
# Transformation of Sterile Compounding Services

## Implementation of IV Workflow Software & A Quality Improvement Program

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Medication Safety & Technology

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Sterile compounding manager

# DISCLOSURE

**No persons associated with this presentation have any relevant financial relationships to disclose.**

# PRE-TEST QUESTIONS

1. ISMP recommends the syringe pull-back method as a reliable method for checking accuracy of a sterile compound
    A. True
    B. False
2. Which of the following are key elements of IV Workflow Software implementation?
    A. Workflow Design
    B. Compounding Log Development
    C. Staff training plan & competency assessment
    D. All of the above
3. Data analytics can help track productivity and identify opportunities for waste reduction
    A. True
    B. False

# Learning Objectives

1. **Describe** best practice recommendations for safe sterile compounding
2. **Discuss** system design and workflow strategies that can yield utilization of IV workflow software for all sterile preparations
3. **Summarize** key change management tactics to ensure a successful IV workflow software implementation
4. **Identify** system requirements to generate an electronic compounding log which meets regulatory standards
5. **Review** data elements from IVWS that can be exported to facilitate quality improvement activities

# About UC Davis Health

**Academic Health System**

- Level I Trauma Center, Adult & Pediatric
- Level IV Neonatal Intensive Care
- Children's Hospital
- Comprehensive Cancer Center

**Sterile Compounding Facilities**

- Inpatient Central IV Area (CIVA)
- Outpatient Infusion Centers (2)

| | | |
|---|---|---|
| 625 Beds | 81,000 ED Visits | **Daily Sterile Preparation Volume** |
| 35,000 Admissions | 910,000 Outpatient Visits | Hazardous: 100<br>Non-Hazardous: 600 |

# OUTLINE

Project Kickoff

Planning

Implementation

Ongoing Quality Improvement

# PROJECT KICKOFF

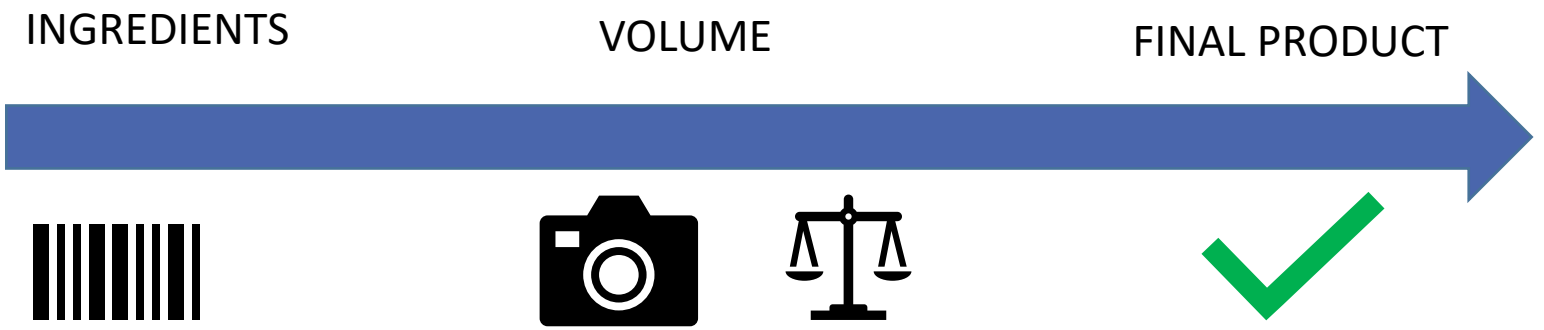
Why IV Workflow Software?

Software Selection

Project Scope & Timeline

# WHY IV WORKFLOW SOFTWARE?

IVWS systems can help detect up to 14-times more errors than manual processes.



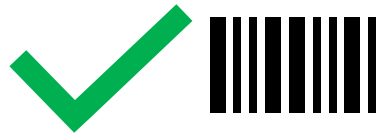

1. Eckel et al. Multicenter study to evaluate the benefits of technology-assisted workflow on i.v. room efficiency, costs, and safety, AJHP, 2019.

2. ISMP. Maximize benefits of IV workflow management systems by addressing workarounds and errors. Acute Care ISMP Safety Alert! September 7, 2017.

# WHY IV WORKFLOW SOFTWARE?

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

**Barcode Scanning: MINIMUM**



**SYRINGE PULL BACK: NEVER**

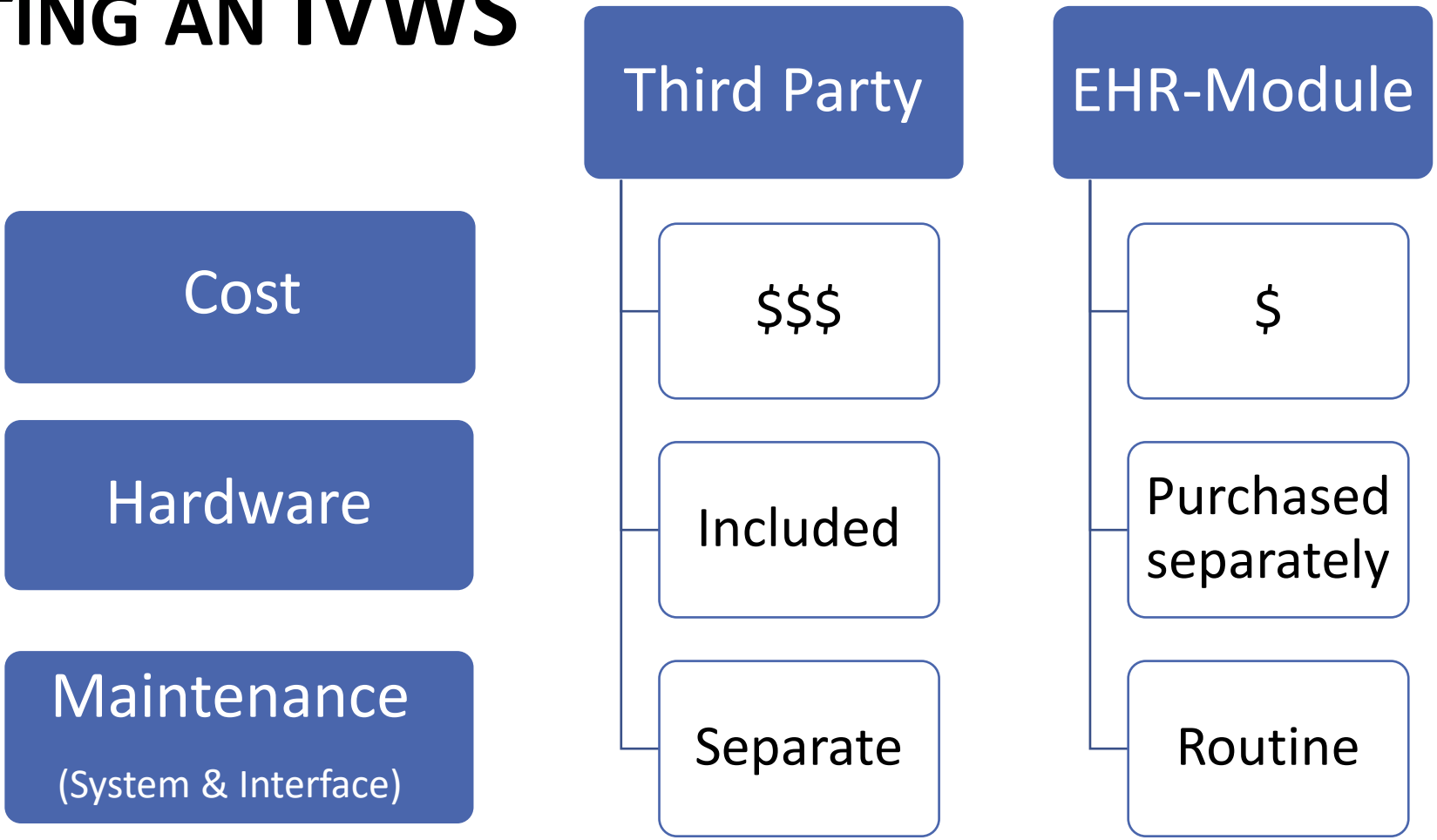


3. Institute for Safe Medication Practices. Guidelines for Safe Preparation of Compounded Sterile Preparations. Revised 2016



CSHP
CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS

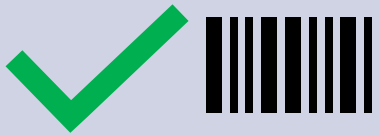
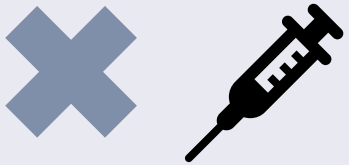
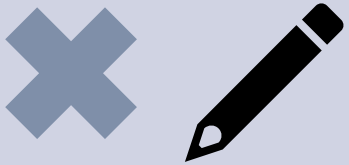
# SELECTING AN IVWS






4. Haston-Leary M and Eckel S. The Selection Process for IV Workflow Technology. Pharmacy Purchasing & Products Magazine. January 2018.

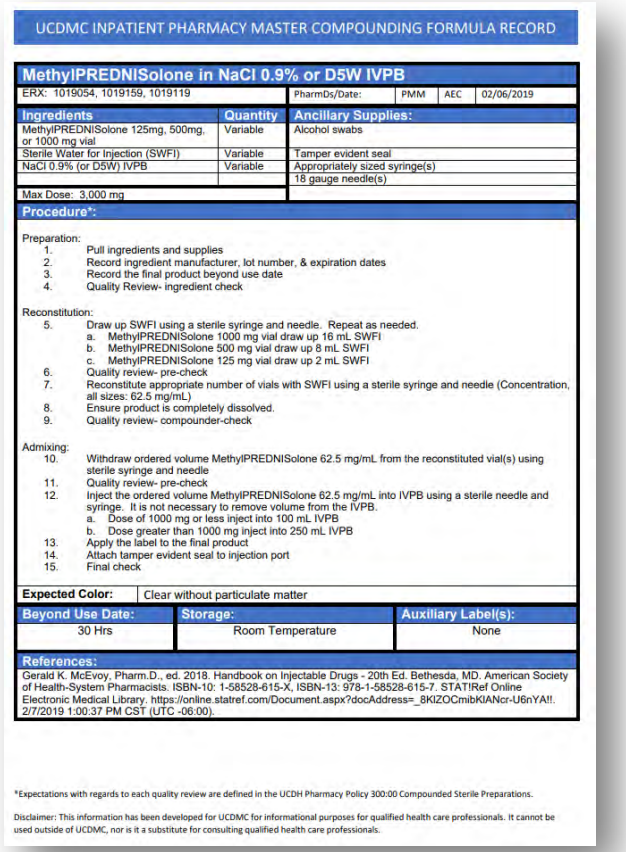
# PROJECT SCOPE

| | BEFORE | AFTER |
|---|---|---|
| Ingredient Check |  |  Quantity Check |
| Volume Check |  |  Non-Hazardous |
| Compounding Records |  |  Electronic Signature<br>Discard-By Time |

5. Institute for Safe Medication Practices. Targeted Medication Safety Best Practices. 2020.

# Pre-Kickoff: Master Formula Review

- Ingredients: Active & Inactive
- Beyond Use Dating
- Equipment
- Compounding Steps
- Quality Reviews
- Post Compounding Processes
- Storage and Handling



UCDMC INPATIENT PHARMACY MASTER COMPOUNDING FORMULA RECORD

**MethylPREDNISolone in NaCl 0.9% or D5W IVPB**

ERX: 1019054, 1019159, 1019119 | PharmDs/Date: PMM AEC 02/06/2019

| Ingredients | Quantity | Ancillary Supplies: |
|---|---|---|
| MethylPREDNISolone 125mg, 500mg, or 1000 mg vial | Variable | Alcohol swabs |
| Sterile Water for Injection (SWFI) | Variable | Tamper evident seal |
| NaCl 0.9% (or D5W) IVPB | Variable | Appropriately sized syringe(s) |
| | | 18 gauge needle(s) |
| Max Dose: 3,000 mg | | |

**Procedure*:**

Preparation:
1. Pull ingredients and supplies
2. Record ingredient manufacturer, lot number, & expiration dates
3. Record the final product beyond use date
4. Quality Review- ingredient check

Reconstitution:
5. Draw up SWFI using a sterile syringe and needle. Repeat as needed.
   a. MethylPREDNISolone 1000 mg vial draw up 16 mL SWFI
   b. MethylPREDNISolone 500 mg vial draw up 8 mL SWFI
   c. MethylPREDNISolone 125 mg vial draw up 2 mL SWFI
6. Quality review- pre-check
7. Reconstitute appropriate number of vials with SWFI using a sterile syringe and needle (Concentration, all sizes: 62.5 mg/mL)
8. Ensure product is completely dissolved.
9. Quality review- compounder-check

Admixing:
10. Withdraw ordered volume MethylPREDNISolone 62.5 mg/mL from the reconstituted vial(s) using sterile syringe and needle
11. Quality review- pre-check
12. Inject the ordered volume MethylPREDNISolone 62.5 mg/mL into IVPB using a sterile needle and syringe. It is not necessary to remove volume from the IVPB.
    a. Dose of 1000 mg or less inject into 100 mL IVPB
    b. Dose greater than 1000 mg inject into 250 mL IVPB
13. Apply the label to the final product
14. Attach tamper evident seal to injection port
15. Final check

| Expected Color: | Clear without particulate matter |
|---|---|

| Beyond Use Date: | Storage: | Auxiliary Label(s): |
|---|---|---|
| 30 Hrs | Room Temperature | None |

**References:**

Gerald K. McEvoy, Pharm.D., ed. 2018. Handbook on Injectable Drugs - 20th Ed. Bethesda, MD. American Society of Health-System Pharmacists. ISBN-10: 1-58528-615-X, ISBN-13: 978-1-58528-615-7. STAT!Ref Online Electronic Medical Library. https://online.statref.com/Document.aspx?docAddress=_8KlZOCmibKlANcr-U6nYA!!. 2/7/2019 1:00:37 PM CST (UTC -06:00).

*Expectations with regards to each quality review are defined in the UCDH Pharmacy Policy 300:00 Compounded Sterile Preparations.

Disclaimer: This information has been developed for UCDMC for informational purposes for qualified health care professionals. It cannot be used outside of UCDMC, nor is it a substitute for consulting qualified health care professionals.

**EMR**



6. California Code of Regulations. Title 16 Section 1735.2(e). Compounding Limitations and Requirements.

# Project Timeline

**Workflow Design**

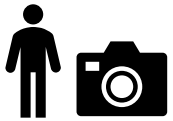
November 2018

January 2019

**System Configuration**

**Workflow Validation & Hardware Testing**

March 2019



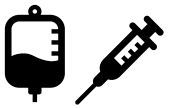
April 2019

**Training Development & End User Validation**

**Staff Training**

May 2019

June 2019



**Go-Live**

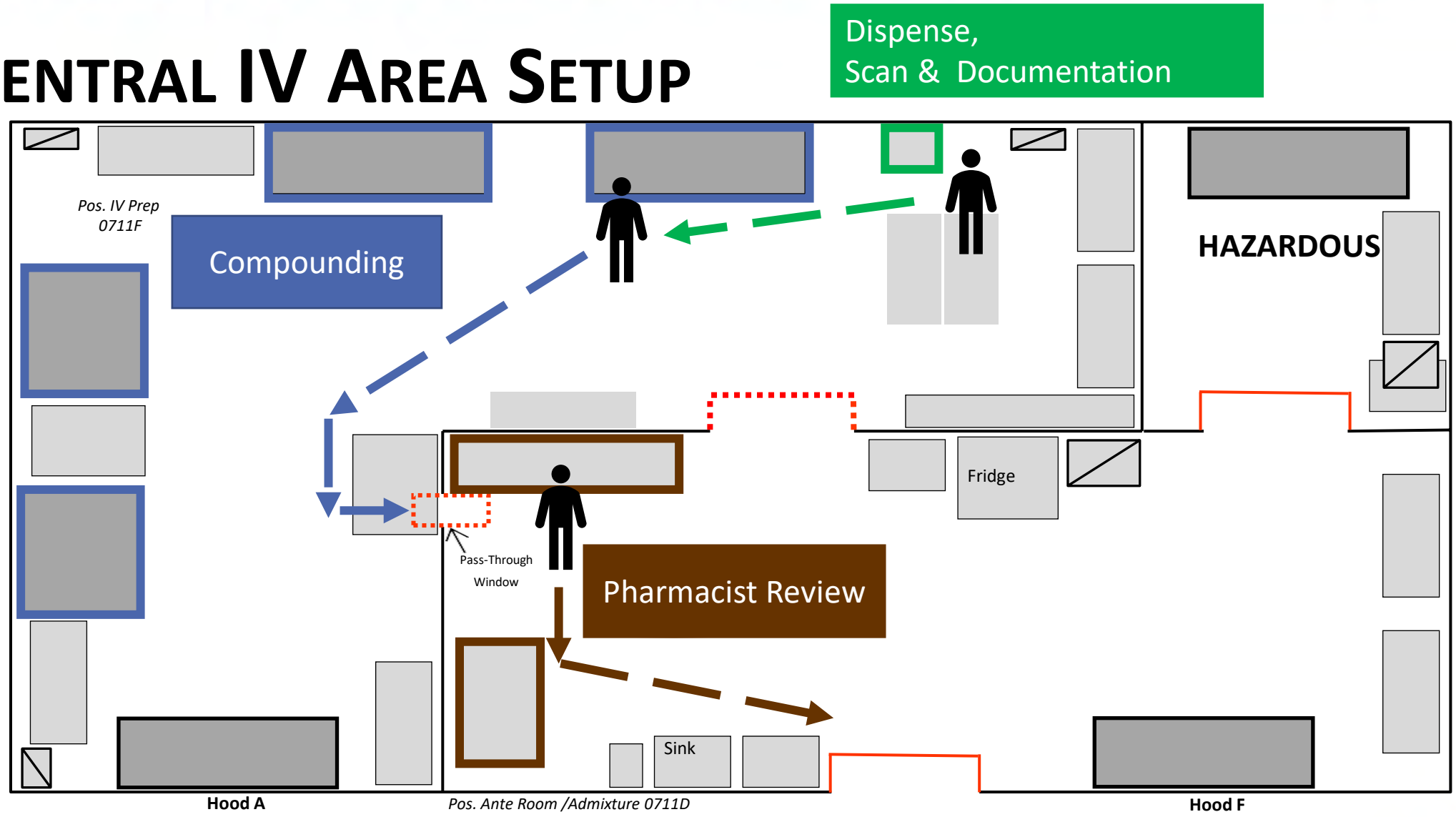
# PROJECT PLANNING

Workflow Design

Hardware

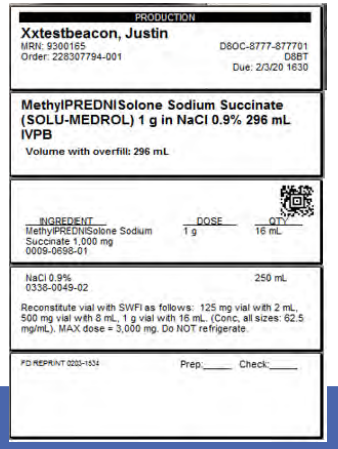
Software Configuration

# CENTRAL IV AREA SETUP



# Workflow Design

## Dispense


PRODUCTION

Xxtestbeacon, Justin

MRN: 9300165
Order: 228307794-001

D8OC-8777-877701
D8BT
Due: 2/3/20 1630

MethylPREDNISolone Sodium Succinate (SOLU-MEDROL) 1 g in NaCl 0.9% 296 mL IVPB

Volume with overfill: 296 mL

| INGREDIENT | DOSE | QTY |
|---|---|---|
| MethylPREDNISolone Sodium Succinate 1,000 mg 0009-0698-01 | 1 g | 16 mL |
| NaCl 0.9% 0338-0049-02 | | 250 mL |

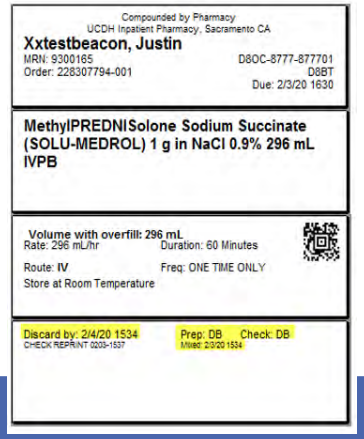
Reconstitute vial with SWFI as follows: 125 mg vial with 2 mL, 500 mg vial with 8 mL, 1 g vial with 16 mL. (Conc, all sizes: 62.5 mg/mL). MAX dose = 3,000 mg. Do NOT refrigerate.

