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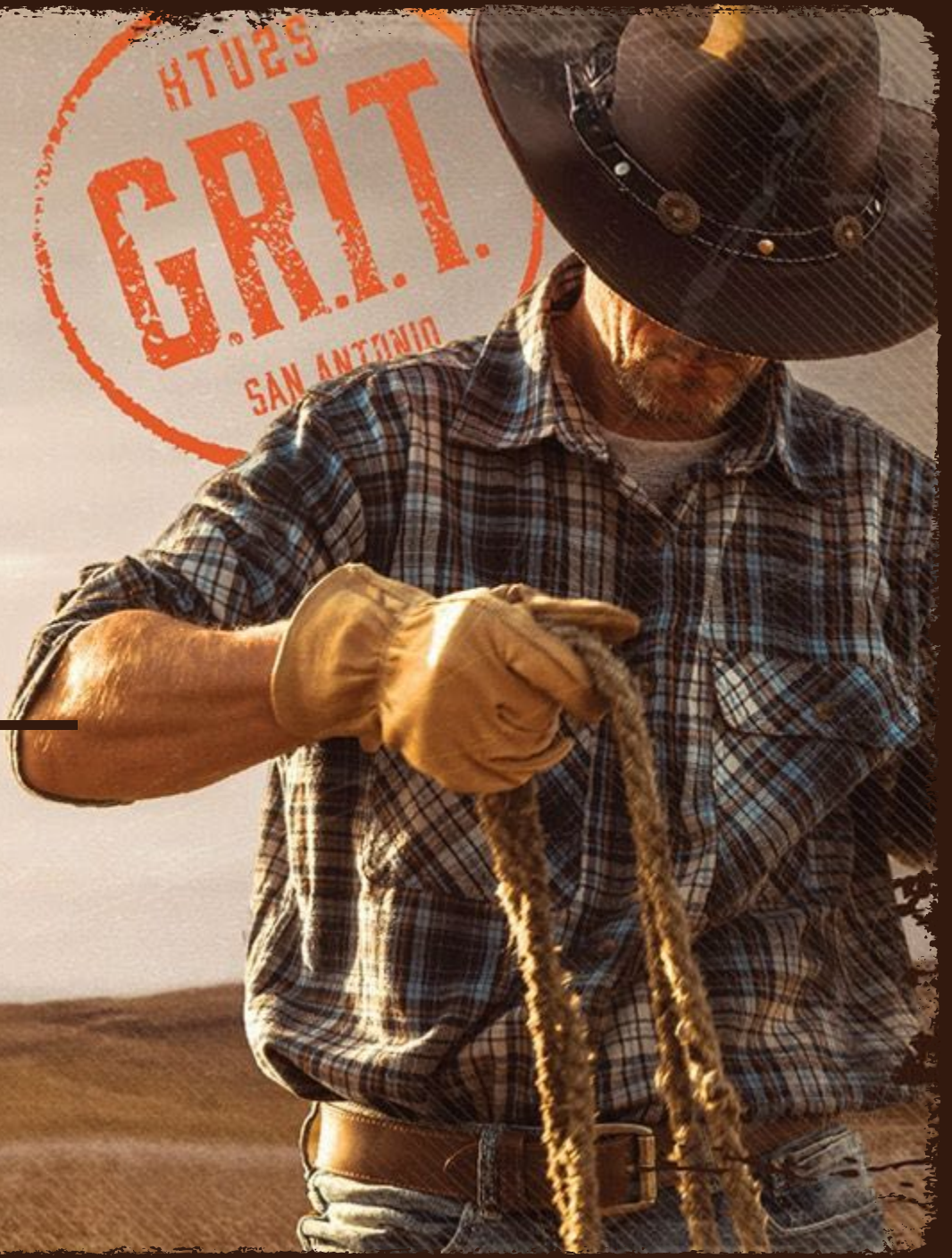
Sterile Compounding & IV Room Inspections in 2025—Are you ready?



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CE Deadline: 09/30/25

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Sterile Compounding & IV Room Inspections in 2025—Are you ready?

