers are often in a hurry to terminate poor performers.
- Managers don't want to wait for counseling, warnings, documentation because "the business can't wait".

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Why Should You Care?

- Thorough, accurate performance reviews and well-executed corrective action mitigate legal risk.
- Improve job performance.
- Assist employee retention and promotion.
- Help avoid and successfully defend litigation.
- Smooth termination process.
- Improves employee morale because process is perceived as fair.
- More likely to have employee related decisions approved.

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The Top Mistakes Managers Make

- Not confronting/documenting performance issues.
- Rewarding poor conduct/bad behavior with comp.
- “Looking the other way” for top performers.
- Treating out-of-office settings to lesser standard of conduct.
- Poor documentation.

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Documentation Best Practices

- To write or not to write?
- Why/When/How

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Why Document?

- Memory
  - Speculation can replace fact without documentation
  - Prevents later "he said, she said"

- Credibility
  - Critical to defending legal actions against Company by employees
  - Provides "visible" support to testimony
  - Notes are more difficult to confuse than witnesses
- Fairness
  - Establish fair treatment, particularly when employee acknowledges receipt
  - Record of basis for decisions (promotion, termination, etc.)
  - Supports compensation decisions

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When to Document – Performance

The good. . .

- Record of basis for promotion, qualifications, etc.
- Record of fair treatment – rebut the "out to get me" narrative

. . . and the bad

- Record of basis for later discipline/termination – if needed
- Record of employee acknowledgement of problems
- Be critical when warranted – avoid "Midwestern nice" trap
- Can be formal performance review or counseling as-needed – but be consistent

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When to Document – Discipline

- What counts?
  - Counseling (even if verbal, make a record it happened)
  - Written warnings
  - Termination
- Documentation ensures discipline has:
  - Substantive fairness (reason for taking action)
  - Procedural fairness (carried decision out properly)

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When to Document

- Documentation Reminders:
  - There are no “off the record” notes or conversations
  - “Shadow files” are not a safe harbor
  - All computer files are written documents
  - E-mails are written documents
  - Text messages are written documents
  - Keep medical information separate and confidential
    - If you come into this info, immediately contact HR

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How to Document

- Contemporaneously
  - You cannot go back and create records later (operates as an admission of wrongdoing)
- Consistently
  - Do not treat similar employees/situations differently
  - Do not "target" an employee with documentation
- Clearly
  - Objective notes with "who, what, where, when" facts
  - Avoid subjectivity
- Confidentially (when needed)
  - Investigation files

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Take Aways

- Bottom line:
  - Know the law
  - Know the rules
  - Apply them consistently
  - Lead by example
  - Involve HR
  - Understand the employment relationship is a lifecycle
  - Keep consequences in mind before taking action

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Hypotheticals

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Hypothetical 1

Jeff is a supervisor and Claudia, one of his direct reports, tells him that a co-worker keeps asking her out and making other remarks that make her uncomfortable at work. To Jeff, the situation doesn't sound like sexual harassment. Claudia wears tight clothes and short skirts and is known around the office to be quite a flirt. Jeff thinks Claudia is being overly sensitive and exaggerating the situation.

What are Jeff's responsibilities, if any?

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Answer to Hypothetical 1

Jeff must report Claudia's complaint to Human Resources.

- Supervisors must report all employee complaints to Human Resources.
- Jeff's subjective opinion of the situation is not relevant.
- Supervisors have a duty to maintain a respectful workplace and not permit inappropriate behavior to go unchecked. If uncertain about appropriate activities or behavior, supervisors should consult Human Resources.
- Supervisors should also support the company in its responsibility to investigate complaints of discrimination. At the end of the investigation, supervisors should work with Human Resources to implement any disciplinary action.

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Hypothetical 2

Brian sometimes makes comments to his administrative assistant, Alice, about how attractive she is. She never says anything when he makes these comments. One day, Alice requests a raise. Brian says that he will consider the request if she goes out to dinner with him. Alice makes it clear that she wants to keep their relationship purely professional and would prefer not to go out with him. Brian says he understands.

Alice mentions casually to a friend in Human Resources that Brian has been making inappropriate comments and that he would only consider a raise if she went out with him. Human Resources investigates the comments and Brian and gives a written warning. Several months later Brian gives Alice an unfavorable performance evaluation. Alice's prior evaluations were always stellar.

Does Brian's act constitute retaliation?

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Answer to Hypothetical 2

Likely Yes.

- Harassment reporting is a protected activity.
- Assuming that there is documented performance issues prior to the Alice's protected activity, Brian's poor evaluation certainly would seem to be retaliatory.

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Hypothetical 3

- Wanda, who is Black, works in the main office. On Wanda's first day, a customer, who is White, was very rude to her. Since then, the customer's rude behavior continues, including some comments that could be considered racist.
- Does the customer's conduct violate your policy? If so, what should Wanda do?

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Answer to Hypothetical 3

- Yes.
  - Employers may be held responsible for harassment, even when the harasser is not an employee, if the employer knew about the harassment and did not try to stop it. The company could, for example, contact the vendor company, tell them about the harassment, and insist that it stop immediately. TMM could also request that a different person be assigned to deal with the customer..
- Wanda should:
  - tell the customer that she finds his behavior offensive, and that it must stop immediately.
  - report the harassment to her supervisor or Human Resources immediately. Once the company knows Wanda is being harassed because of her race, it has a responsibility to stop the harassment and to protect her from further harassment.

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Other Issues You May See:

- How do I accommodate an employee with a disability?
  - Obligation to accommodate / duty to have an “interactive dialogue.”
- How do I balance leave requests with obligation not to discriminate?
  - This includes FMLA leave.

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Other Issues You May See:

- What if an employee has a medical marijuana card?
- How do I respond to threats of workplace violence?
- What about mental health issues?
- Can employees bring guns to work?

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