FD REPRINT 0203-1534

Prep:_____ Check:_____

## Compounding

### With Image Capture



Compounded by Pharmacy
UCDH Inpatient Pharmacy, Sacramento CA

Xxtestbeacon, Justin

MRN: 9300165
Order: 228307794-001

D8OC-8777-877701
D8BT
Due: 2/3/20 1630

MethylPREDNISolone Sodium Succinate (SOLU-MEDROL) 1 g in NaCl 0.9% 296 mL IVPB

Volume with overfill: 296 mL
Rate: 296 mL/hr
Duration: 60 Minutes

Route: IV
Freq: ONE TIME ONLY

Store at Room Temperature

Discard by: 2/4/20 1534
CHECK REPRINT 0203-1537

Prep: DB Check: DB
Mixed: 2/3/20 1534

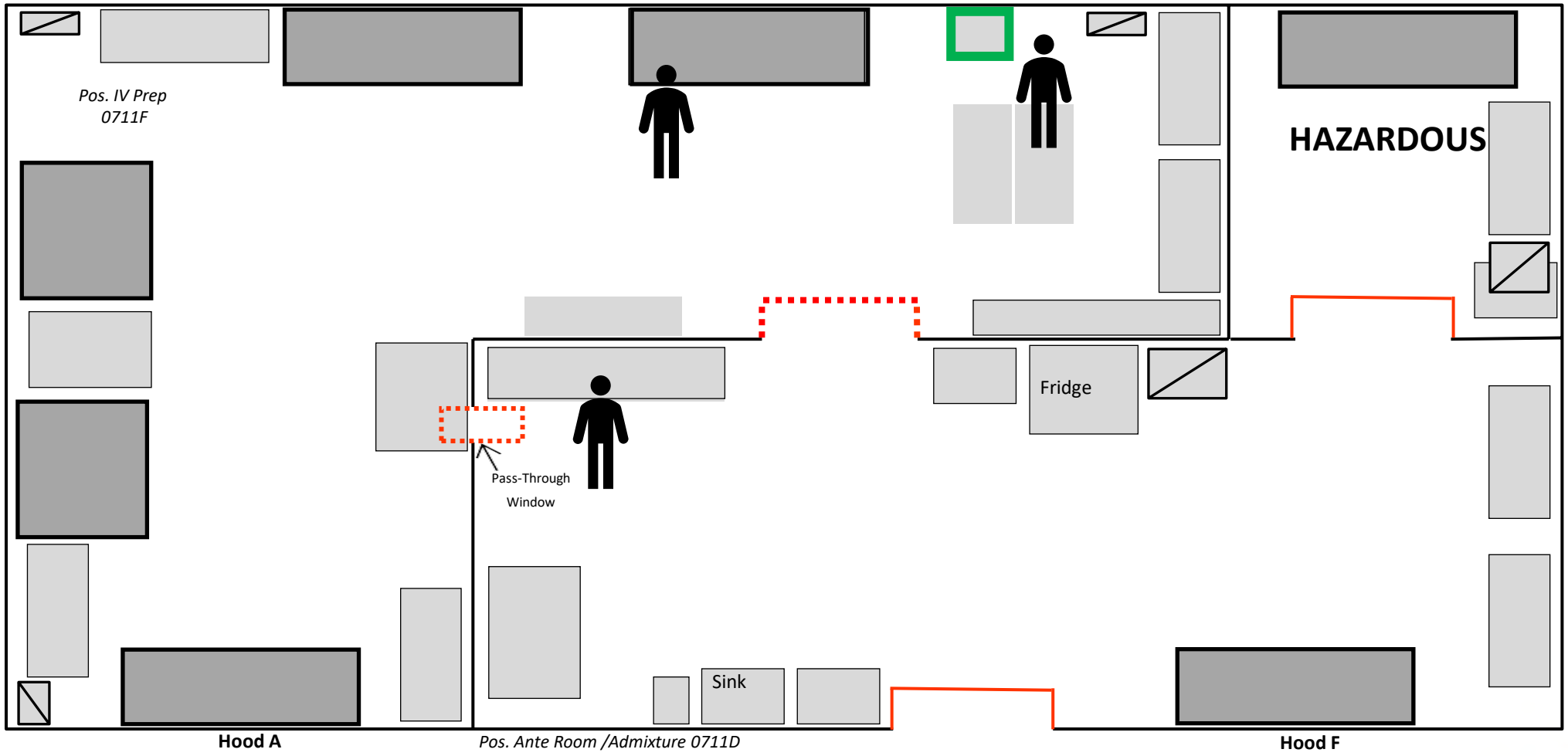
**Barcode Scan & Documentation**

**Pharmacist Review**

**Ready for Delivery**

# CENTRAL IV AREA SETUP

Dispense,
Scan & Documentation



# DISPENSE

PRODUCTION

**Xxtestbeacon, Justin**
MRN: 9300165
Order: 228307794-001

D8OC-8777-877701
D8BT
Due: 2/3/20 1630

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**Volume with overfill: 296 mL**

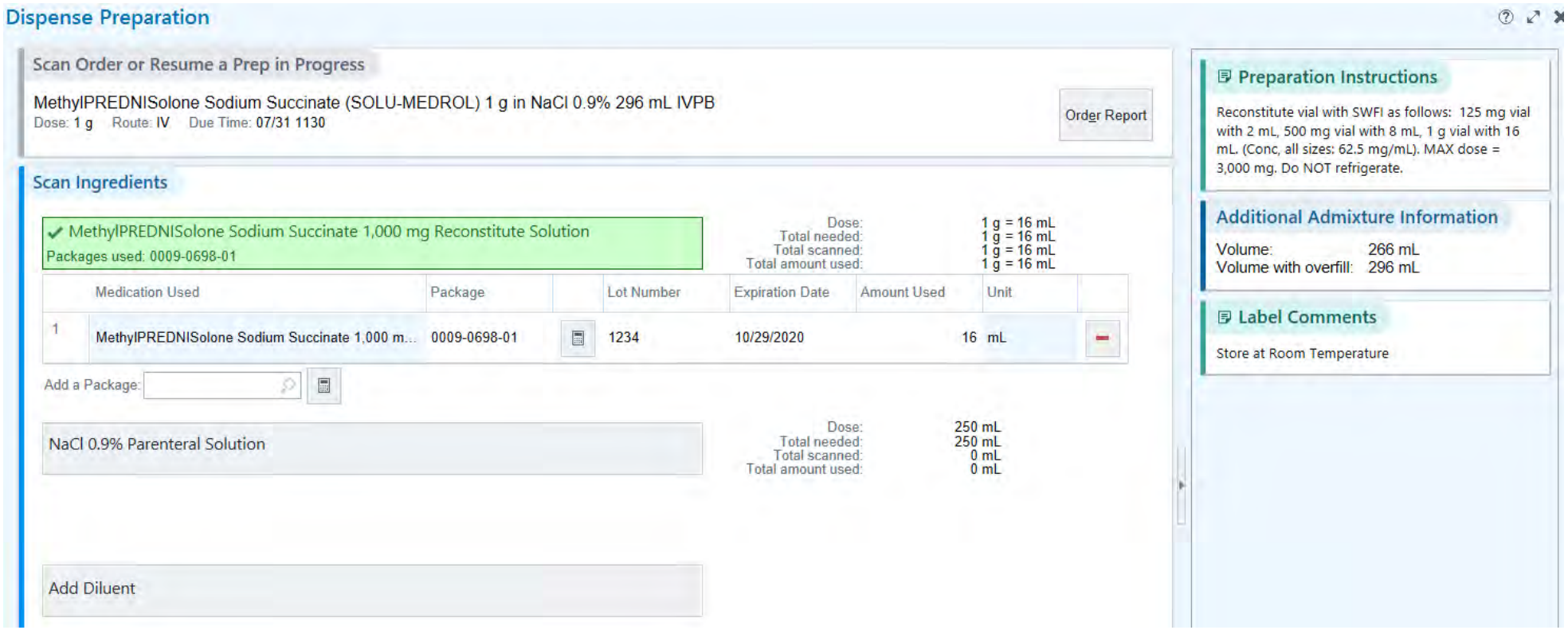
| INGREDIENT | DOSE | QTY |
|---|---|---|
| MethylPREDNISolone Sodium Succinate 1,000 mg<br>0009-0698-01 | 1 g | 16 mL |
| NaCl 0.9%<br>0338-0049-02 | | 250 mL |

Reconstitute vial with SWFI as follows: 125 mg vial with 2 mL, 500 mg vial with 8 mL, 1 g vial with 16 mL. (Conc, all sizes: 62.5 mg/mL). MAX dose = 3,000 mg. Do NOT refrigerate.

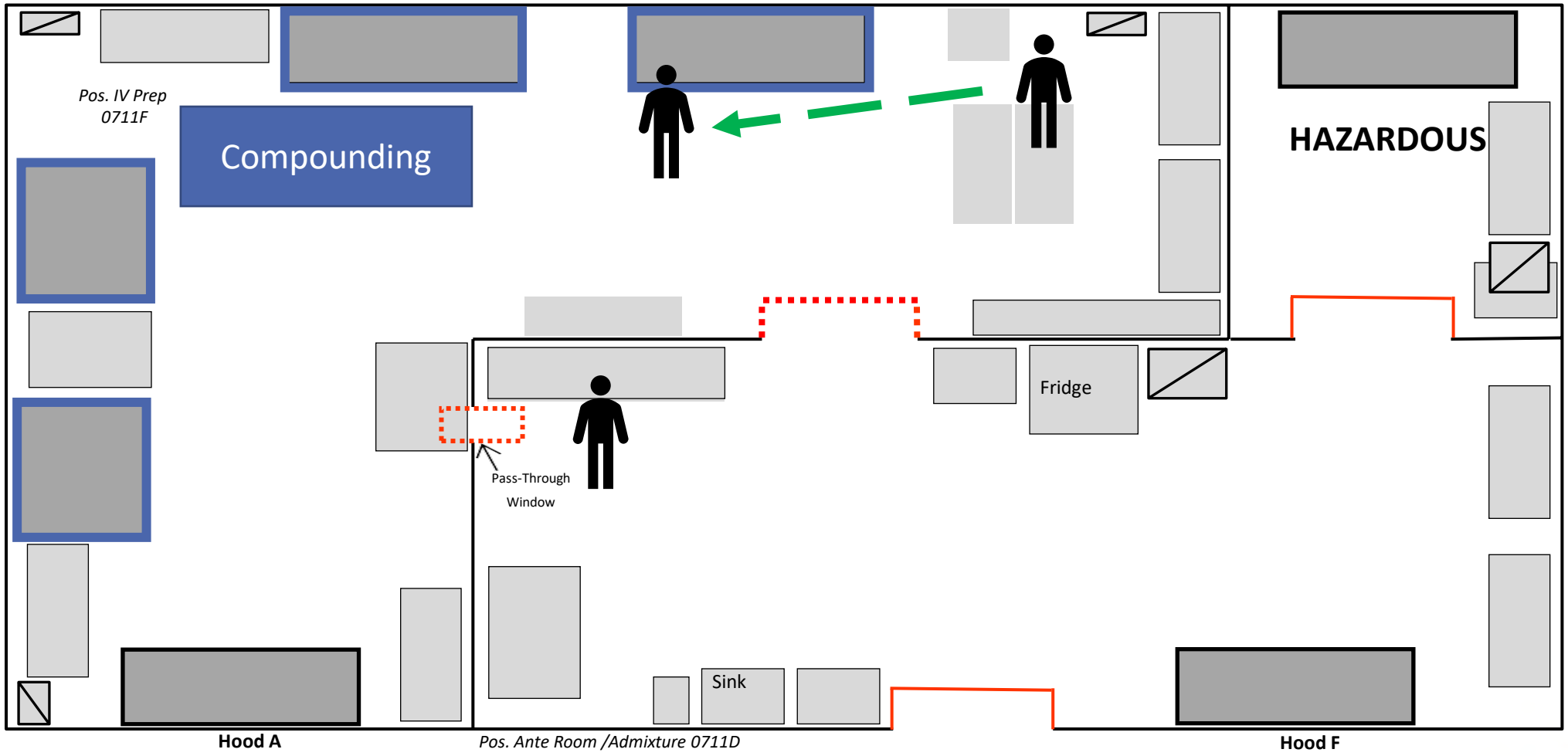
FD REPRINT 0203-1534

Prep:_____ Check:_____

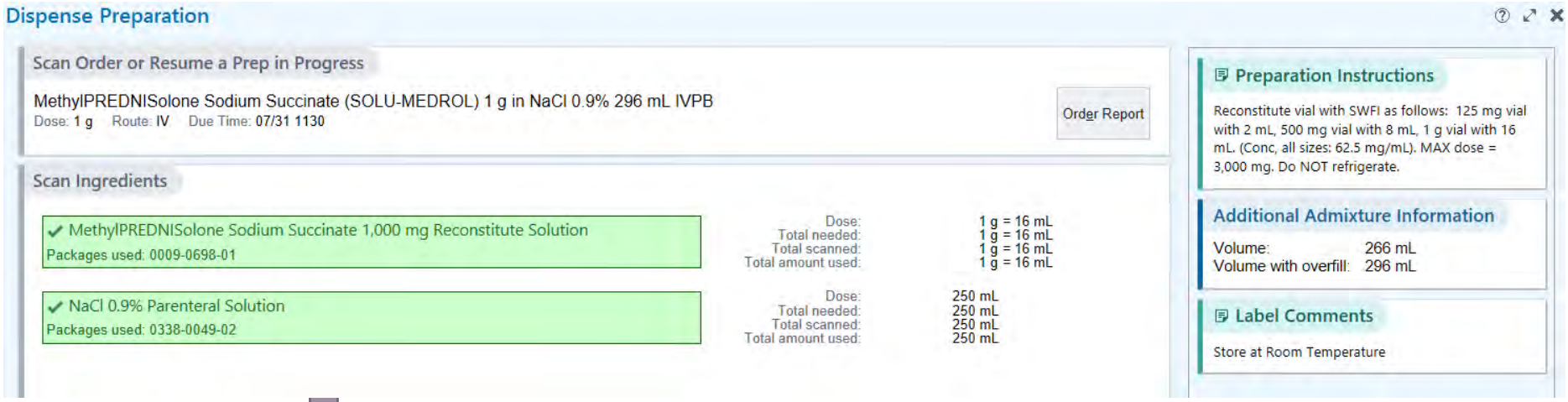
# BARCODE SCANNING & DOCUMENTATION



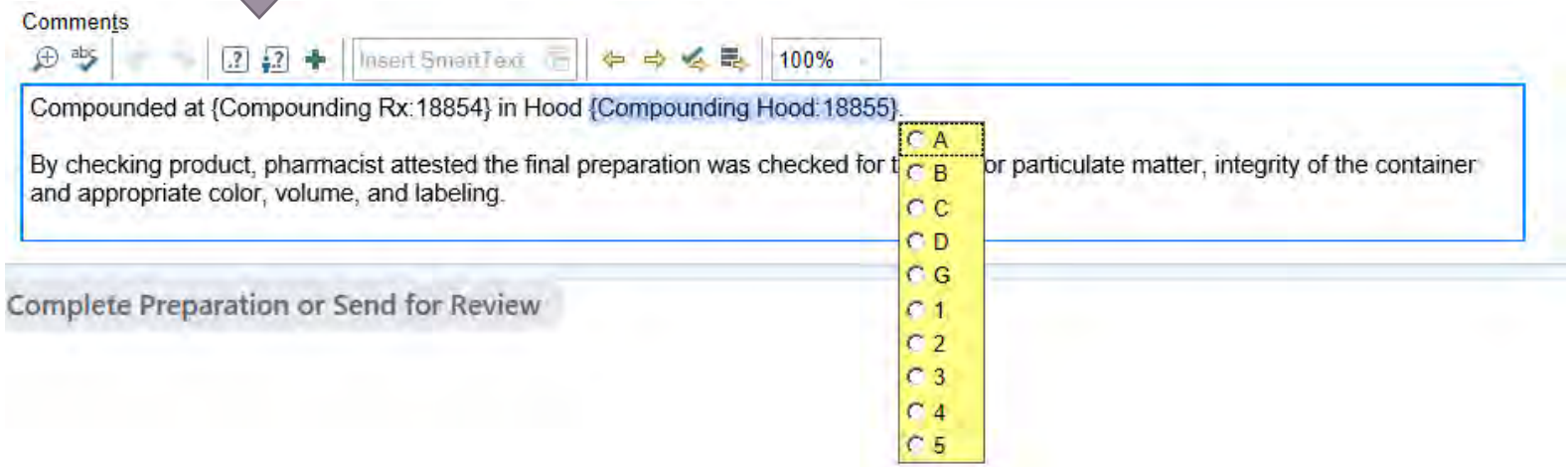
# CENTRAL IV AREA SETUP



# COMPOUNDING LOCATION DOCUMENTATION

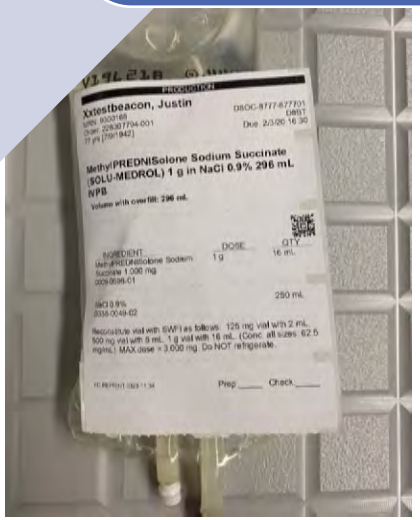



**Pharmacy Hood**



# Compounding Steps

- Confirm all ingredients
- Reconstitute additive with diluent
- Draw up intended additive quantity
- Inject into base solution
- Flag Production Label onto product




One preparation in hood at a time!