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Disclosures

The presenter has no real or perceived conflicts of interest related to this presentation

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Learning Objectives

At the end of this session, participants should be able to:

- Identify potential gaps in pharmaceutical compounding for sterile preparations policy and practice based on USP<797>.
- Recall strategies for successful survey compliance and inspection that align with USP<797>.
- Recognize evidence-based methodologies for interdisciplinary collaboration related to USP <797> compliance in preparation for surveys and state board inspections.

WHY ARE WE HERE TODAY?

A sad story,
could've been prevented…

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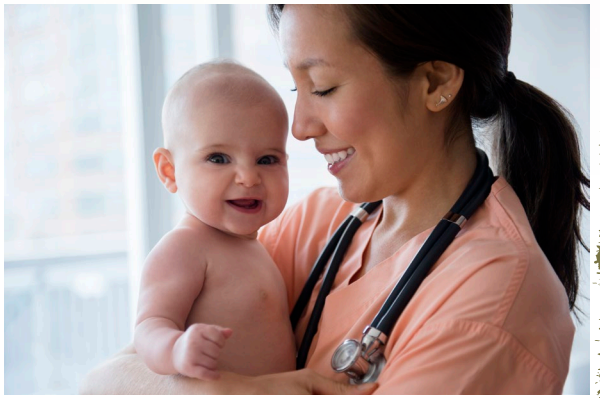
A Tragic Parenteral Nutrition Compounding Error

Background

- **Who?** An infant born prematurely, weighing less than 1 kg at birth but thriving at 6 weeks (ISMP Report ~ 2014)
- **Nutritional requirements:** Parenteral nutrition (PN).
- **Order:** Rx – total of 14.7 mEq of sodium chloride & 982 mg of calcium in the infant's PN
- **Order Entry:** Order faxed to pharmacy after midnight; **pharmacy technician made an error when entering order** into **automated compounder** machine's software
- Technician accidentally entered prescribed dose of calcium (**"982" mg**) into the **mEq** field for sodium
- **Sterile Compounding:** Technician then prepared the PN, which contained a **total of 982 mEq of sodium**, using an automated intravenous (IV) compounder
- **Labeling:** Technician affixed the printed label to the PN, which showed the erroneous sodium content



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A Tragic Error, *continued*

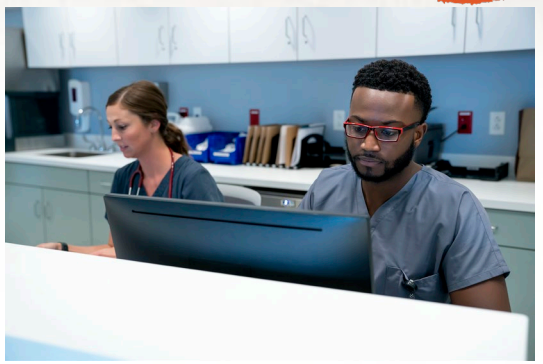
Problem

Pharmacy

- **Error:** Not detected when a pharmacist checked the final product
- **Label:** A different label that listed the sodium content as 14.7 mEq, the originally prescribed amount, was applied directly over the label produced by the compounder software that had listed the actual amount of sodium (982 mEq) in the solution

Nursing/Administration

- **Nurse:** Nurse who eventually started administration of the PN solution missed the error



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A Tragic Error, *continued*

Result

- A few hours after the PN was started, routine lab studies showed that the infant's sodium level was abnormally high
- The infant's physician assumed the study results were inaccurate & asked for the lab test to be redone
- This was never accomplished before **the infant experienced a cardiac arrest & died**

Source: Getty Images. Used with permission of HealthTrust.

Source: Grissinger M. Another tragic parenteral nutrition compounding error. P T. 2014;39(12):826-827. https://pmc.ncbi.nlm.nih.gov/articles/PMC4264666/

Poll #1: Do you know where your IV Room compliance gaps are?