# Compounding Area Setup

Hood Mount


Workstation on Wheels

**Camera:** HoverCam Solo 8+

**Workstation:** Tangent M24T

**Platform:**

- Hood Mount: ICW-Ergonomic High Duty Arm Special kit (no drill)
- Workstation on Wheels

**Magnet:**

- Neodymium, 10.9 lb Pull; 0.187" thick, 0.75“ diameter

**Barcode Scanner:**

- Honeywell Xenon 1902 (older); 1952 (newer)

# Compounding Area Setup

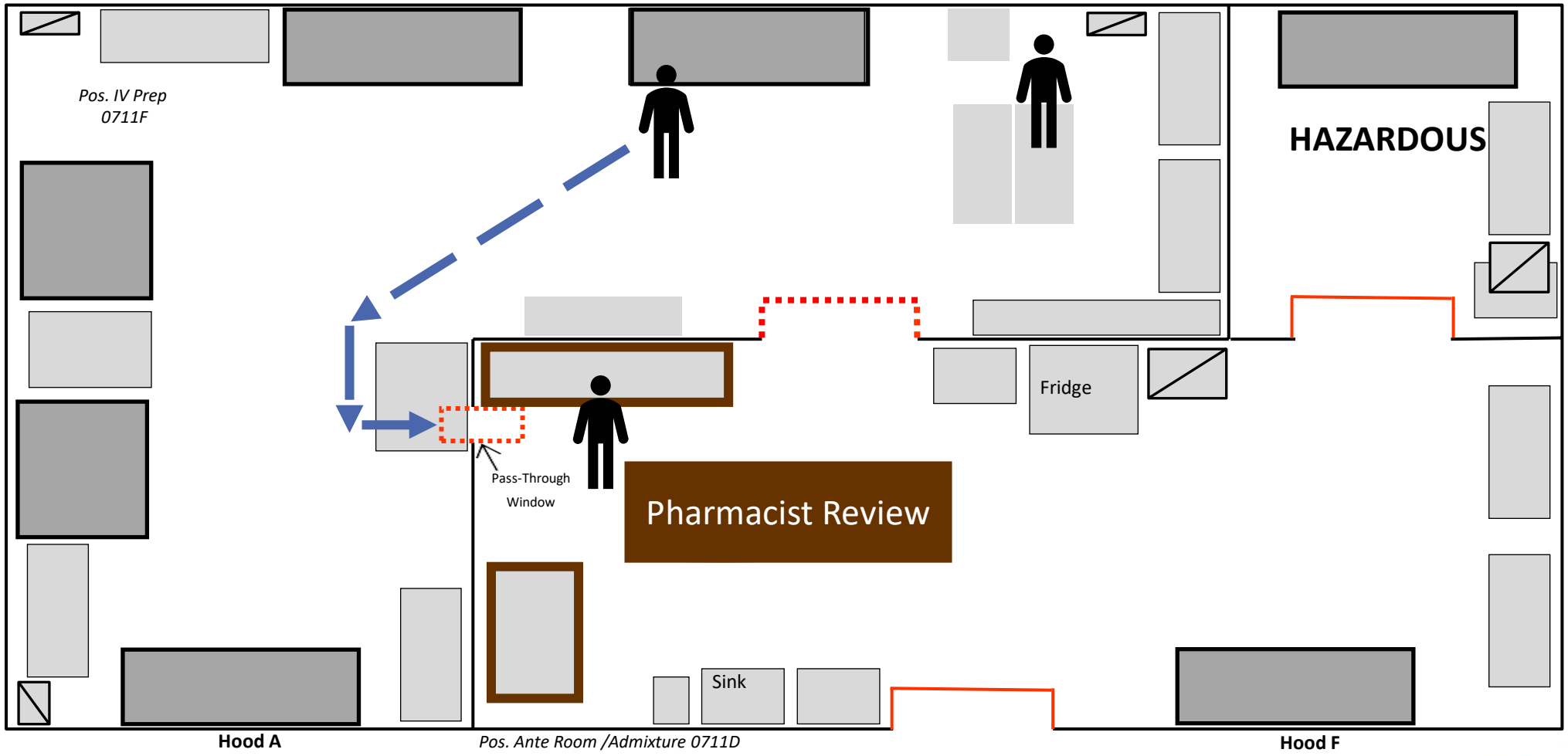

## Compounding Tray:

StarBoard®

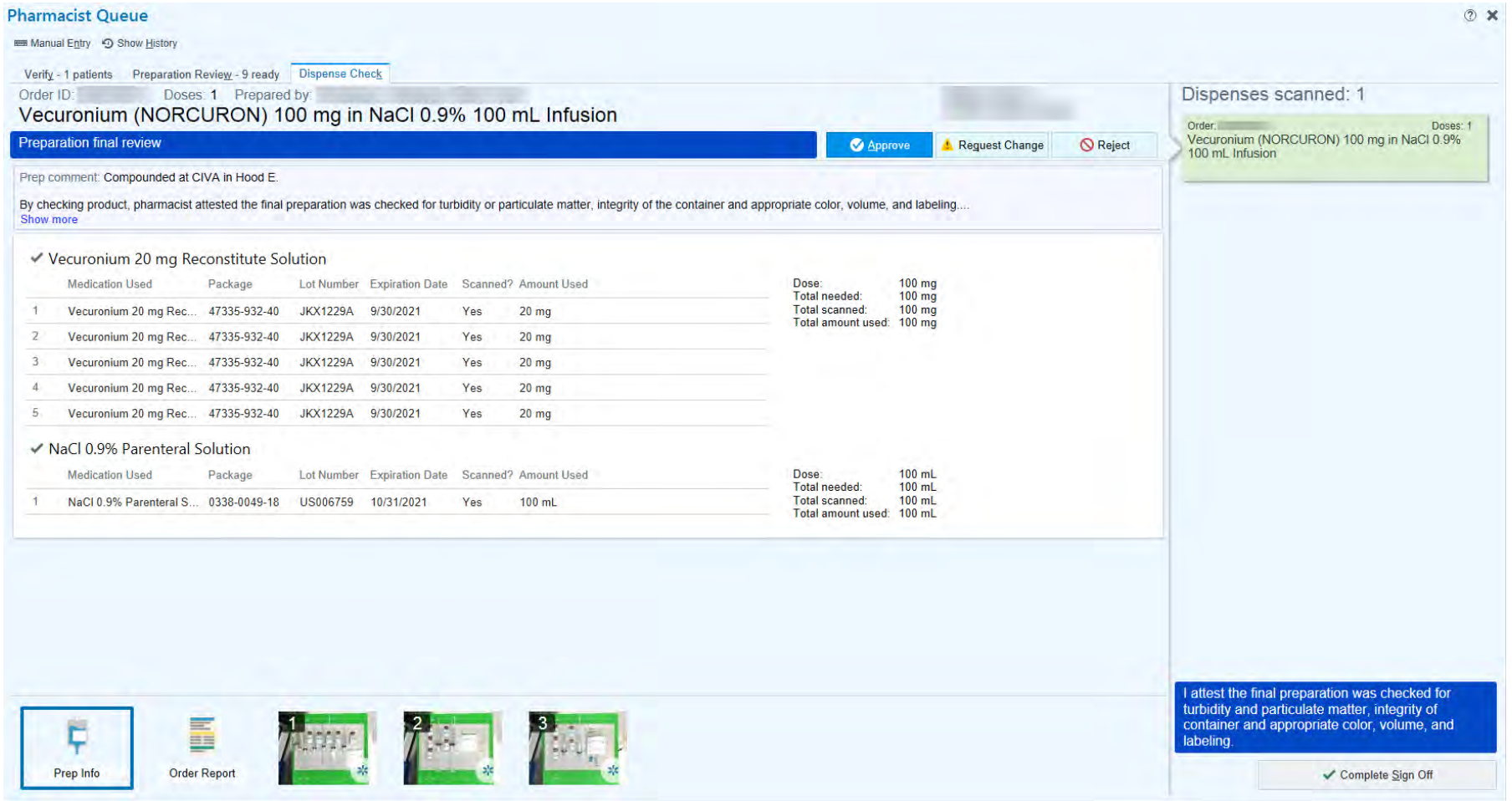
Size: 10.25” x 15.5”

Groove Depth: 1.75” x 1.75”

# CENTRAL IV AREA SETUP



# DISPENSE CHECK

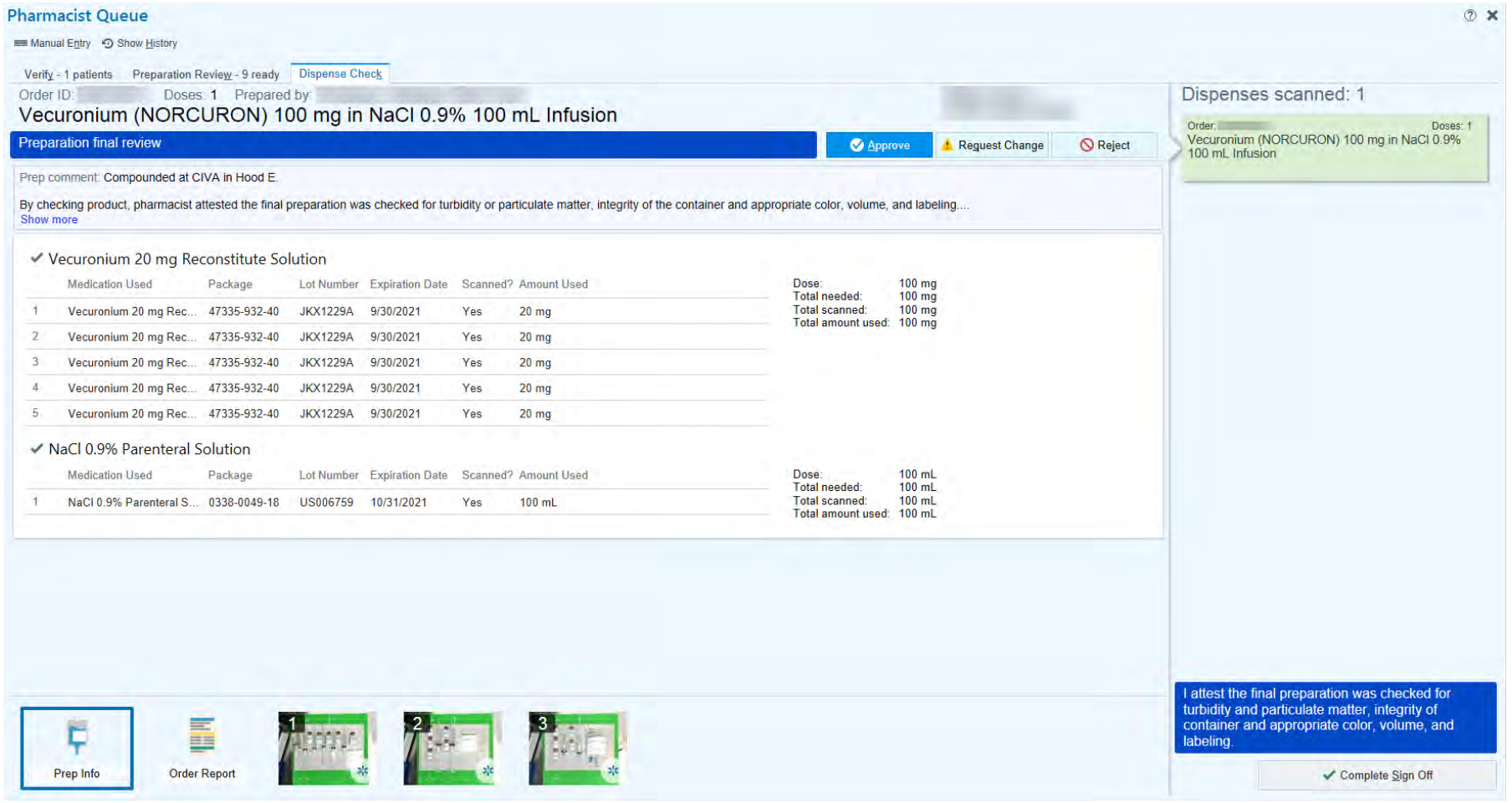



Check ingredient documentation

Check pictures

Complete Sign Off

# DISPENSE CHECK




Check ingredient documentation

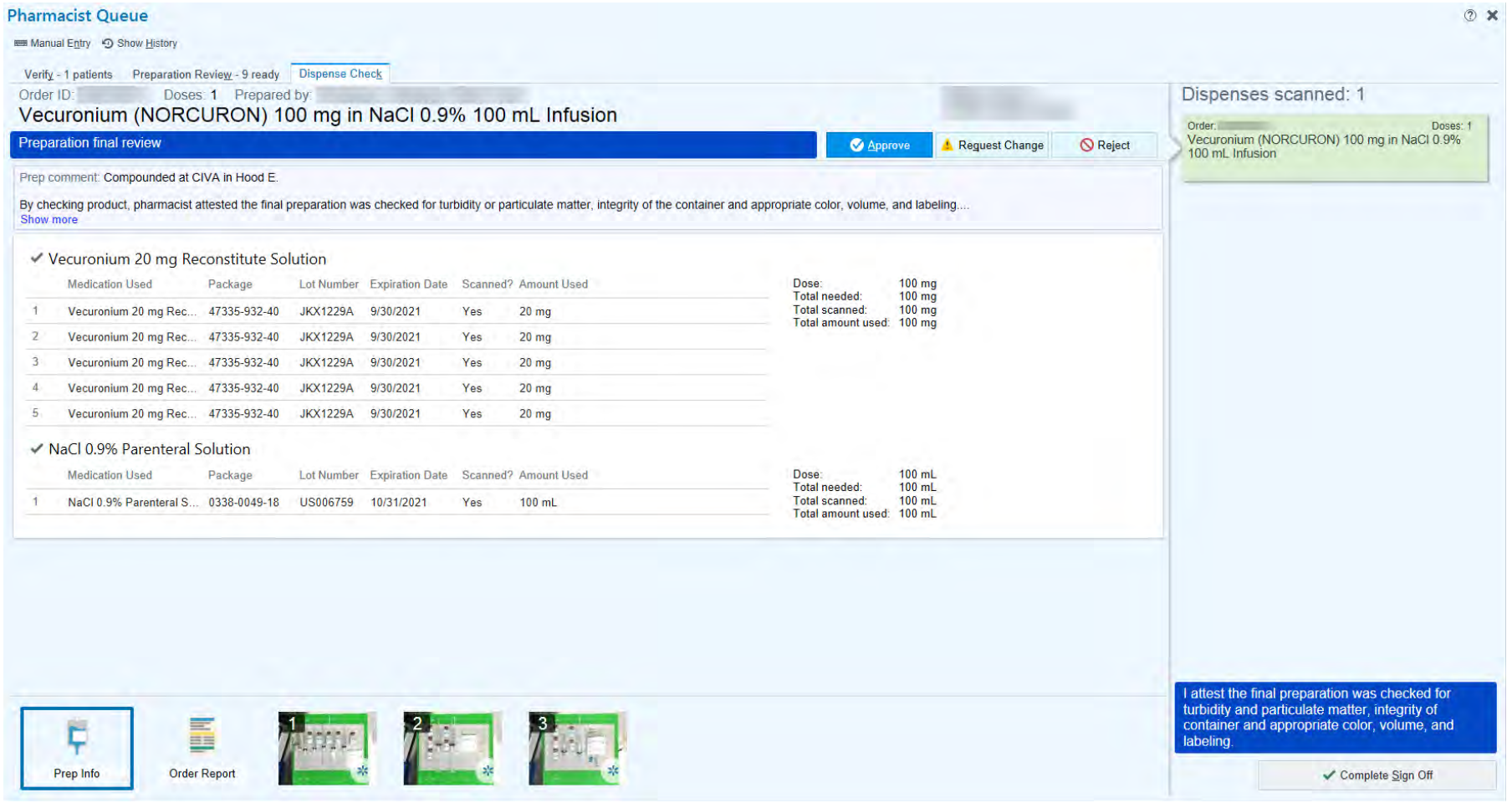
- Lot & Expiration
- Scanned = Yes
- Warnings

# DISPENSE CHECK

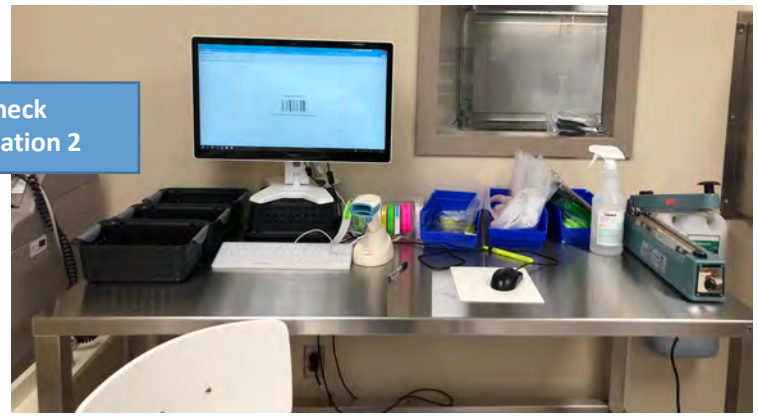

Check pictures

- Syringe pull
- Ingredients
- Before & after

# DISPENSE CHECK




Complete Sign Off


## Dispense Check

1. Complete Sign Off
2. Final Label print
3. Remove Production Label
4. Affix Final Label

## Final Product

Compounded by Pharmacy
UCDH Inpatient Pharmacy, Sacramento CA

**Xxtestbeacon, Justin**
MRN: 9300165
Order: 228307794-001
D8OC-8777-877701
D8BT
Due: 2/3/20 1630

**MethylPREDNISolone Sodium Succinate (SOLU-MEDROL) 1 g in NaCl 0.9% 296 mL IVPB**

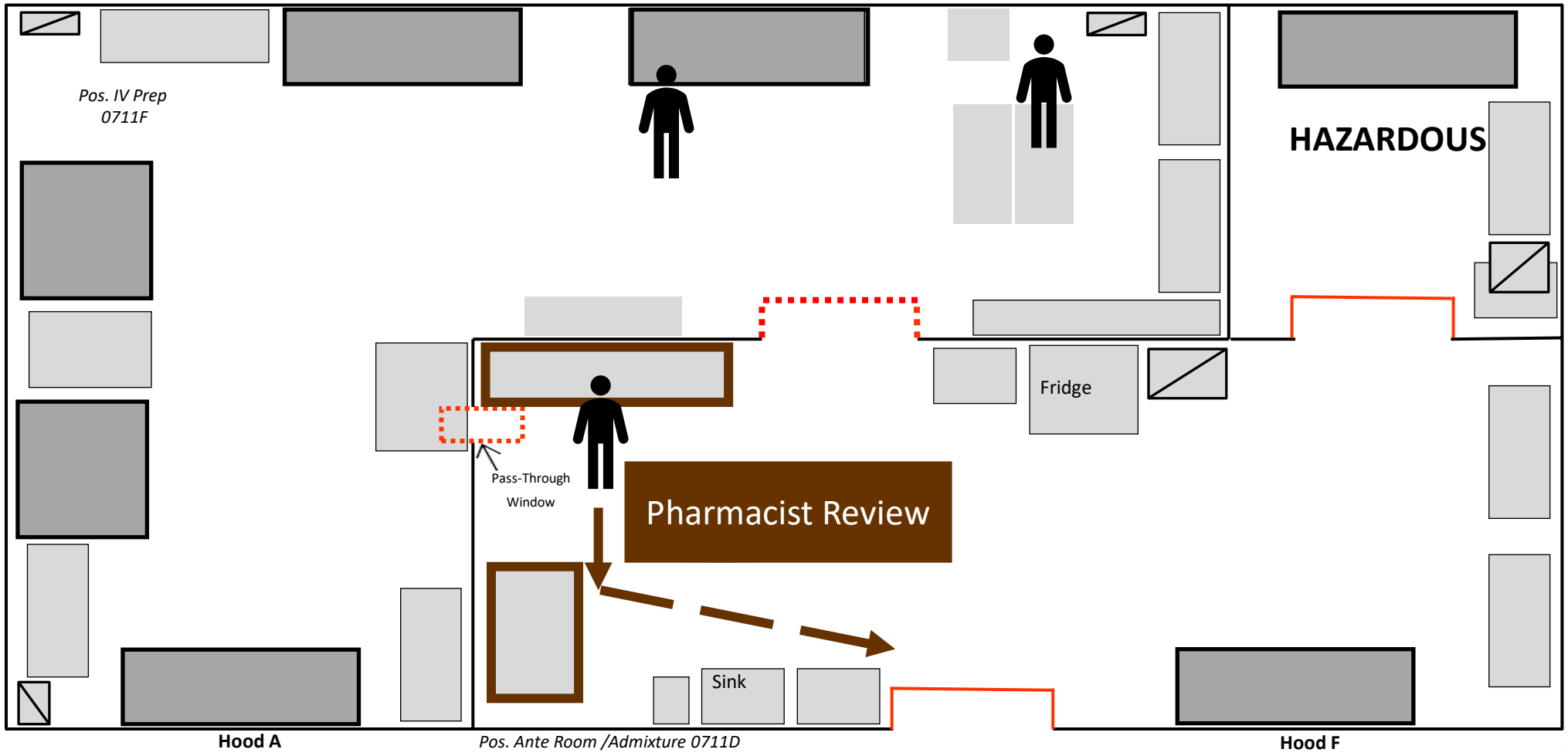
Volume with overfill: 296 mL
Rate: 296 mL/hr
Duration: 60 Minutes
Route: IV
Freq: ONE TIME ONLY
Store at Room Temperature

Discard by: 2/4/20 1534
CHECK REPRINT 0203-1537
Prep: DB Check: DB
Mixed: 2/3/20 1534

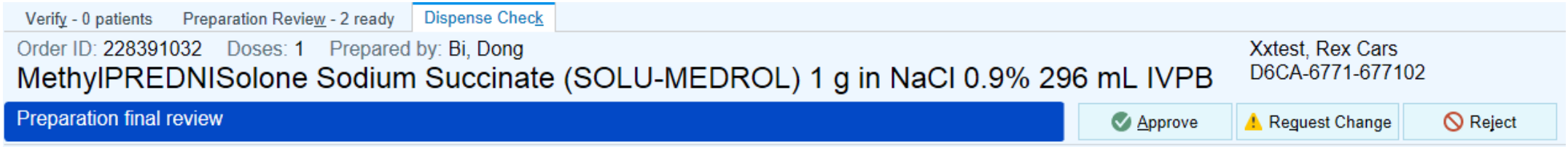
**Discard by = Prep Finalize time + Stability**

One preparation at a time!

# CENTRAL IV AREA SETUP



# DISPENSE CHECK: REQUEST CHANGE VS REJECT




Most likely due to documentation issue. Existing preparation can be used.

**Request Change** → Dispense sent back to Dispense Prep → Make correction in Dispense Prep → Send to Dispense Check

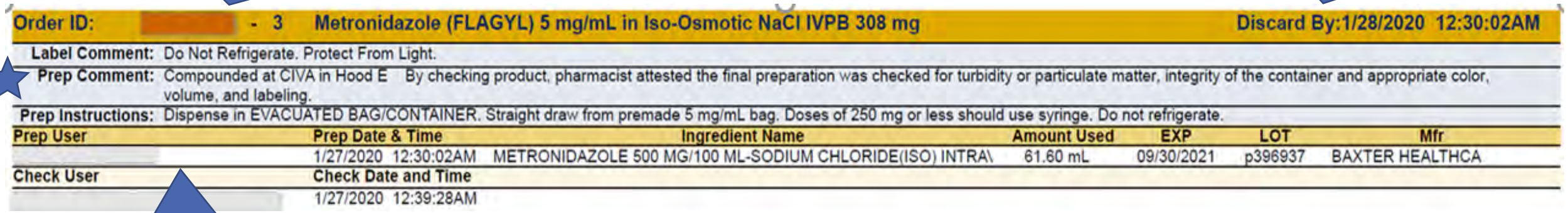
Most likely due to compounding issue. Existing preparation needs to be discarded.

**Reject Change** → Dispense is cancelled, new Dispense auto-generated → Start over with new preparation in Dispense Prep → Send to Dispense Check

# Compounding Log Design

Unique Order Identifier

Calculated based on:
- Prep Finalize Time
- Product Stability



| | | | | | | |
|---|---|---|---|---|---|---|
| **Order ID:** [redacted] - 3 | **Metronidazole (FLAGYL) 5 mg/mL in Iso-Osmotic NaCl IVPB 308 mg** | | | | | **Discard By:1/28/2020 12:30:02AM** |
| **Label Comment:** | Do Not Refrigerate. Protect From Light. | | | | | |
| **Prep Comment:** | Compounded at CIVA in Hood E By checking product, pharmacist attested the final preparation was checked for turbidity or particulate matter, integrity of the container and appropriate color, volume, and labeling. | | | | | |
| **Prep Instructions:** | Dispense in EVACUATED BAG/CONTAINER. Straight draw from premade 5 mg/mL bag. Doses of 250 mg or less should use syringe. Do not refrigerate. | | | | | |
| **Prep User** | **Prep Date & Time** | **Ingredient Name** | **Amount Used** | **EXP** | **LOT** | **Mfr** |
| | 1/27/2020 12:30:02AM | METRONIDAZOLE 500 MG/100 ML-SODIUM CHLORIDE(ISO) INTRA\ | 61.60 mL | 09/30/2021 | p396937 | BAXTER HEALTHCA |
| **Check User** | **Check Date and Time** | | | | | |
| | 1/27/2020 12:39:28AM | | | | | |

Pharmacist Check Action required for preparation completion

★ **Quality Review required for CA Compounding Log: Post-compounding process & procedures.**

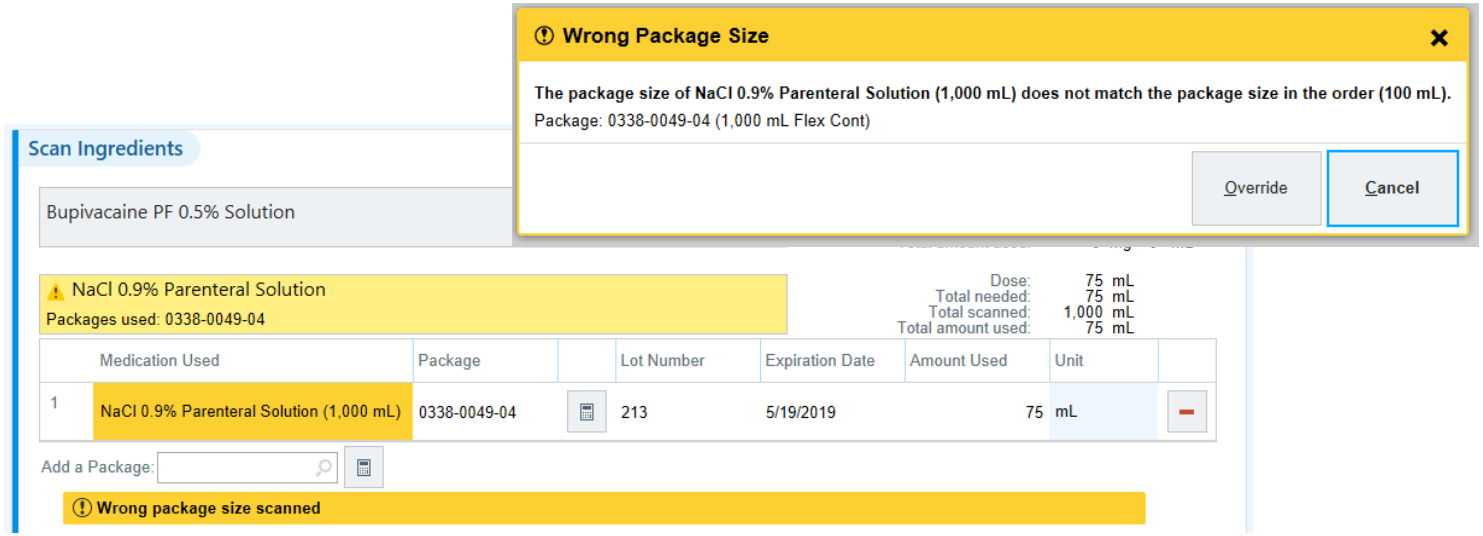


7. California Code of Regulations. Title 16 Section 1735.3. Recordkeeping for Compounded Drugs

# Dispense Prep Warnings

## 1. Wrong Package Size Scanned

- Yellow Warning – require individual judgement, can override if appropriate.
  - ➢ No IT follow up needed.
- Acceptable example scenario:
  - ➢ Order expects 100 mL NaCl 0.9% bag to be used.
  - ➢ User scan NDC for 1,000 mL NaCl 0.9% bag due to use with repeater pump.

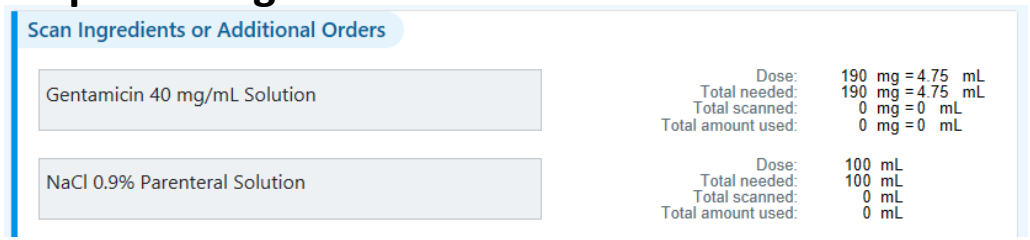


# Dispense Prep Warnings

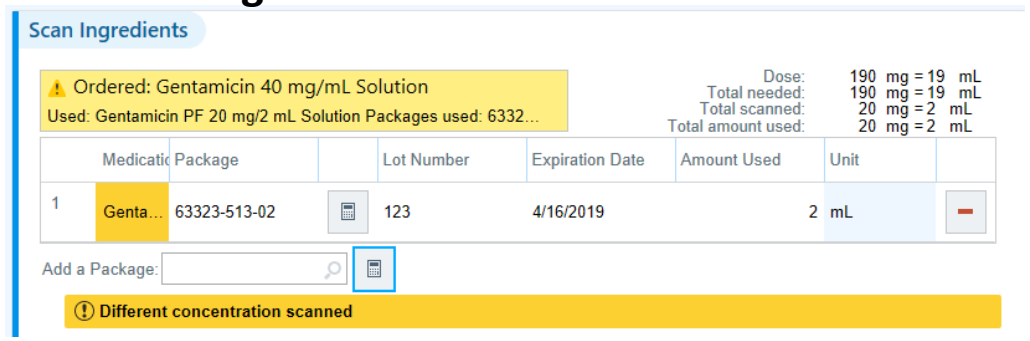
**2. Different Concentration Scanned (compared to concentration on Order)**

- Yellow Warning – require individual judgement, can override if appropriate.
  - ➢ No IT follow up needed.
- Acceptable example scenario:
  - ➢ Order expects Gentamicin 40 mg/mL solution.
  - ➢ User scan Gentamicin PF 20 mg/2 mL solution.

**Expected Ingredient**



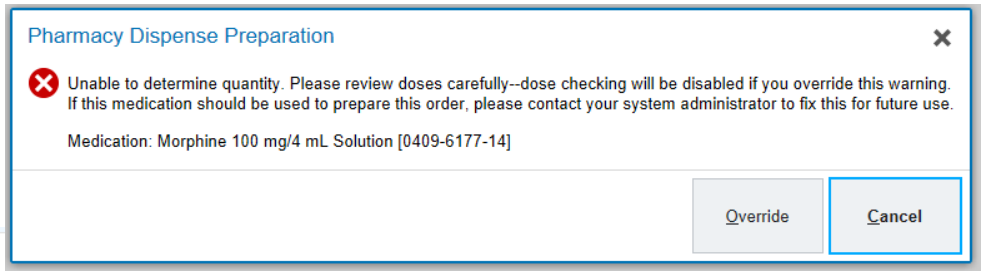

**Scanned Ingredient**

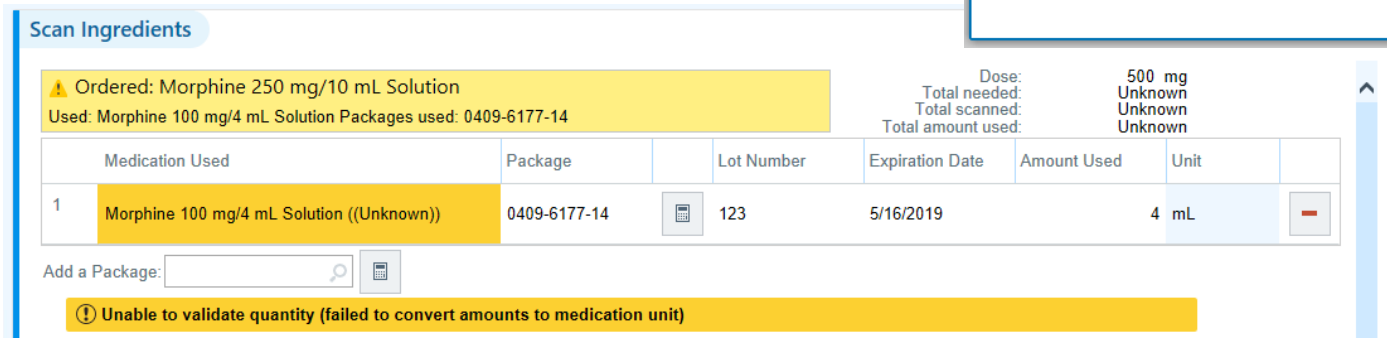


# Dispense Prep Warnings

**3. Unable to Determine Quantity.**

- Red Warning – require pharmacist check before override
  - ➢ Submit IT Ticket for evaluation.
- Acceptable Reason: mg to mL equivalence not yet configured in Epic. Due to new NDC in inventory.

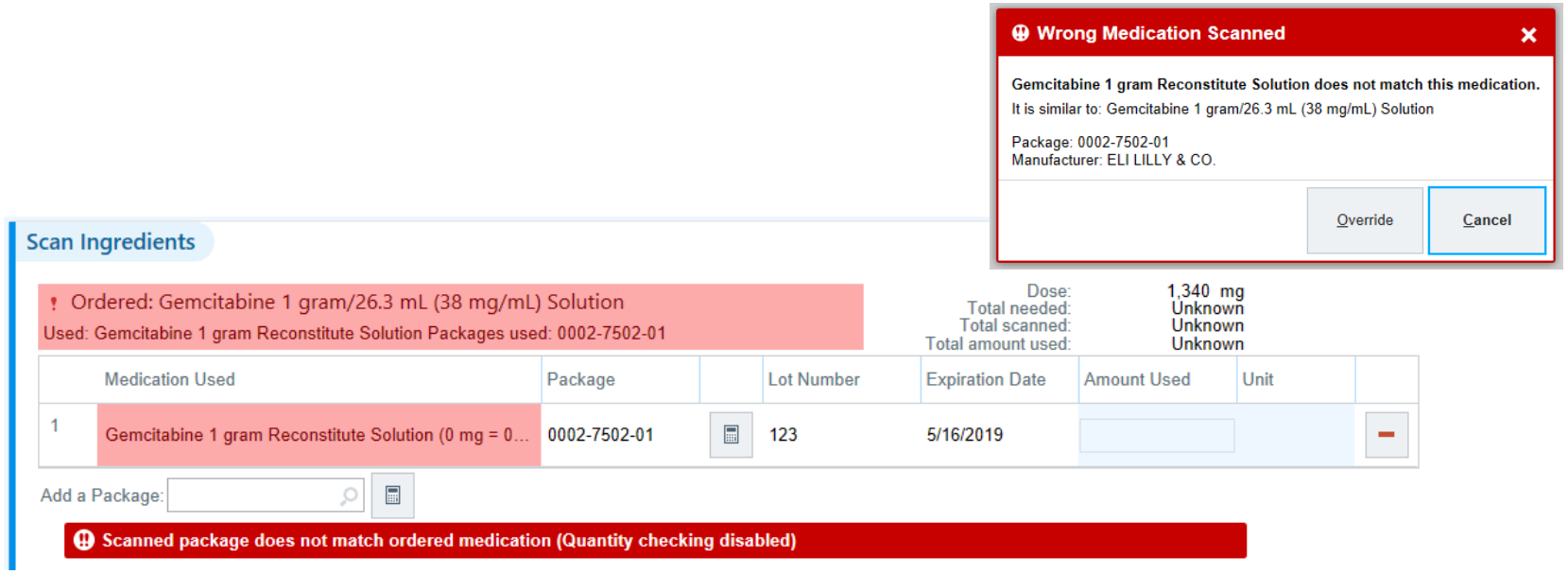


# Dispense Prep Warnings

**4. Different Form Scanned.**

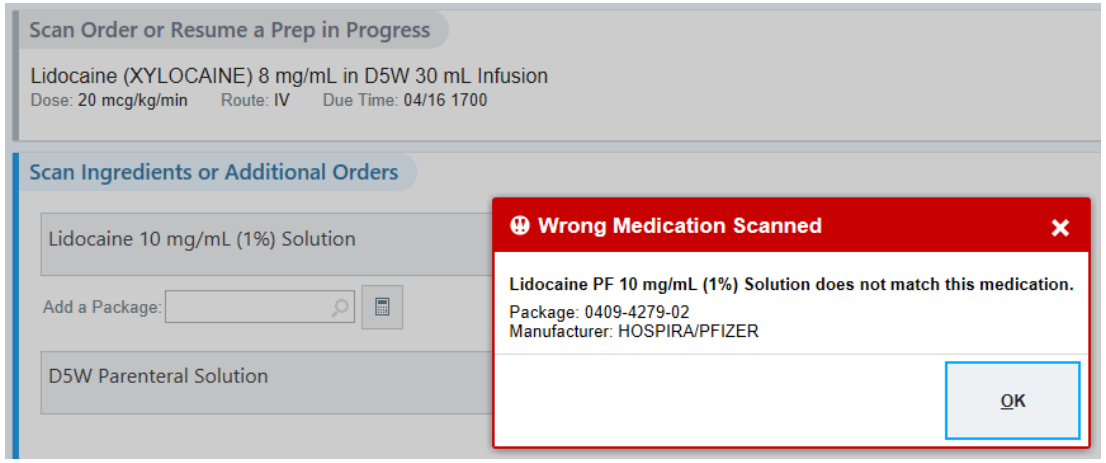
- Red Warning – require pharmacist check before override.
  - ➢ Submit IT Ticket for evaluation.
- Acceptable Reason: pre-supplied powder vs vial. Due to new NDC in inventory.



# Dispense Prep Warnings

**5. Wrong Medication Scanned.**

- Red Warning – require pharmacist check before override.
  - ➢ Epic will not accept NDC for documentation. See NDC Unable to Scan workflow.
  - ➢ Submit IT Ticket for evaluation.
- Acceptable Reason: PF vs non-PF. Due to new NDC in inventory.