1. Yes
2. Yes – but need support* to implement
3. No – but have support*
4. No – no idea, need support*

*Support = Executive support, finance, subject matter expertise, labor hours, remodeling, location, etc…

Presentation Focus

Today's Goal: To best prepare you for the next Board of Pharmacy (BOP) inspection, The Joint Commission (TJC) survey & any other state-specific departments with jurisdiction over sterile compounding

- Not your typical presentation (areas often covered)
- Focus is on hot topics / grey areas not in USP <797>
- Strategies to compliance
- Learning lessons in IV room remodeling toward compliance
- Immediate use sterile compounding compliance strategies
- Gap analysis tools
- Case study uncommon regulatory body – IV Room reconstruction
- Case study temporary solution – IV Trailer

IV ROOM STRATEGIES TO COMPLIANCE

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Strategies to Compliance

1. Completing mock survey months in advance
   - Identify gaps; be honest with yourself & team
   - Prepare action plan with dates
   - Team effort; hold each other accountable
   - Build relationship with Plant Operations / IT / supporting depts
   - Escalate PRN (only high priority; don't over do)
   - Continuous quality improvement/monitoring
2. Smoke study – Hold up label with dates @ start of video; keep backup copies
3. Certification label peeling off from hood – Use laminate sheet; take picture as backup

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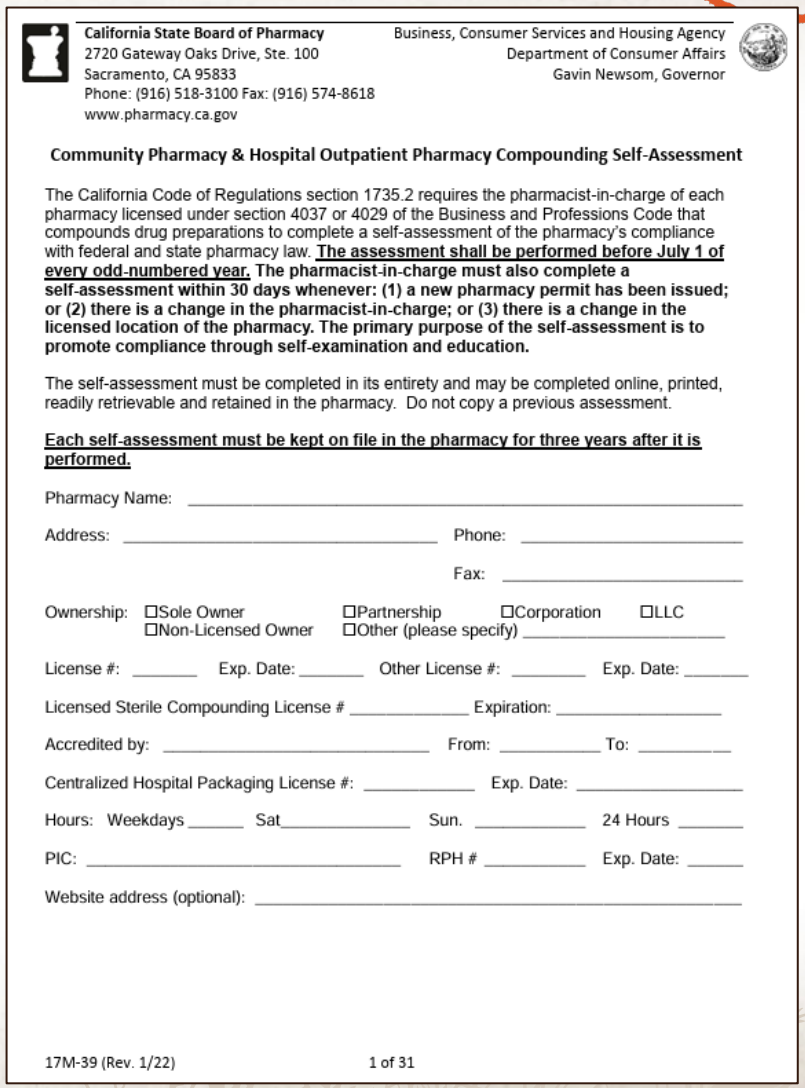
Strategies – Mock Inspections & Surveys

- Designated Person & Director of Pharmacy
  - Cross training
- Use Board of Pharmacy (BOP) inspection form
  - e.g., California – Sterile compounding self assessment
  - e.g., Florida – Inspection form surveyors use onsite
  - Most states have inspection forms online
- Sterile compounding readiness binder
  - Think Drug Enforcement Agency (DEA) or BOP readiness binder
  - Aesthetically pleasant; first impression counts



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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

Ownership: ☐Sole Owner ☐Partnership ☐Corporation ☐LLC
☐Non-Licensed Owner ☐Other (please specify) _____

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

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Strategies to Compliance, *continued*

- **Trust** but **verify** on a cadence, document, coach
- **Common non-compliance areas**
  - Personnel techniques – blocking first air → contamination
  - Environmental quality control – fluctuation of humidity, pressure, temperature (multiple rooms affected by air handler, weather)
    - Managing deviations outside of range strategies
  - Practice vs. policy
  - Does master formulation record exist & is it followed?
  - Quality assurance – last step, often forgotten…
- **Maintenance challenges**

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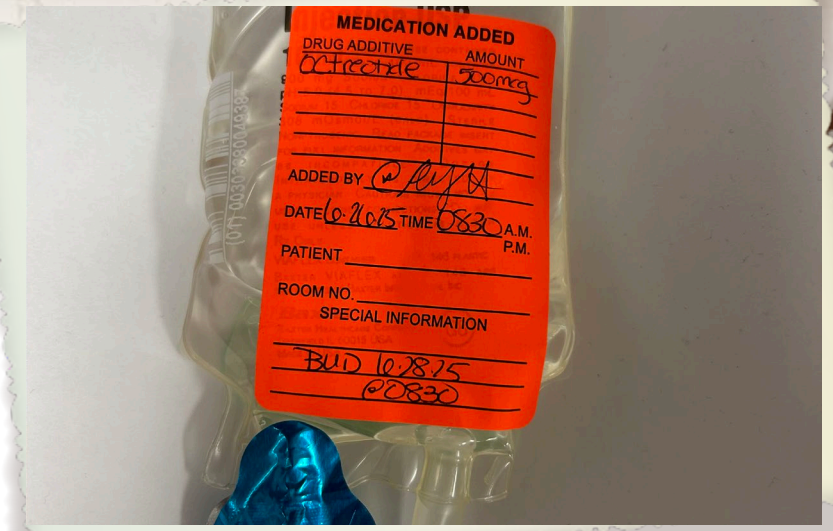
IMMEDIATE USE STERILE COMPOUNDING

Challenges & Solutions



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Fun, Hands-on Exercise

6 x Immediate Use Sterile Compounding Bags

- Challenges: Correct vs. Incorrect labeling and why
- Discussion at the end of presentation

Largest Syringe Withdrawal

- Challenges
  - Walk in the role of a compounder
  - No touching or blocking of direct first air to plunger
  - Imagine with needle and vial attached, withdrawing large volume

- Discussion at the end of presentation: How did it feel?

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Immediate Use Sterile Compounding – Challenges

Who's involved in immediate use sterile compounding?

- **Challenges**
  - Understanding of immediate use sterile compounding definition & new standards by other disciplines
  - Which unit? Which nurse? How often? Training sign off needed?
  - E.g., Anesthesiologist compounds; how do we get their training signed off for regulatory requirements?
- **Strategies**
  - Inservice to different groups
  - Train-the-trainer
- **Results**
  - Competency signed off; kept in personnel records
- **Audience Feedback…**

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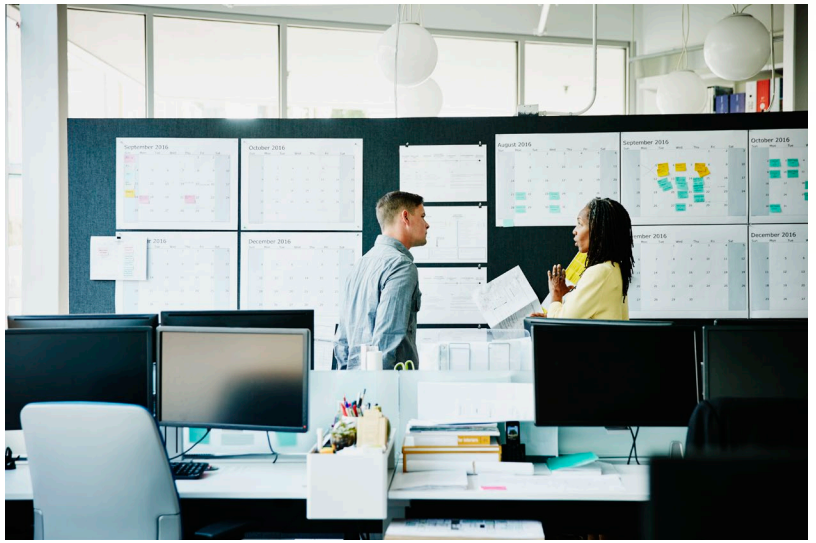
Immediate Use Sterile Compounding – Action Plan