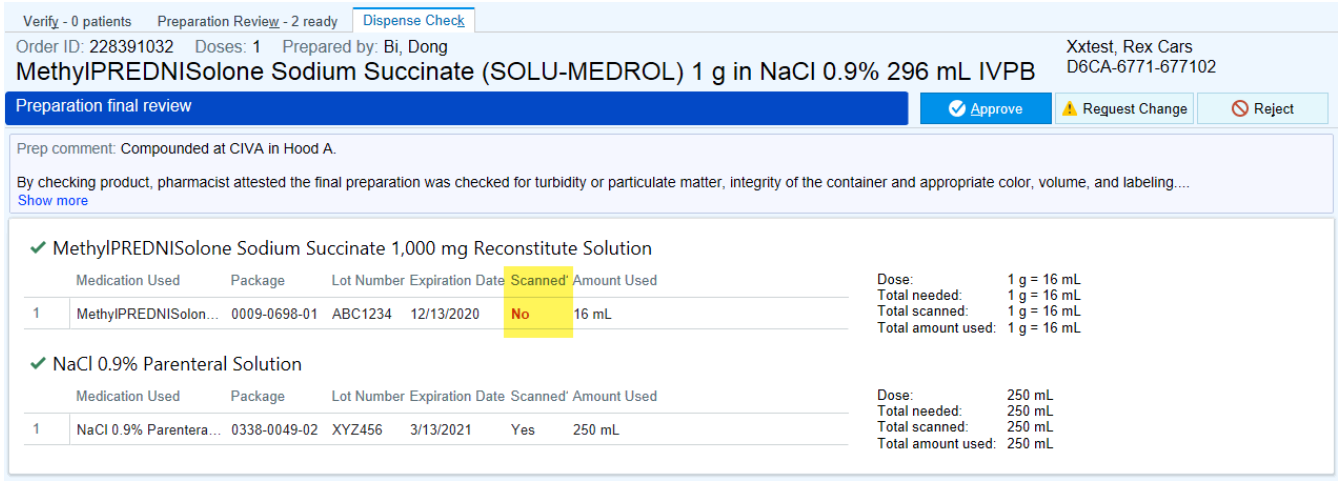
# NDC Unable To Scan

**Reasons for Unable to Scan (1 of 2)**

NDC barcode damaged or unrecognized, ingredient NDC is acceptable in Epic

Workaround : manually key in NDC printed on vial.

Consideration: Ingredient not scanned is audited & recorded:



# NDC Unable To Scan

**Reasons for Unable to Scan (2 of 2)**

Ingredient NDC is not acceptable in Epic, but clinically acceptable for compounding; Epic interchange allowance not yet configured.

<u>Workaround:</u>

1. Manually key in representative NDC from Production label
2. Manually record NDC used + Lot + Exp in Prep Comments field

Comments

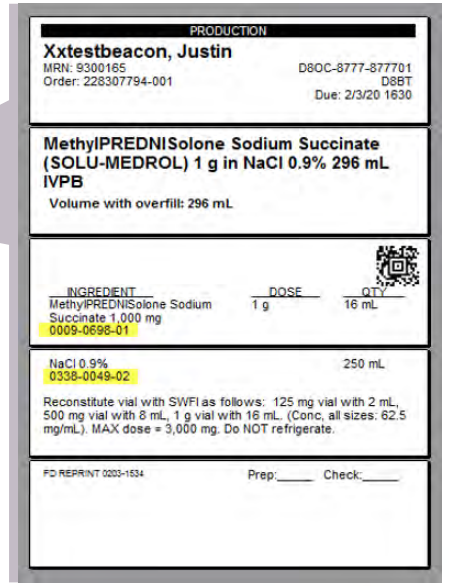
Insert SmartText | 100%

Methylprednisolone NDC: 12345-123-12 Lot: ABC1234 EXP: 12/31/2020

Compounded at CIVA in Hood A.

By checking product, pharmacist attested the final preparation was checked for turbidity or particulate matter, integrity of the container and appropriate color, volume, and labeling.

3. Submit IT ticket for NDC interchange allowance



# Ingredient Interchange Allowance

## Package differences: SOLUTION vs SYRINGE

- MORPHINE 2 MG/ML INJECTION **SOLUTION**
- MORPHINE 2 MG/ML INJECTION **SYRINGE**

## Package differences: pre-supplied liquid vs powder

- Build mg-mL equivalence for on-the-fly volume calculations
  - GEMCITABINE **200 MG** INTRAVENOUS SOLUTION
  - GEMCITABINE **200 MG/5.26 ML (38 MG/ML)** INTRAVENOUS SOLUTION

## Preservative Free vs Non-Preservative Free

- Allow 1-way scan (allow PF to be used when non-PF is ordered)
  - LIDOCAINE HCL 20 MG/ML (2 %) INJECTION SOLUTION
  - LIDOCAINE **(PF)** 20 MG/ML (2 %) INJECTION SOLUTION

# PROJECT LAUNCH

User Acceptance Testing

End User Training

Go-Live & Follow-up

# User Acceptance Testing

**Two Pharmacists** [validation- 80 hours]

- Scanning
- Master formula elements

**Two Technicians**

- Image Capture
- Hands on training of staff
- Time Trials

# TRAINING

**Web-Based** → **Hands-On** → **Competency** → **Go-Live**

Interactive

Step-by-Step Guides (#6)
Training Environment

Super-User Sign-Off

## Standard Workflow

FUROSEMIDE DRIP [1012036]


| ERX | NDC Size | NDC # |
|---|---|---|
| FUROSEMIDE 10 MG/ML INJECTION SOLUTION [3605] | 4 mL | 0409-6102-04 |
| SODIUM CHLORIDE 0.9 % INTRAVENOUS SOLUTION [29607] | 100 mL | 0338-0049-18 |

In Production Environment:

- Pharmacist verification → Dispense action → only production label generates. Final label does not print with each Dispense action.
- Tech "Finalize" Dispense Prep → Pharmacist "Complete Sign Off" Dispense Check → Final label prints with electronic Prep and Check user initials.

In Training Environment:

- We do not have label printers in training environment. Instead a patient-specific reference sheet with Dispense Prep barcode has been provided for each order under that patient. This mimics the Dispense Prep barcode on production label.

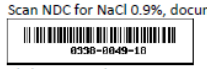
### Pharmacy Technician: in staging area outside of hood

1. Pharmacist verified label → Dispense action → production label prints. Refer to training reference sheet for production label and Dispense Prep barcode to use for this order.
2. Gather ingredients needed on production label.
3. Open Dispense Prep activity.
4. Scan Dispense Prep barcode on production label. If production label barcode unavailable, can manually enter order ID.
5. Dispense Prep window for Furosemide Infusion opens. Preparation Instructions and Label Comments are displayed on right side.
6. We don't have Furosemide 10 mL vials in stock. NDC provided to scan is for 4 mL vial.
   a. Scan 4 mL NDC. Single scan results in Total scanned = 4 mL. Total needed = 10 mL. Enter Lot & Expiration Date for vial.



   - Training Note: Lot Number & Expiration Date auto-populate if same NDC documented within last 24 hour. Ensure auto-populated value matches product used for that specific scan.


   b. Scan 4 mL NDC again. Second line item for same NDC populates with ability to document different Lot Number & Expiration. Amount used for second line item prepopulates to 4 mL. Total Scanned = 8 mL
   c. Scan 4 mL vial NDC third time. Amount used for third line item prepopulates to 2 mL despite scanning the 4 mL vial. Total scanned is now 12 mL, Total amount used is 10 mL.
   Training note:
      - When Dispense Prep scans package sizes larger than ordered amount, Total scanned will always be NDC package size, but Total amount used will always auto-populate to amount ordered.
      - When Dispense Prep scans package size smaller than order amount, multiple scans are required to fulfill order amount. Each package is expected to be scanned for validation.
   d. Click on ingredient line for Furosemide to show all 3 separate line-item documentation, each with Lot, Expiration Date, amount used. Amount used for each vial can be edited if prepopulated value is inaccurate.
7. Scan NDC for NaCl 0.9%, document Lot Number & Expiration Date.




8. Click Save Work. Dispense Prep window automatically closes.
9. Place all ingredients and Production into basket and/or ziplock bag. A single basket and/or ziplock bag should be used per Dispense (each production label).

### Pharmacy Technician: at IV hood

10. Take single basket and/or ziplock bag with ingredients and Production label into IV hood.
11. Open Dispense Prep activity.
12. Scan Dispense Prep barcode on production label. If production label barcode unavailable, can manually enter order ID.
13. Receive Prompt for: Resume, Start Over, Cancel. Click Resume to resume previously documented preparation.
    - Start Over – wipe out previously documented scans, Lot Number, Expiration Date.
    - Cancel – cancel opening saved preparation, return to Dispense Prep window. Saved preparation data is unmodified.
14. Dispense Prep window for Furosemide Infusion opens. Preparation Instructions and Label Comments are displayed on right side.
15. Once all ingredients are validated (green), proceed to draw up Furosemide amount into syringe.
16. Place production label, drawn up Furosemide syringe, Furosemide vial, NaCl 0.9% 100 mL IVPB under camera.
17. Click Take a Picture. Ensure production label, syringe volume, drug name on vial, IVPB name, hood location identifier, are all clearly visible in picture under preview. Adjust picture capture window as necessary to capture all required information. Click Red Camera icon to take a picture.
18. Captured Picture is brought into Image Review screen. Keep, Keep and Take Another, Retake, and Discard available actions. Multiple pictures can be taken for a single dispense. You may place mouse pointer over picture, and use mouse scroll wheel to zoom in/out on picture. When finished, click Keep.
19. Inject drawn-up syringe into IVPB.
20. Securely place production label onto of IVPB.
21. Place empty syringe, vial, completed IVPB with production label attached under camera.



22. Click Take a Picture. Ensure production label, empty syringe, drug name on vial, IVPB with production label, hood location identifier are all clearly visible in picture under preview. Repeat take picture camera workflow.
23. Click Finalize.
24. Place completed IVPB with production label securely attached, along with all prep materials and vials used in basket. Take basket to counter for pharmacist to place final dispense label.

### Pharmacist:

25. Open Pharmacist Queue:
    a. If production label available to scan, go to Dispense Check tab, scan production label barcode.
    b. If production label unavailable, go to Preparation Review tab, under Ready for Review section, find order for Furosemide Infusion for your test patient. Status should be "Prep Complete". Double click on order to open for Dispense Check.
26. Check Dispense Details report. Ensure ingredient information is correct, ensure captured warnings from Dispense Prep are appropriate.
27. Click on all pictures on bottom to view. Unviewed pictures have * watermark. Viewed pictures have binocular watermark. You may place mouse pointer over picture, and use mouse scroll wheel to zoom in/out on picture.
28. Once Prep is determined to be appropriate, click Complete Sign Off.
29. Final Dispense Label prints in IV room. Final label contains initials of Dispense Prep & Dispense Check user.
30. Take final dispense label, find compounded IVPB, match up final dispense label to production label already on IVPB. Affix final dispense label onto IVPB on top of and covering production label.
31. Save leftover PHI containing labels for shred bin disposal.

Prep and Check complete. Dispense ready to be delivered.

## DPDC Competency | **Assessment – Technician**

| EMPLOYEE NAME | | DATE: | |
|---|---|---|---|
| AUDITOR NAME | | PASS | FAIL |

| GENERAL COMPETENCY | No Assistance Needed | Minimal Assistance | Needs improvement |
|---|---|---|---|
| 1. **Demonstrates making Furosemide Infusion unassisted** – Is able to prepare non-hazardous simple CSP without asking for help or referencing script. | | | |
| 2. **Demonstrates making Ceftriaxone Infusion unassisted** – Is able to prepare non-hazardous reconstituted medication without asking for help or referencing script. | | | |
| 3. **Demonstrates making Bupivacaine Epidural unassisted** – Is able to prepare epidural without asking for help or referencing script. | | | |

| QUALITY ASSURANCE / ERROR RATE | Super User | Standard | Not Ready |
|---|---|---|---|
| 4. **Type A errors** (wrong dose, wrong drug, wrong concentration, mislabeled final product, technique issues – failure to use filter needle, failure to use sterile technique) | No errors | No errors | 1 or more Errors |
| 5. **Type B errors** (failure to follow prep instructions, failure to obtain mid prep review, failure to capture image or poor-quality image obtained) | No errors | 1 Error | More than 1 Error |
| 6. **Type C errors** (multiple preps in hood at same time, failure to document substitution in comments, failure to document correct lot #) | No errors | 2 Errors | More than 2 Error |

**COMMENTS**

## DPDC Competency | **Assessment – Pharmacist**

| EMPLOYEE NAME | | DATE: | |
|---|---|---|---|
| AUDITOR NAME | | PASS | FAIL |

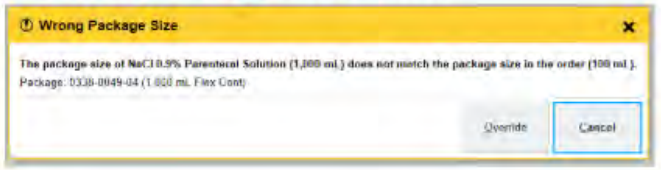
| OBSERVE UNASSISTED USE OF DISPENSE CHECK | No Assistance Needed | Minimal Assistance | Needs improvement |
|---|---|---|---|
| 1. Pulls up order using barcode scan (not applicable with Hazardous workflow) | | | |
| 2. Confirms correct ingredients used | | | |
| 3. Confirm correct lot number and expiration date | | | |
| 4. Able to evaluate barcode warnings | | | |
| 5. Verifies image | | | |
| 6. Describes correct process if image is blurry / missing / inadequate | | | |

| OBSERVE FINAL LABEL PLACEMENT ON PRODUCT | YES | NO |
|---|---|---|
| 7. Double checks patient name (not applicable with Hazardous workflow) | | |
| 8. Places auxiliary stickers as appropriate | | |

**COMMENTS**

# TROUBLESHOOTING GUIDE & COMPETENCY

## 2. Wrong Package Size Scanned



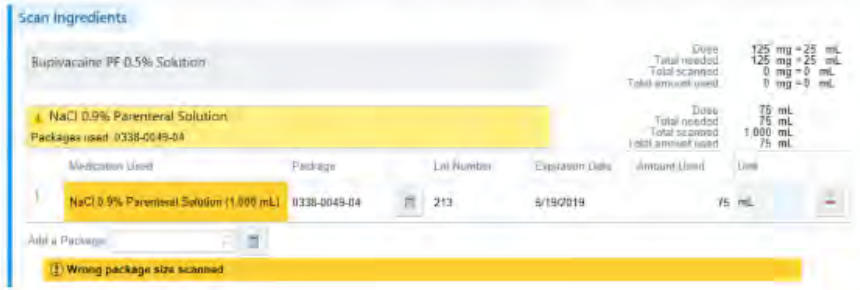

Cause:

Scanned package size doesn't match package size ordered.

- In this case the alert can be overridden because we are using the repeater pump to prepare the product.
- This may NOT be appropriate if you're scanning a 1 Liter bag, and the order is for an insulin drip made in a 100 mL bag (warning = near miss medication error).

Immediate steps to move forward:

1. Double check what the order calls for
2. If determine scanned product is ok to use:
   a. Click Override.
3. If not appropriate to use, click cancel, swap out with the correct product, and re-scan product.
4. There is no need to escalate this situation to the EMR or pharmacy manager.




Escalate to Pharmacy Management? No

Escalate to EMR? No

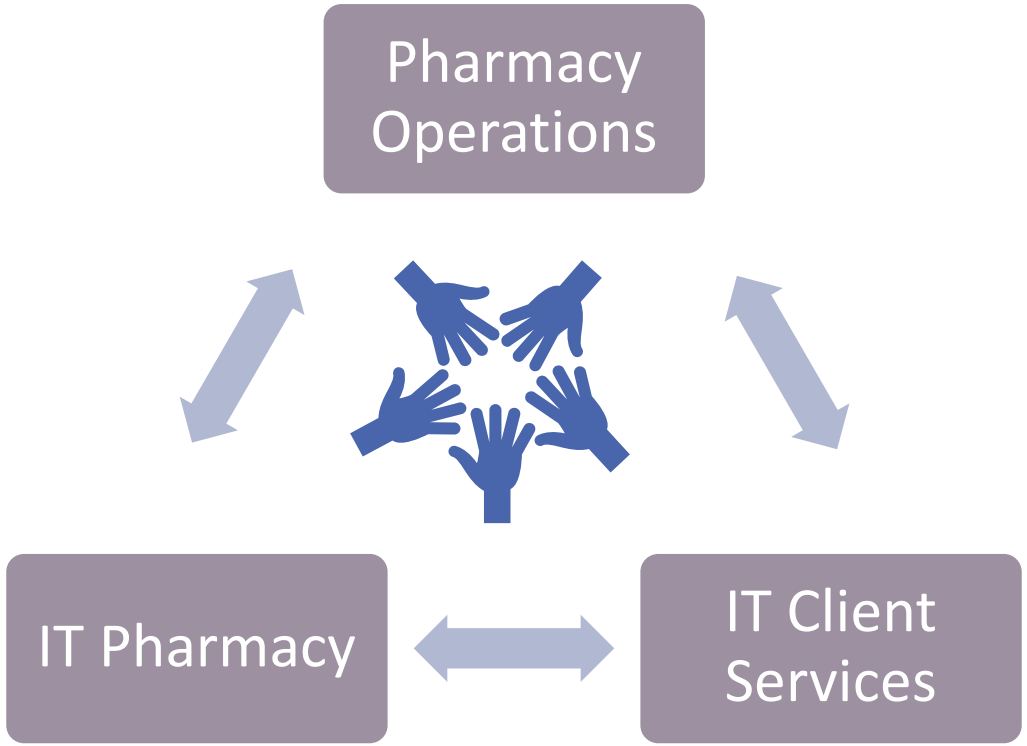
## Scenario 1: You are preparing a ketamine infusion that requires an exact volume base.