1. Develop specific immediate use sterile compounding policy
2. Identify compounders
3. Develop competency checklist
4. Over communicate / educate x 3
5. Train the trainer or pharmacy led
6. Group Training – Physicians & nursing inservice
7. C-suite & corporate support
8. Flagship for other sites in health system
9. Trust but verify – rounding procedural areas for non-compliance (labeling)



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IV Room – Grey Areas

1. **Eyes & lashes** – temporary vs. permanent
2. **Fingernails** – length, gel nails
3. **Consistency of policy reinforcement 24/7**
4. **Policy updates** – how do you ensure staff are informed/signed off if asked by accreditation (pharmacy/other departments)?
5. **IV room out of range** – when to change to segregated compounding area
6. **Cameras in IV room** (controlled substances)
7. **Competency/training sign off on air & surface sampler** (in house)
8. **Competency of designated person** –
   - American Society of Health-System Pharmacists®
   - Board Certified Sterile Compounding Pharmacist

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Common Sterile Compounding Issues

1. **Beyond Use Date (BUD) vs. bag hang time** understanding organization wide
   - Immediate use sterile compounding policy
2. **Immediate use label** – What's required?
3. **Case study – particles in IV room from unknown source**
   - Gemba walk
4. **IV room clutter** – supplies, overstock, stationeries
5. **Techniques** – touching plunger, blocking air flow to plunger, recapping needles method, quality check & mixing of IV bag
6. **Fire sprinkler type**

Common Sterile Compounding Issues, *continued*

1. **Workflow improvement** – Making IV in X hours advance of due time
   - Gemba walk
2. **Designated person**
   - Pharmacist or tech?
   - Backup designated person
   - Training resources
3. **Annual training resources** – USP <795>, <797>, <800> & timing challenges, new staff
   - Didactic
   - Fingertip glove test, media fill
4. **Timing of handwashing** for 30 seconds
5. **Compounding Supervisor Role**

IV ROOM REMODELING

A Permanent Solution to Compliance

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IV Room Remodeling – Challenges

1. **Project management** – USP <797, 800> subject matter expertise
2. **Vetting of materials used**
3. **Down time planning & unexpected delays**
4. **Designated person/pharmacy leader inspection** – throughout & at end of project
5. **Regulatory bodies** – Case study | OSHA
6. **IV Room Trailer Case Study** – Temporary solution
7. **Other temporary compounding solutions during reconstruction** – 12 hours BUD (Segregated Compounding Area)
8. **OSHA Case Study**

not an all-inclusive list

IV Room Remodeling – Strategies

1. **Designated Person/Director of Pharmacy** – Project Manager
2. **Partners** – Plant Operations, IT, EVS, Vendors, Senior Leadership, Pharmacy Team…
3. **Air filtration** – Air handler, venting, clean/dirty zone
4. **Hygiene** – Faucet size, sink size, water operation, storage, sink location & workflow, handwash timer, hand sanitizer type & installation
5. **Workflow/Accessibility** – Layout efficient workflow, lighting appropriateness, placement of IV hood
6. **Storage** – Non-sterile & sterile supplies
7. **Waste Management** – Appropriately sized & quantity (Hazardous Drug [HD], non-HD, sharps, regular waste)

BUT THERE'S MORE…

More IV Room Remodeling Strategies

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IV Room Remodeling – Strategies, *continued*

1. **Furniture** – Compatibility with cleaning agents; avoid clutter, metal tables against walls
2. **Technology** – IV Workflow system, robotics, intercom, cameras, work stations, location/sensitivity of self opening hand wave
3. **Budget/Timeline** – Build in buffer time & unexpected costs. Add additional time for terminal cleaning, hood certification, sampling of air/surface results to come back before opening IV Room
4. **Contractor** – Be selective, use referrals where possible, trust but verify
5. **Supplies in IV Room** – Less is more, enough for 24 hours, cactus sink? Mixer? Others?
6. **Staffing** – IV Room Pharmacist's workflow, comfort
7. **Trust but Verify** – Complete walk through at each phase of completion and verify examples
    - **Example:** Wrong materials flooring, smooth/impervious surface, dings, nicks, corners & junctions, paint chips, vendor revisit different paint color

IV ROOM TRAILER

A Temporary Solution

IV Room Trailer Case Study – Temporary Solution

- Location: California
- Timeline: During COVID-19. Practical (9 months) vs. theoretical (3–4 months)
- Cost: Millions
- Regulatory bodies:
  - California Board of Pharmacy
  - California Department of Public Health
  - Office of Statewide Health Planning and Development (OSHPD) is the former name of the California Department of Healthcare Access & Information (HCAI)
- Applications – Unexpected barriers, concurrent, approval of one before the other can commence
- Operationalize w/12 hours BUD segregated compounding area concurrently
- Policies & Procedures, Certification, Air/Surface Sampling
- Inspection by multiple regulatory bodies
- Full approval & licensed: 1 year max

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EXPECT THE UNEXPECTED

OSHA
Case Study

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Case Study: OSHA Complaint IV Room

- **Situation:** Pharmacy staff filed a complaint with Occupational Safety & Health Administration (OSHA) due to chemical smells in the pharmacy during IV Room remodeling.
- **Background:** IV Room remodeling required certain chemicals to be used. Safety Data Sheet (SDS) was sent out, but pharmacy staff still had concerns of carcinogenicity. All mitigation strategies had been taken to reduce the smell & communication was timely to the department.
- **Assessment:** Timely response was required by the department leader to OSHA.
- **Response:** Different approach in responding than The Joint Commission or State Board of Pharmacy. A "story" had to be told, circumstances, actions taken, outcomes. Supporting documents provided to OSHA.
- **Result:** Pharmacy leadership completed the appropriate steps. Case not substantiated; it was closed by OSHA.

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Hands-on Exercise: Audience Participation

6 x Immediate Use Sterile Compounding Bags

- Challenges: Correct vs. Incorrect labeling and why
- **Discussion: Which label is correct or incorrect and why?**

Largest Syringe Withdrawal

- Challenges
  - Walk in the role of a compounder
  - No touching or blocking of direct first air to plunger
  - Imagine with needle and vial attached, withdrawing large volume
- **Discussion at the end of presentation: How did it feel?**