**Question 1:** Upon scanning a NaCl 0.9% 1 Liter bag, you see the alert below, you interpret the alert as follows.


Answers:

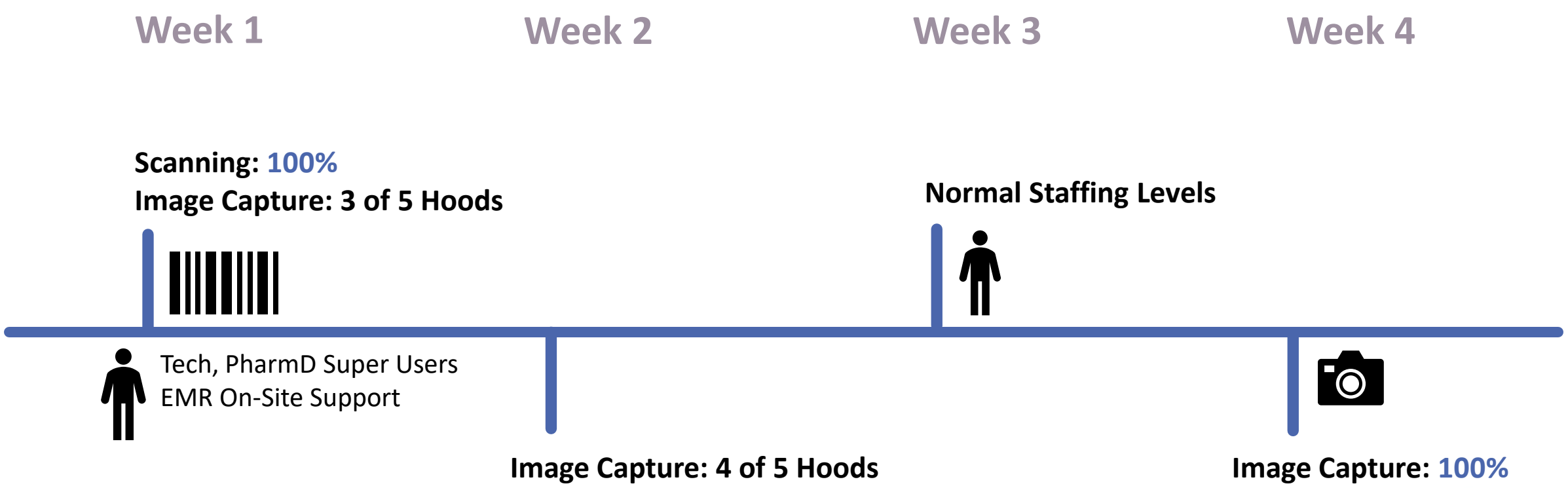
a) **The volume scan doesn't match the ordered volume for this preparation**
b) The scanned medication is a different formulation (preservative free) but non-preservative free is ordered
c) A look alike/sound alike medication has been scanned
d) Not sure

# Go-Live Communication




- Daily Huddles
- Interactive Issues Tracker
- IT On-Site Support (all sites)

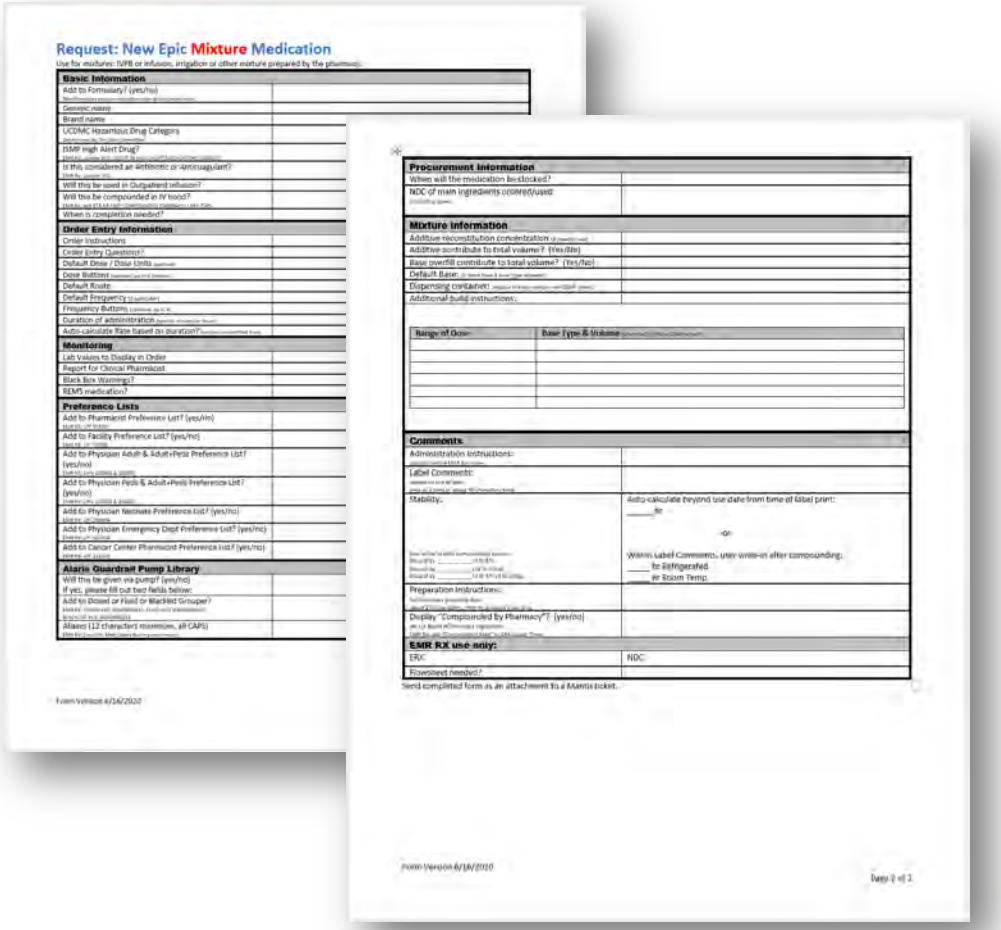
# Go-Live Timeline



# MAINTENANCE: MASTER FORMULA

**Consistent Configuration**

- Additive Reconstitution Volume
- Stability
- Label Comments-- storage
- Prep Instructions



# PROJECT WRAP-UP

## Keys to Success & Lessons Learned

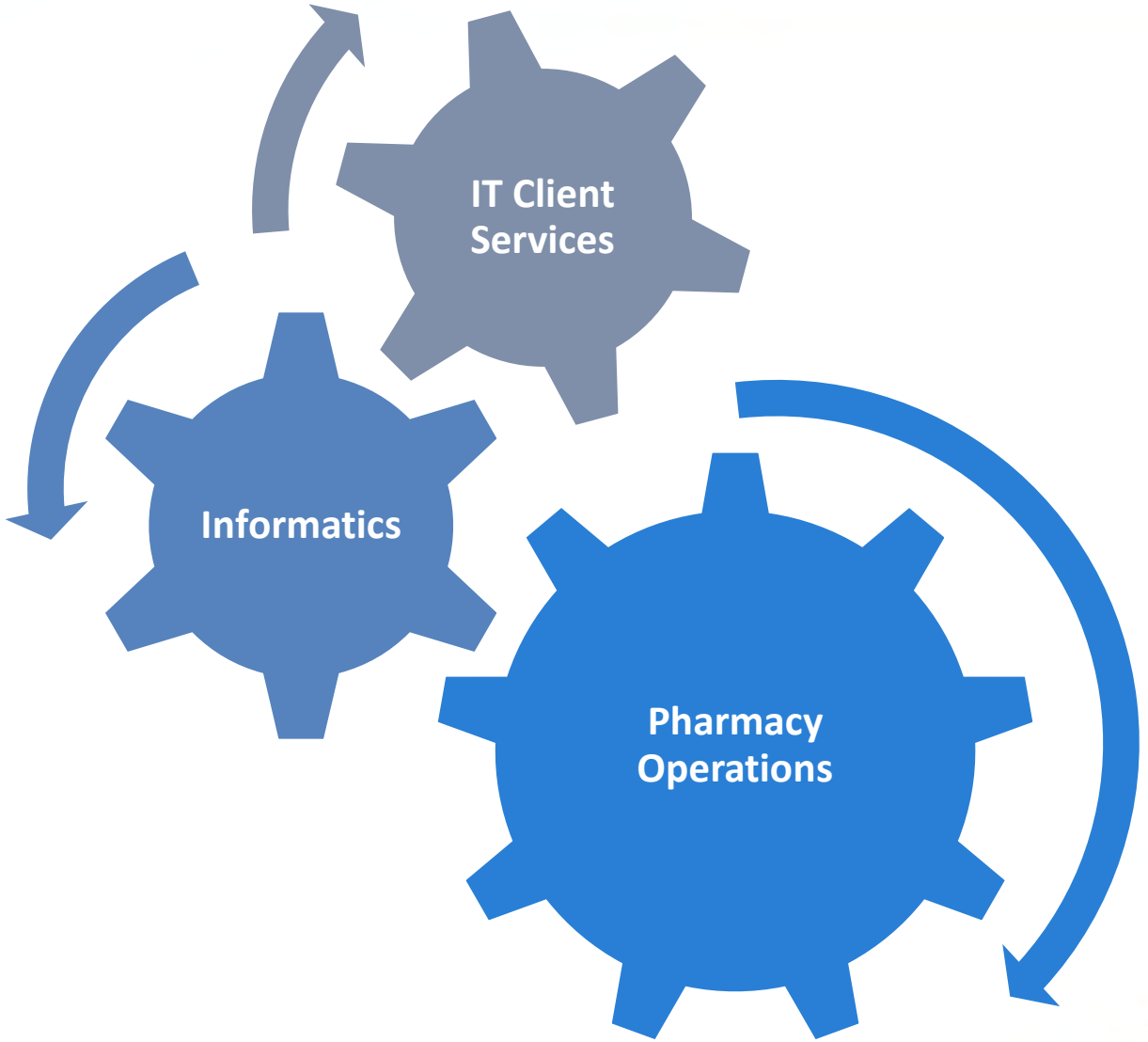
**Task Tracking**

**Communication Plan**

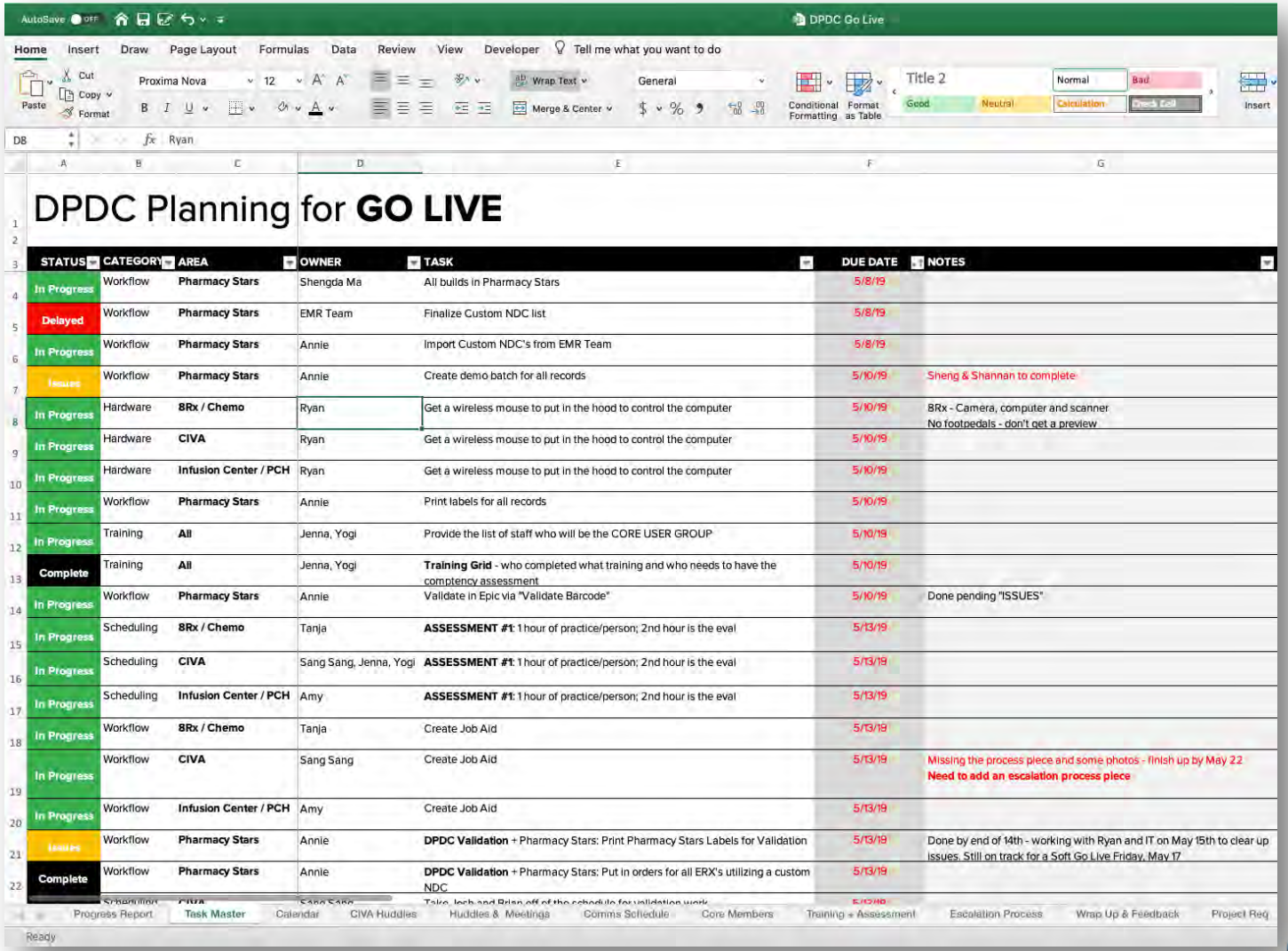
**Multidisciplinary Project Team**

**File Sharing**

# PROJECT TEAM



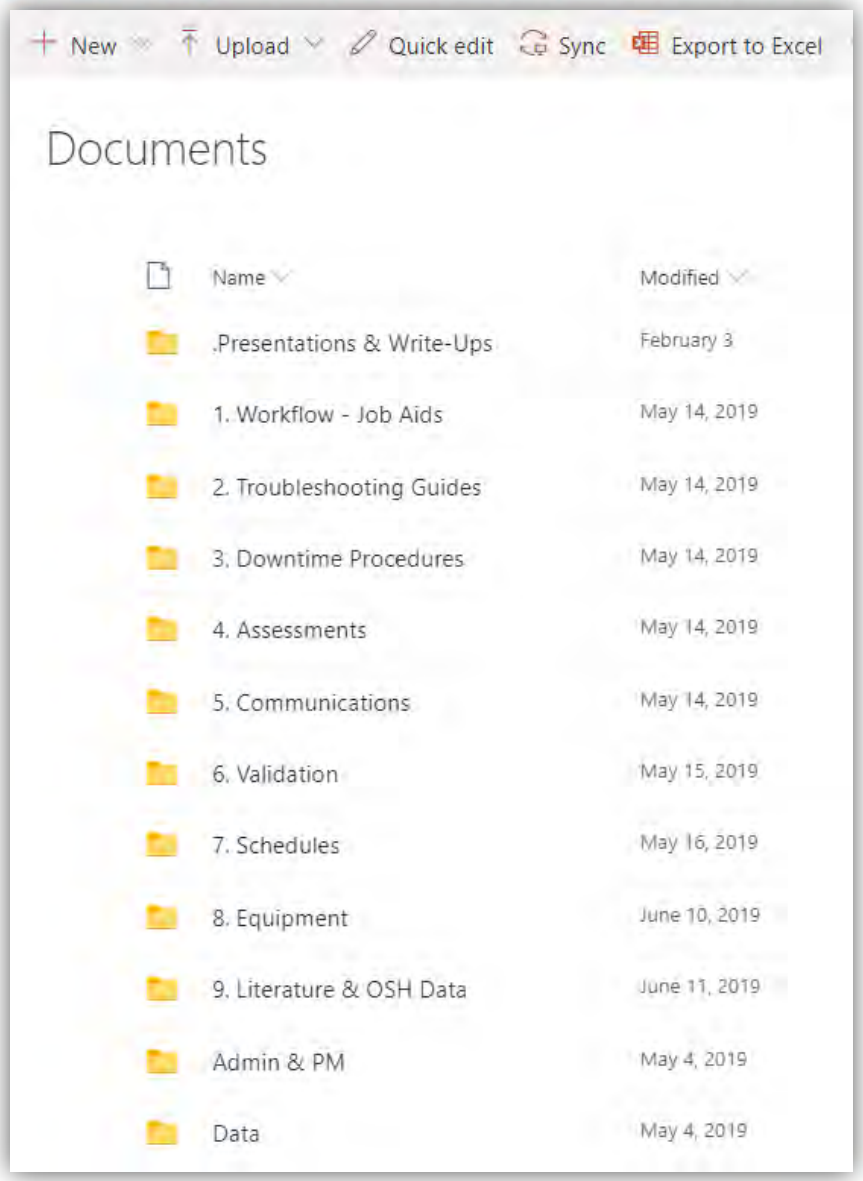
# TASK TRACKING



DPDC Planning for **GO LIVE**

| STATUS | CATEGORY | AREA | OWNER | TASK | DUE DATE | NOTES |
|---|---|---|---|---|---|---|
| In Progress | Workflow | **Pharmacy Stars** | Shengda Ma | All builds in Pharmacy Stars | 5/8/19 | |
| Delayed | Workflow | **Pharmacy Stars** | EMR Team | Finalize Custom NDC list | 5/8/19 | |
| In Progress | Workflow | **Pharmacy Stars** | Annie | Import Custom NDC's from EMR Team | 5/8/19 | |
| Issues | Workflow | **Pharmacy Stars** | Annie | Create demo batch for all records | 5/10/19 | Sheng & Shannan to complete |
| In Progress | Hardware | **8Rx / Chemo** | Ryan | Get a wireless mouse to put in the hood to control the computer | 5/10/19 | 8Rx - Camera, computer and scanner<br>No footpedals - don't get a preview |
| In Progress | Hardware | **CIVA** | Ryan | Get a wireless mouse to put in the hood to control the computer | 5/10/19 | |
| In Progress | Hardware | **Infusion Center / PCH** | Ryan | Get a wireless mouse to put in the hood to control the computer | 5/10/19 | |
| In Progress | Workflow | **Pharmacy Stars** | Annie | Print labels for all records | 5/10/19 | |
| In Progress | Training | **All** | Jenna, Yogi | Provide the list of staff who will be the CORE USER GROUP | 5/10/19 | |
| Complete | Training | **All** | Jenna, Yogi | **Training Grid** - who completed what training and who needs to have the comptency assessment | 5/10/19 | |
| In Progress | Workflow | **Pharmacy Stars** | Annie | Validate in Epic via "Validate Barcode" | 5/10/19 | Done pending "ISSUES" |
| In Progress | Scheduling | **8Rx / Chemo** | Tanja | **ASSESSMENT #1**: 1 hour of practice/person; 2nd hour is the eval | 5/13/19 | |
| In Progress | Scheduling | **CIVA** | Sang Sang, Jenna, Yogi | **ASSESSMENT #1**: 1 hour of practice/person; 2nd hour is the eval | 5/13/19 | |
| In Progress | Scheduling | **Infusion Center / PCH** | Amy | **ASSESSMENT #1**: 1 hour of practice/person; 2nd hour is the eval | 5/13/19 | |
| In Progress | Workflow | **8Rx / Chemo** | Tanja | Create Job Aid | 5/13/19 | |
| In Progress | Workflow | **CIVA** | Sang Sang | Create Job Aid | 5/13/19 | Missing the process piece and some photos - finish up by May 22<br>**Need to add an escalation process piece** |
| In Progress | Workflow | **Infusion Center / PCH** | Amy | Create Job Aid | 5/13/19 | |
| Issues | Workflow | **Pharmacy Stars** | Annie | **DPDC Validation** + Pharmacy Stars: Print Pharmacy Stars Labels for Validation | 5/13/19 | Done by end of 14th - working with Ryan and IT on May 15th to clear up issues. Still on track for a Soft Go Live Friday, May 17 |
| Complete | Workflow | **Pharmacy Stars** | Annie | **DPDC Validation** + Pharmacy Stars: Put in orders for all ERX's utilizing a custom NDC | 5/13/19 | |

# FILE SHARING

# COMMUNICATION PLAN

AutoSave On | DPDC Go Live.xlsx - Saved

File Home Insert Page Layout Formulas Data Review View Help ACROBAT Search

C17

## Communications Schedule

| | | HUDDLE MESSAGES | 7:10 am Huddle | 2:30 pm Huddle | 3:00 pm Huddle (CIVA) |
|---|---|---|---|---|---|
| WEEK 2 | Monday, May 20, 2019 | **TRAINING SCHEDULE**: Content, Time, Who<br>- Who? Most pharmacists and techs working in the IV area regularly have received the 2 hour initial training and have completed the online module. Superusers have completed some validation. Training documents are located:????. Secondary training on more complex products/compounds will be ????. Staff are encouraged to practice on the stations located in CIVA/8th/Cancer center.<br>- What? Pharmacy Stars 5/21 and 6/25 for DPDC<br>- When? Go LIVE schedule posted throughout pharmacy along with overall project time line. | | Julianna | Julianna |
| | Tuesday, May 21, 2019 | | Julianna | | Pam |
| | Wednesday, May 22, 2019 | | | Julianna | Julianna |
| | Thursday, May 23, 2019 | **EXPECTATION / QUESTIONS FROM STAFF**<br>- Poster paper in Central for any questions that come up<br>- Superusers validating all of the products/compounds we usually use. Questions from validation are being reviewed. A list of these questions/answers is available?????.<br>- If they would like more training more can be scheduled. | Julianna | | Pam |
| | Friday, May 24, 2019 | | | Julianna | Julianna |
| | **Saturday, May 25, 2019** | | | | |
| | **Sunday, May 26, 2019** | | | | |
| WEEK 3 | Monday, May 27, 2019 | **FINAL WORKFLOW + DOCUMENTS**<br>- Final workflow documents were created after Superusers reviewed workflow<br>- Documents are located ???<br>- Digicom board updated<br>- Handouts available | | Julianna | Julianna |
| | Tuesday, May 28, 2019 | | Julianna | | Pam |
| | Wednesday, May 29, 2019 | | | Julianna | Julianna |
| | Thursday, May 30, 2019 | **CAMERA DEMO PHOTOS**<br>- New DPDC process requires pharmacists to sign off on products based on pictures taken by the new technology<br>- If the picture isn't clear, the pharmacist should reject the image and ask for another one for safety<br>- Examples of rejected pictures will be on the Digicom board<br>- Tips/Tricks to keep picture clear | Julianna | | Pam |
| | Friday, May 31, 2019 | | | Julianna | Julianna |