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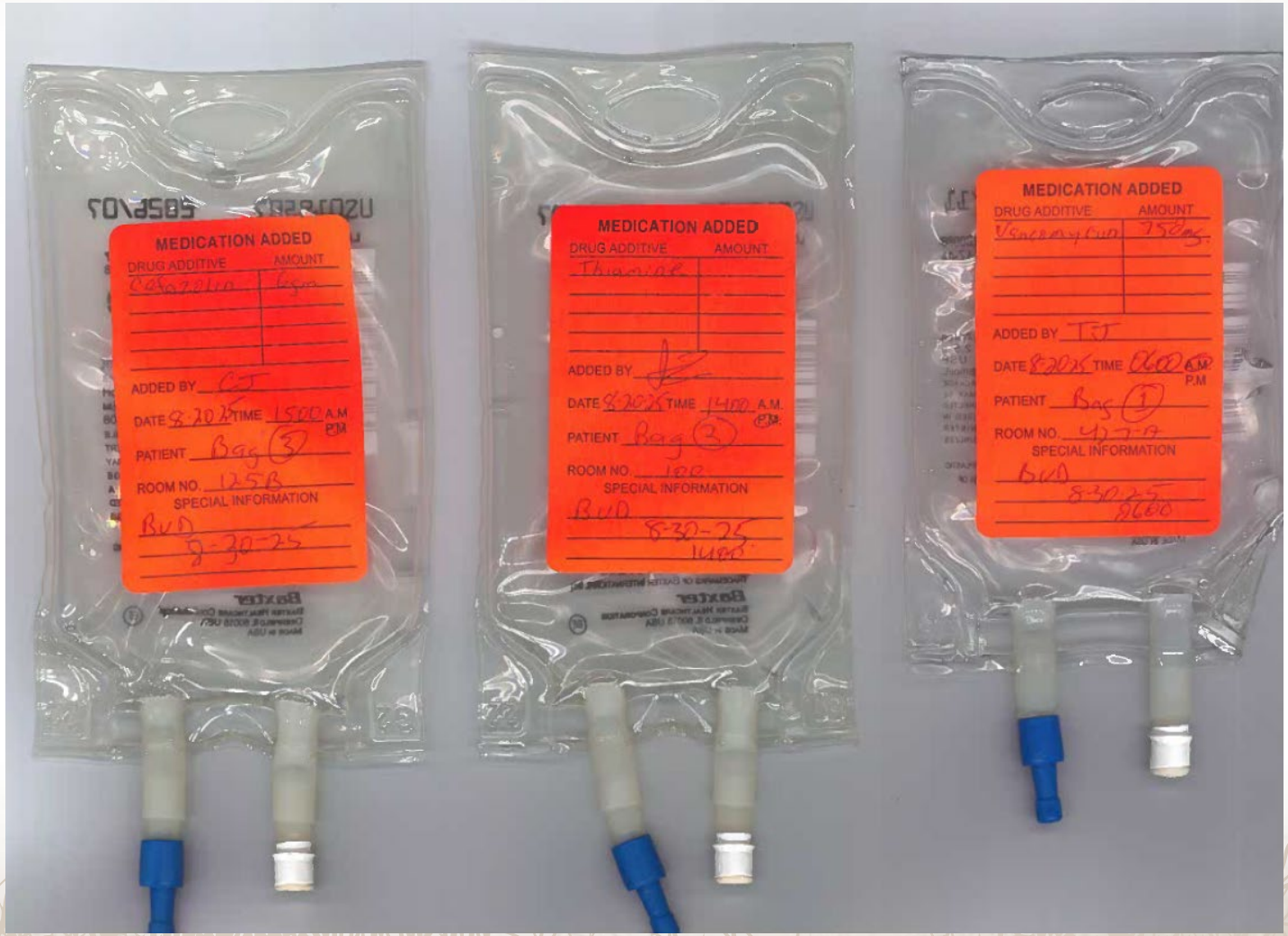
Immediate Use Sterile Compounding – Correct vs. Incorrect Labeling



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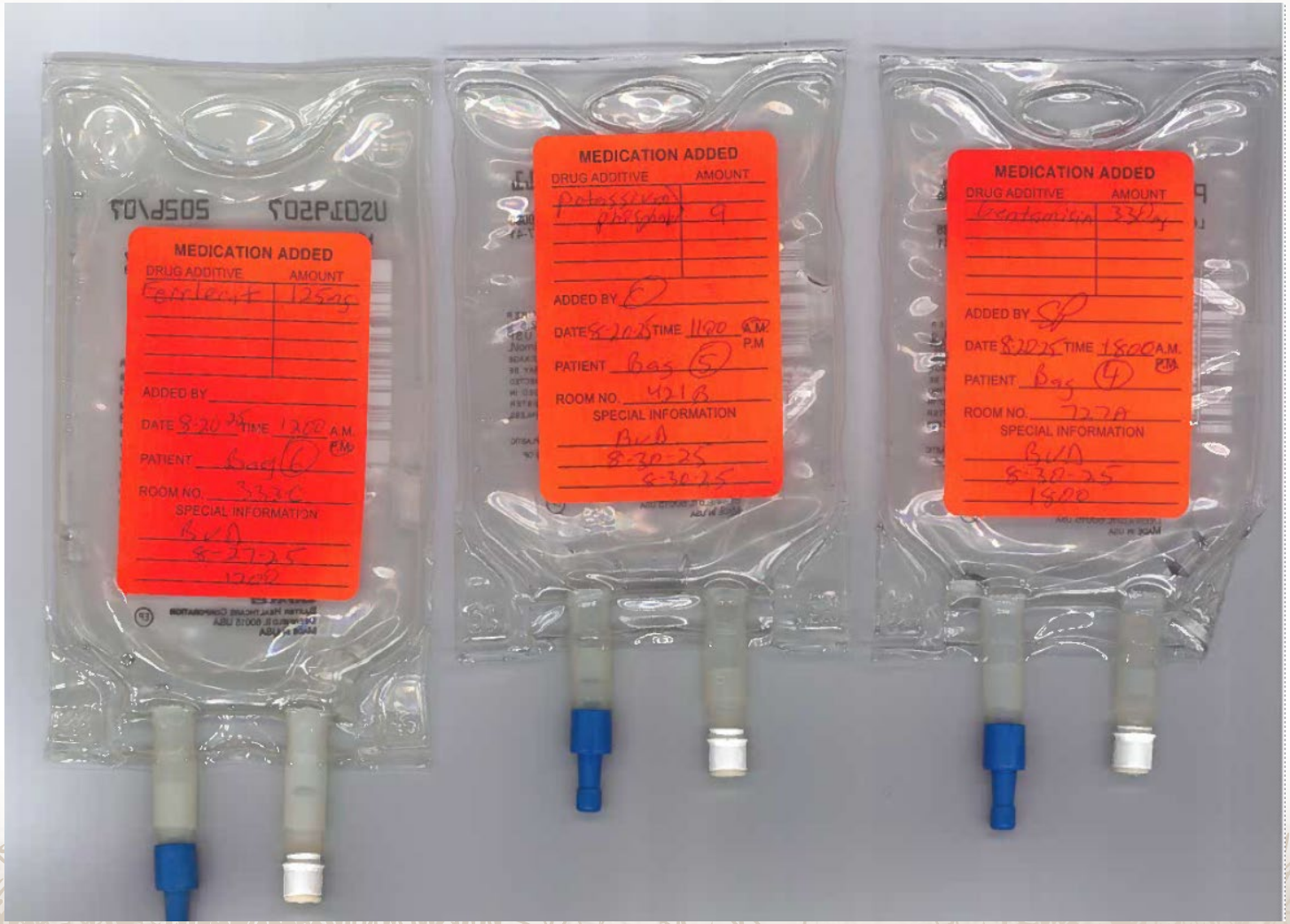

Largest Syringe Withdrawal Audience Participation

Largest Syringe Withdrawal

- Challenges
  - Walk in the role of a compounder
  - No touching or blocking of direct first air to plunger
  - Imagine with needle and vial attached, withdrawing large volume

- **Discussion**
  - **How did it feel?**
  - **Other comments**

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Assessment Question #1:

Based on USP<797>, which of the following are potential gaps in policy & practice around compounding & sterile preparations?

A. Immediate Use Sterile Compounding competency is required by Pharmacy personnel only. Best practice is to train others but not required.

B. A policy and plan is needed for environmental control of the IV Room deviations outside of normal limits.

C. Beyond Use Date cannot be used interchangeably with expiration date

D. Aseptic Techniques: Touching the plunger or blocking the airflow (first air) is unacceptable technique regardless of syringe size.

Assessment Question #1: Correct Response

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Assessment Question #2:

Strategies for survey compliance & inspection that align with USP<797> include which of the following?

A. Completing a mock survey using the Board of Pharmacy inspection form a year in advance

B. A Master Formulation Record is best practice and highly recommended

C. If certification sticker on hood peels off accidentally, as long as you can prove you have a certification record, the BOP will accept it.

D. When making changes to a sterile compounding policy, ensure staff are educated and signed off on education date

Assessment Question #2: Correct Response

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D. When making changes to a sterile compounding policy, ensure staff are educated and signed off on education date

Assessment Question #3:

Which of the following best describes evidence-based methodologies for interdisciplinary collaboration related to USP<797> compliance during surveys and inspections?

A. Timing of hand washing – sing the happy birthday song.

B. Waste Management – always keep the biggest size the IV Room can handle for convenience.

C. IV Room supplies and clutter – Keep 24 hours supply on hand in the rooms, eliminate unnecessary items or limit the number of items (e.g., pens)

D. Unexpected regulatory body accusations – always respond the same, give minimal information.

Assessment Question #3: Correct Response

Which of the following best describes evidence-based methodologies for interdisciplinary collaboration related to USP<797> compliance during surveys and inspections?

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References

1. Grissinger M. Another tragic parenteral nutrition compounding error. P T. 2014;39(12):826-827. https://pmc.ncbi.nlm.nih.gov/articles/PMC4264666/
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