# Using Data to Drive Performance and Quality Improvement Initiatives

# Quality Improvement Strategies

Compounding Stewardship

Data-Driven Culture Change

Regulatory Compliance

Staff Engagement Activities

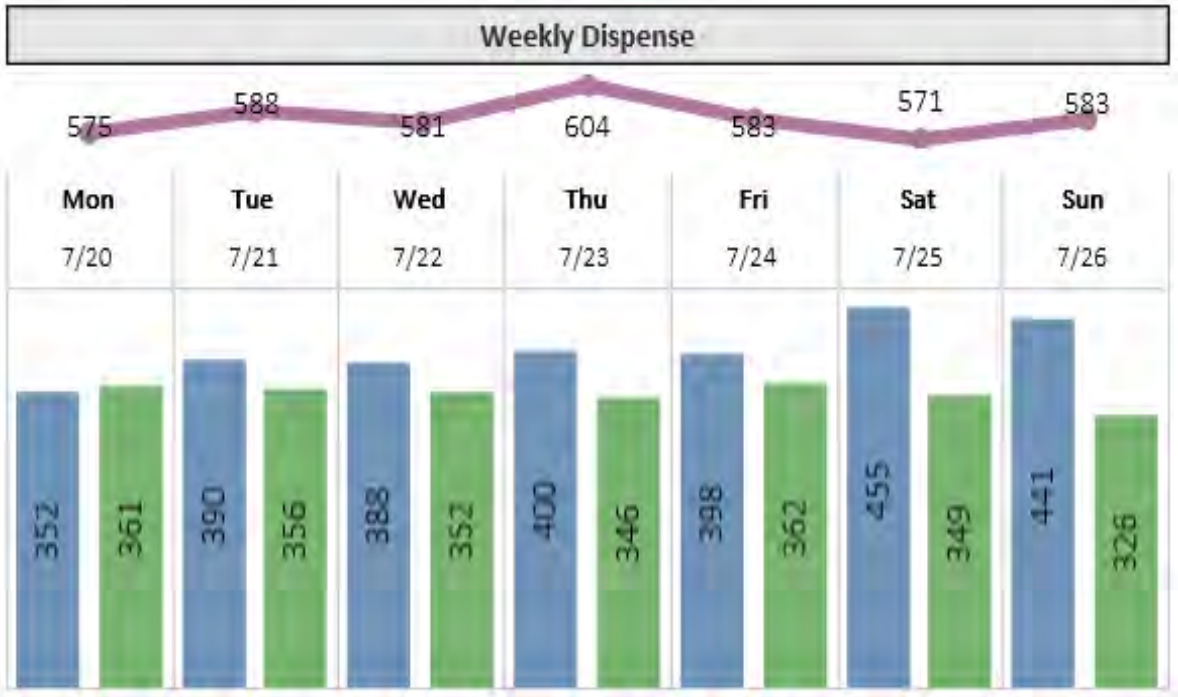
# Management Perspective on Stewardship

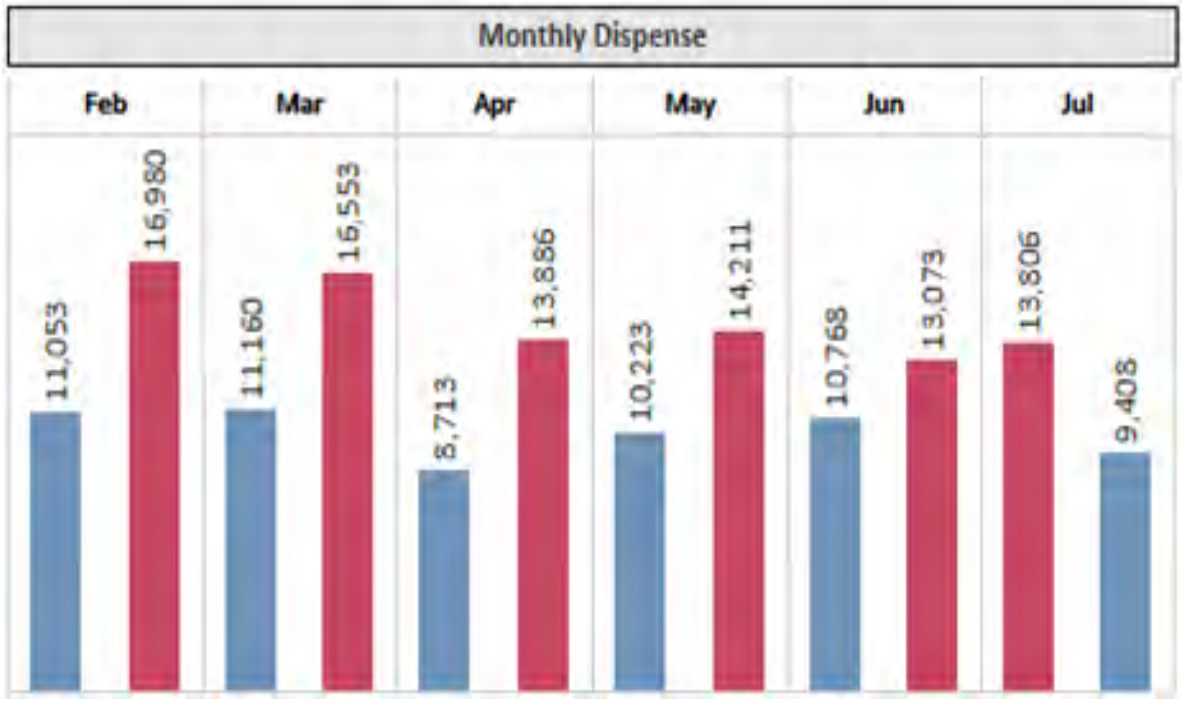
| | |
|---|---|
| Productivity | • Are we compounding things that we shouldn't be?<br>• Do we have enough FTE's to accommodate CSP volume? |
| Regulatory Compliance | • Are there master formula gaps? |
| Financial Stewardship | • Are there opportunities to expand sterile compounding services to reduce drug spend? |
| Supply Chain | • How are drug shortages impacting compounding volume? |
| Employee Engagement | • What is the best strategy to engage staff with data-driven information? |

# "COMPOUNDING STEWARDSHIP"


Daily review of top compounded meds to ensure appropriate stewardship of IV room

- **Compounding Stewardship:** Represents the coordinated effort among multidisciplinary teams to *optimize sterile compounding activities* to balance clinical need, regulatory requirements, & financial considerations

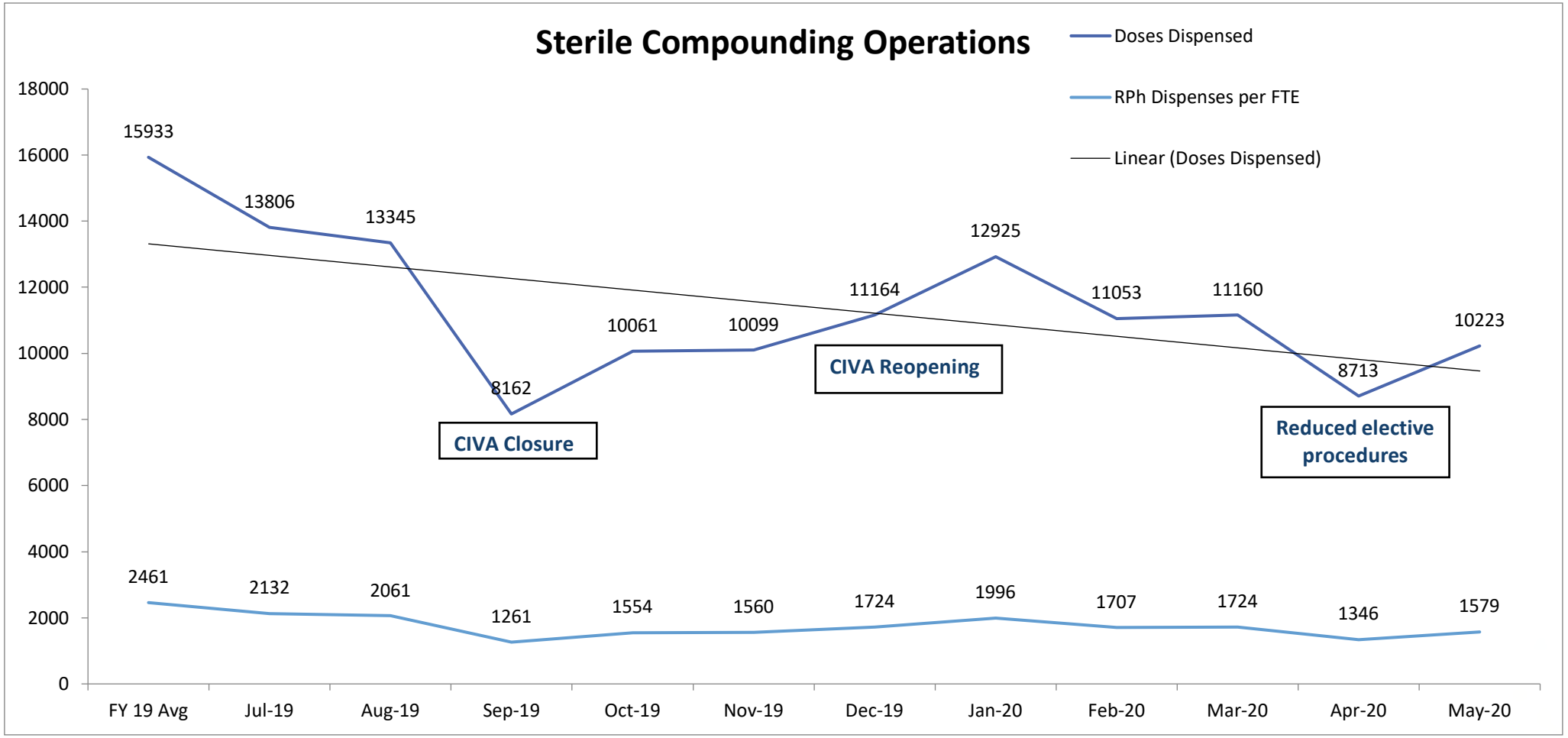


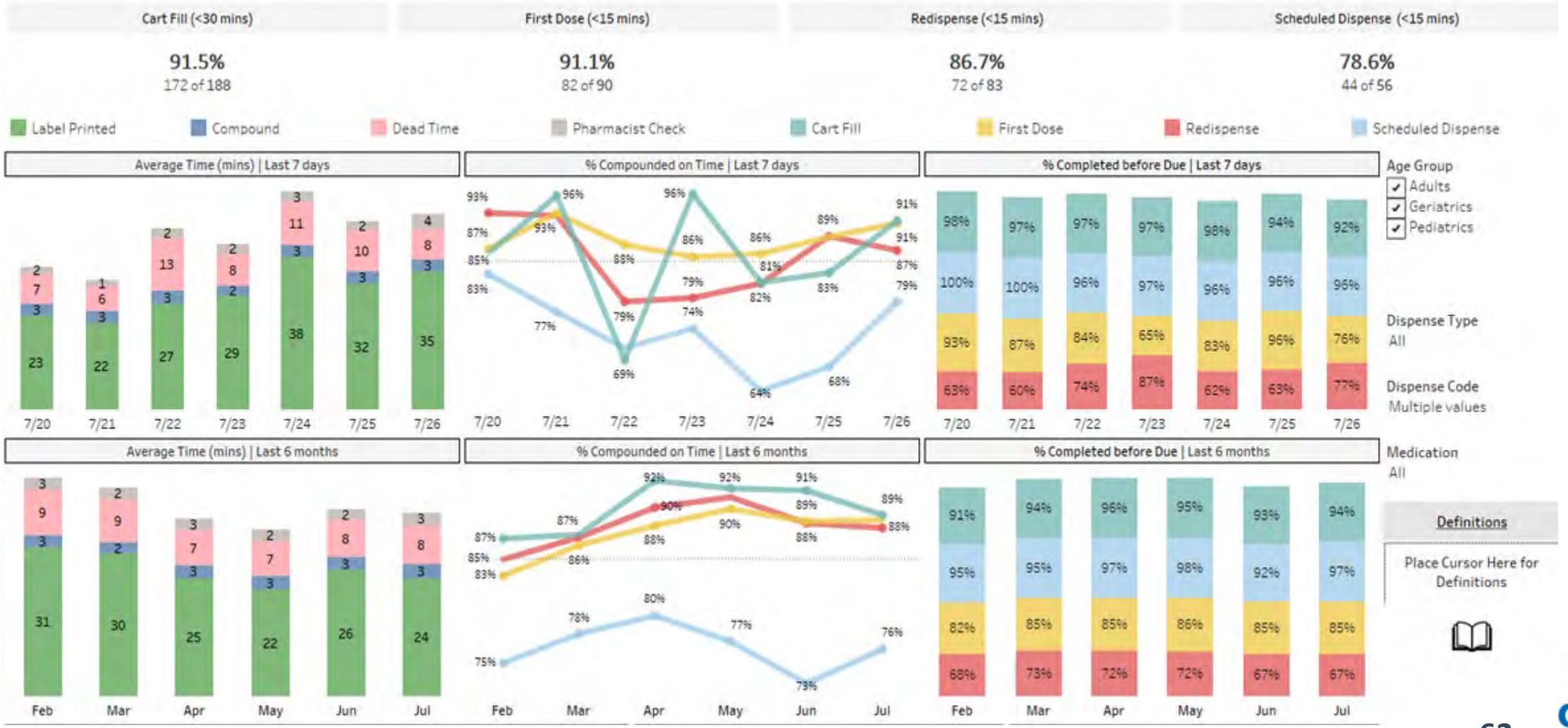

A weekly review to investigate high vs. low volume days/months and the various contributing factors:

- Patient Census trend
- What is being made?
  - Are there opportunities to streamline?
  - Appropriate staff resources?

# COMPOUNDING STEWARDSHIP SURVEILLANCE



# IVWS Dashboard



# % Compounded on Time:

The % represents the percentage of dispenses that were completed from Labels Scanned ▶ Pharmacist Checked within compound goal time:

**Cart:** <30 minutes | **First Dose:** <15 minutes

**Redispense:** <15 minutes | **Schedule Dispense:** <15 minutes

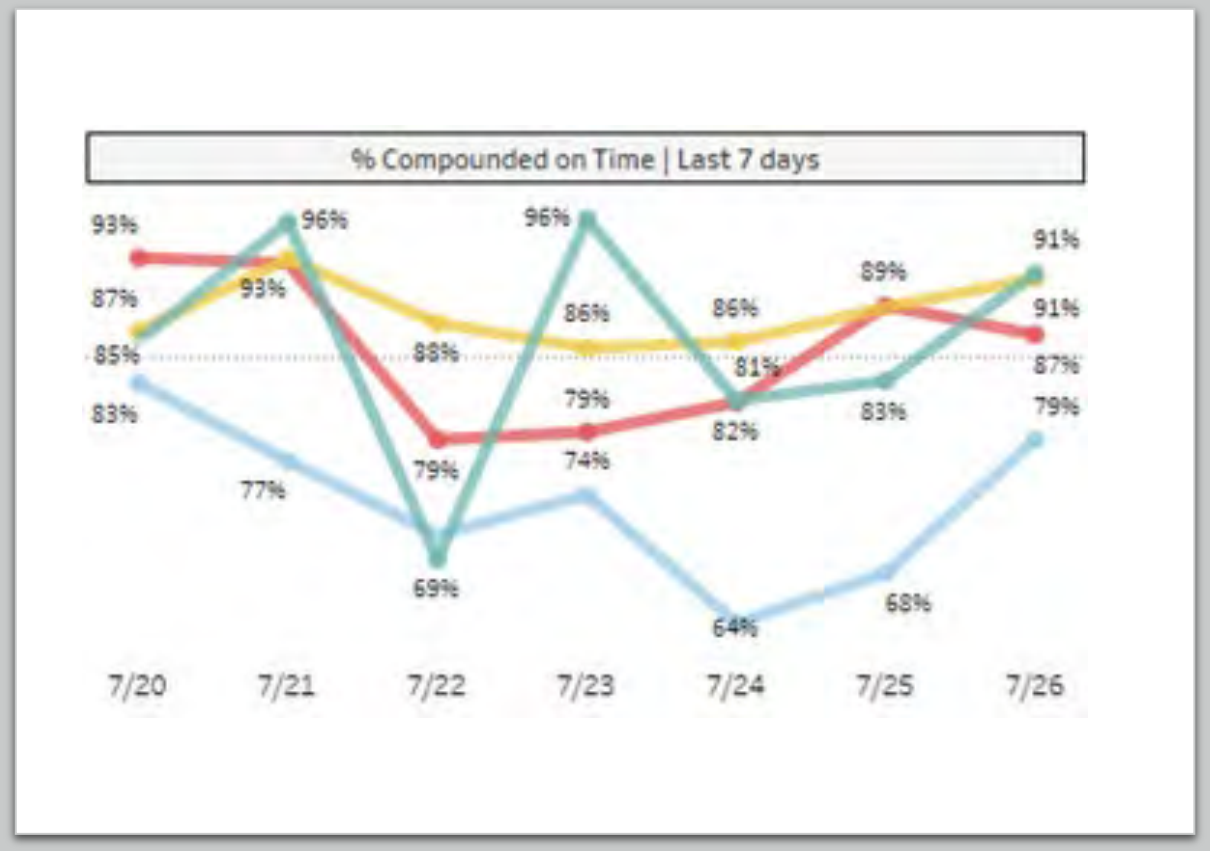
# % Compounded Before Due:

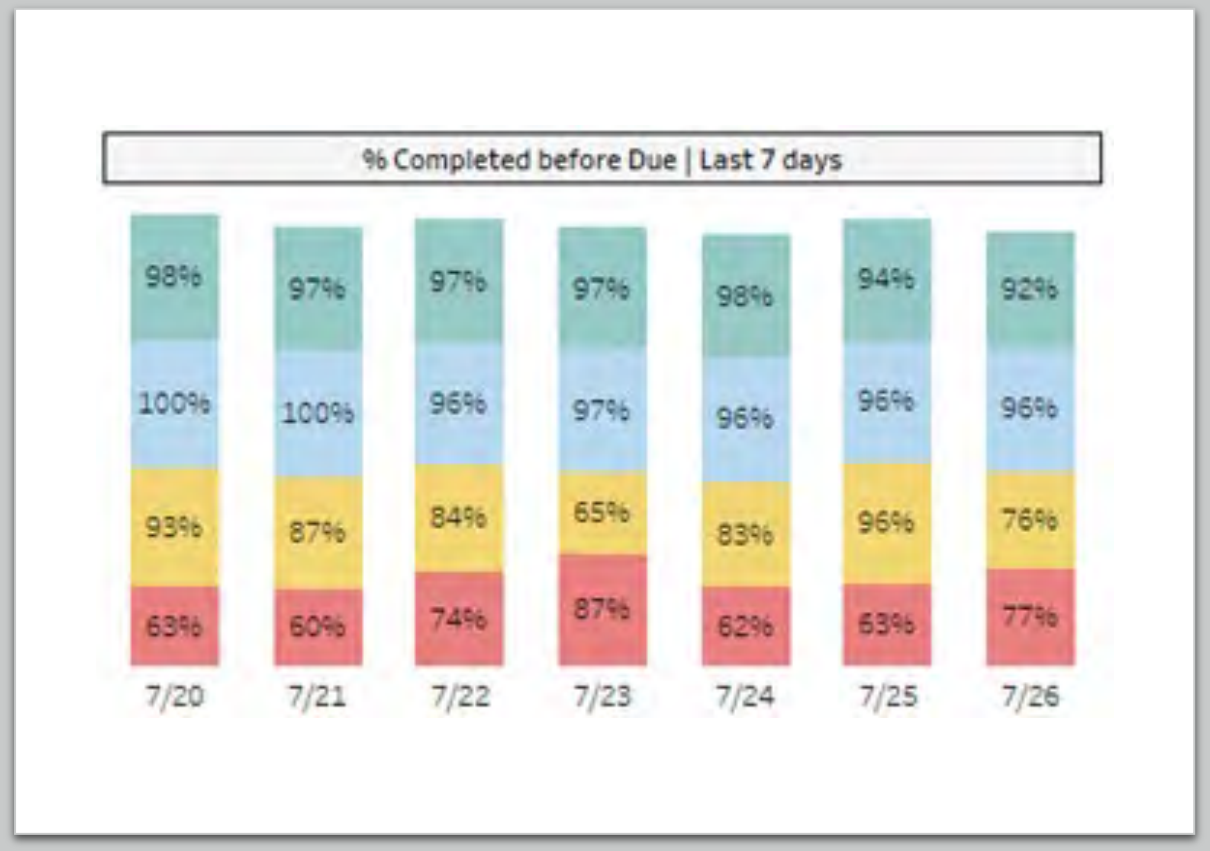
**Cart:** Checked 60 mins before Due Time

**First Dose:** Checked 30 mins before Due Time

**Redispense:** Checked 30 mins before Due Time

**Schedule Dispense:** Checked 60 mins before Due Time



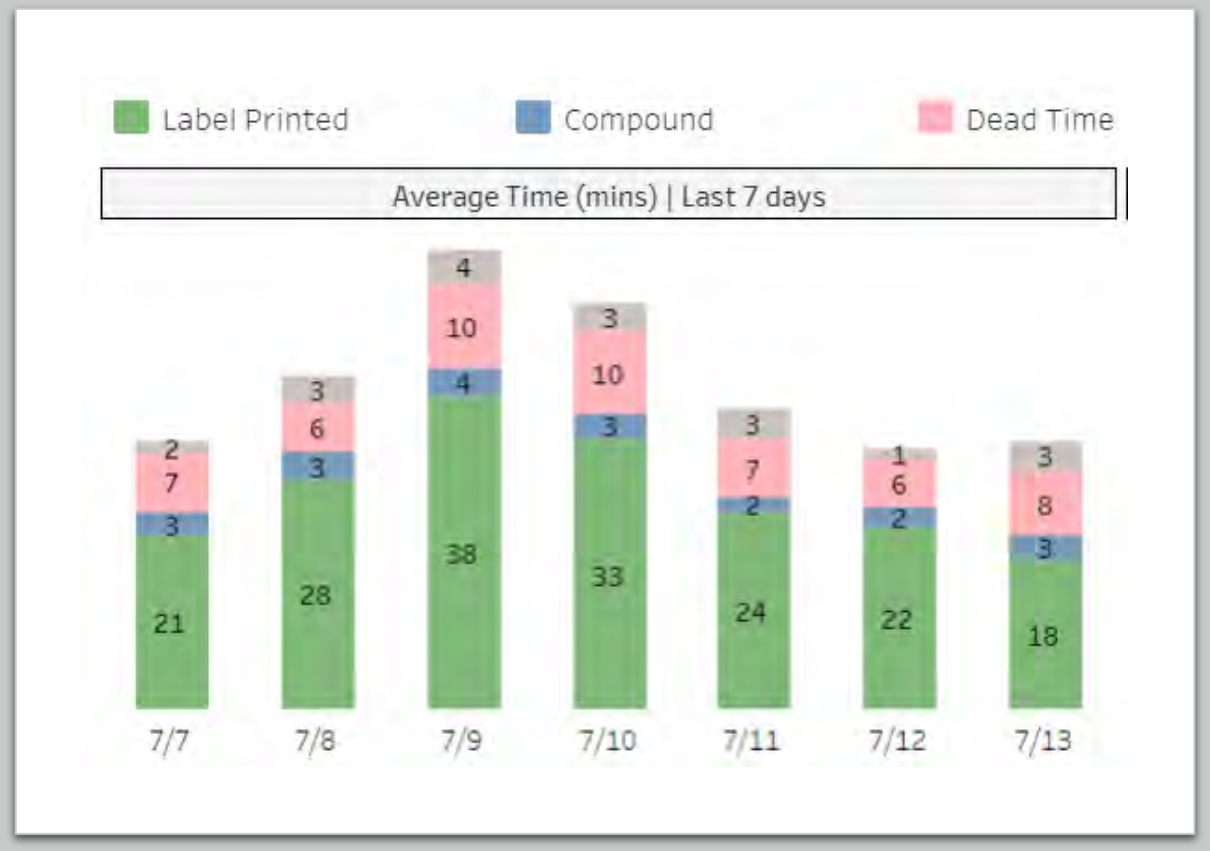



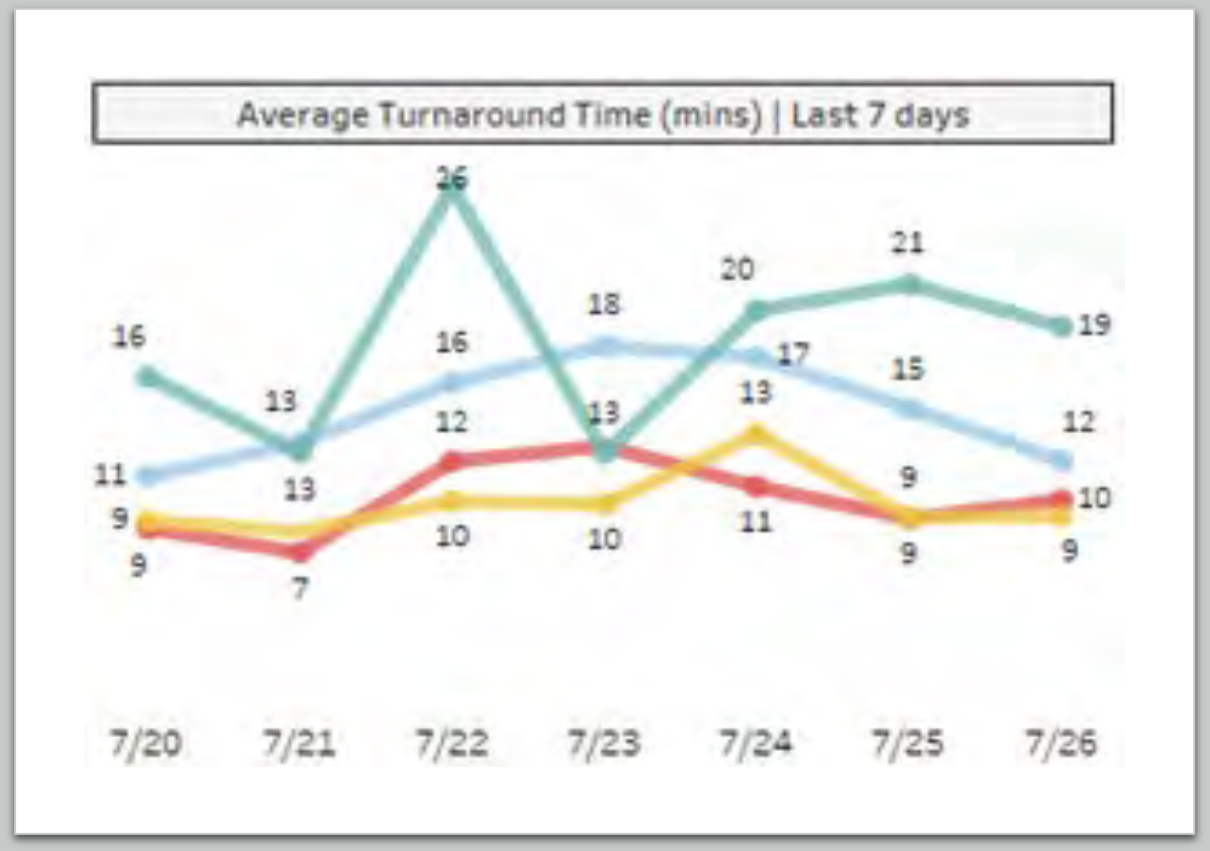
## Average Time (mins):

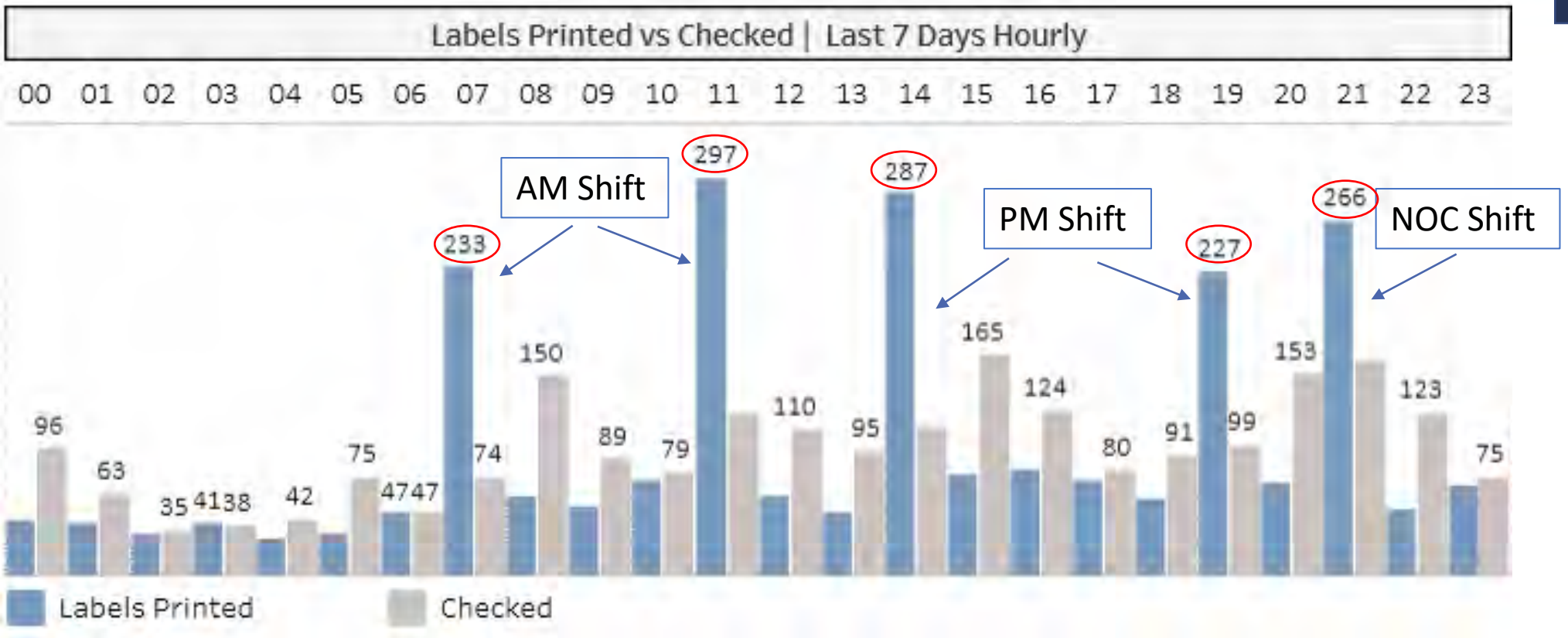
**Green:** Labels Printed ▶ Prep Started
**Blue:** Prep Started ▶ Prepared
**Pink:** Prepared ▶ Check Started
**Gray:** Check Started ▶ Checked

## Average Turnaround Time (mins) :

The turnaround time is calculated from Prep Started to Checked. This includes Compound Time (blue), Dead Time (pink) and Pharmacist Check (gray) time.






## Goal: Workflow Optimization

- Quarterly Reviews – Cartfill Model Assessment
- Prevent bottlenecking
- Technician workload assessment

## Cartfill Due Times

- AM Shift: **0700CF:** 1100-1600 | **1100CF:** 1600-2100
- PM Shift: **1430CF:** 2100-0200 | **1900CF:** 0200-0700
- NOC Shift: **2100CF:** 0200-0700

## Revised/Rejected Definitions:

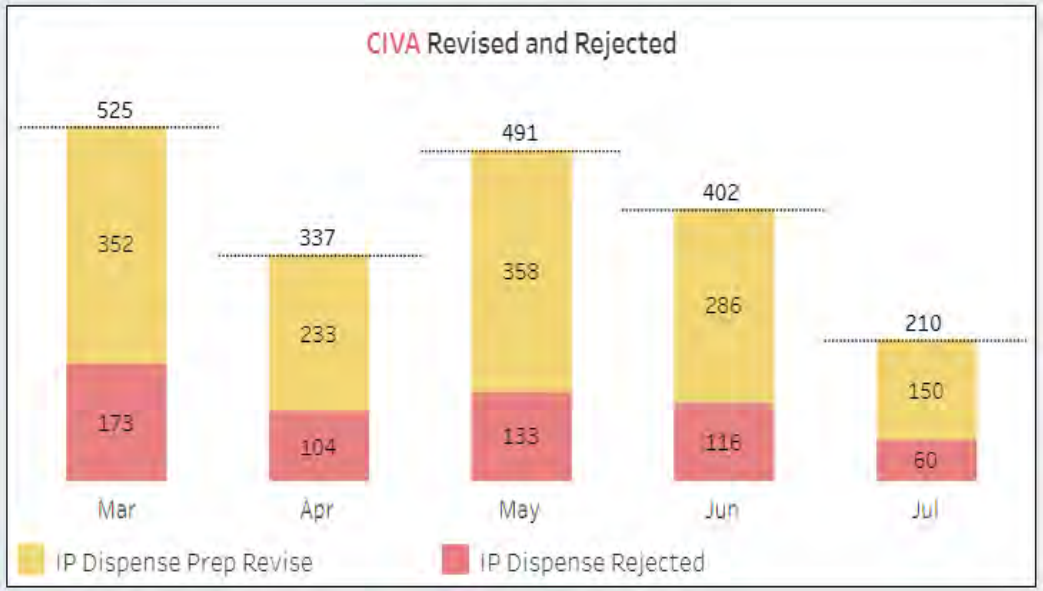
**Rejected:** Products that were fully rejected by pharmacist and must be remade.

**Revised:** Products that were revised by pharmacist but does not need to be remade.

## More Definitions:

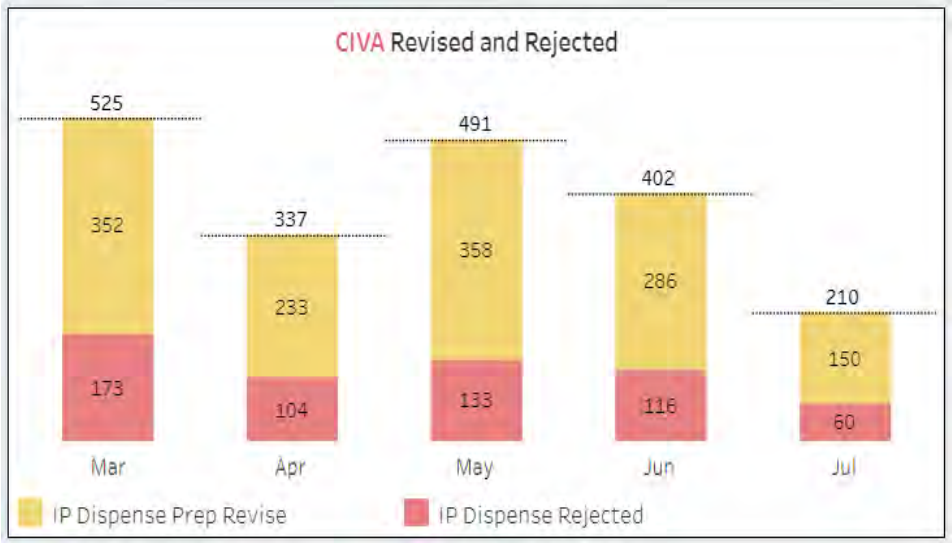
**Compound Time:** The time it takes to compound a product from Dispense Prep Started to Dispense Prepared.

**Outliers:** Products that were compounded longer than three times the product standard deviation




| Compounds | Compound Time (avg) | Outliers | Rejected | Revised |
|---|---|---|---|---|
| 9,917 | 2.7 | 126 | 131 | 365 |
| 489 | 1.8 | 8 | 8 | 13 |
| 114 | 3.9 | 2 | 5 | 15 |
| 190 | 4.4 | 1 | 4 | 19 |
| 34 | 4.2 | 1 | 4 | 1 |
| 141 | 7.2 | 3 | 4 | 9 |
| 150 | 1.9 | 1 | 4 | 5 |
| 46 | 2.9 | 1 | 3 | 1 |

# Using Data to Drive Quality- Case Example




**Plan**

- Characterize the frequency & nature of errors intercepted by pharmacists
- Identify opportunities for system improvements and waste reduction.

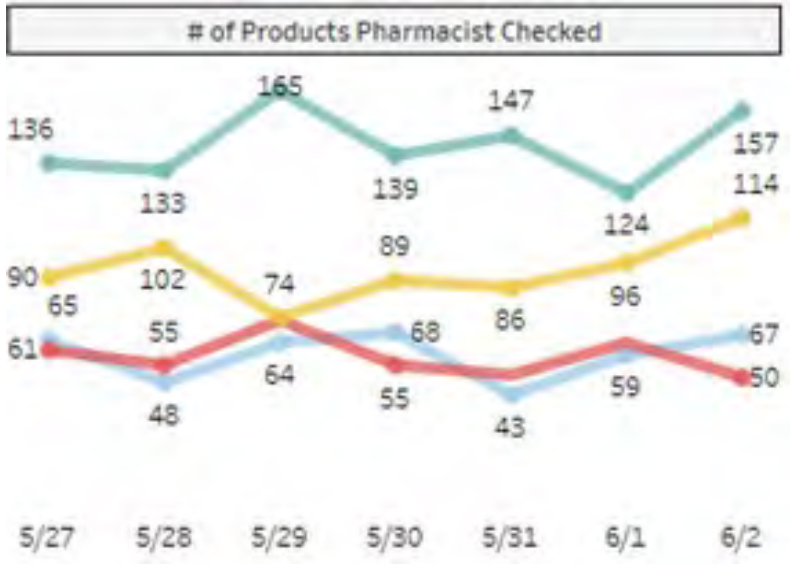
**Evaluation**

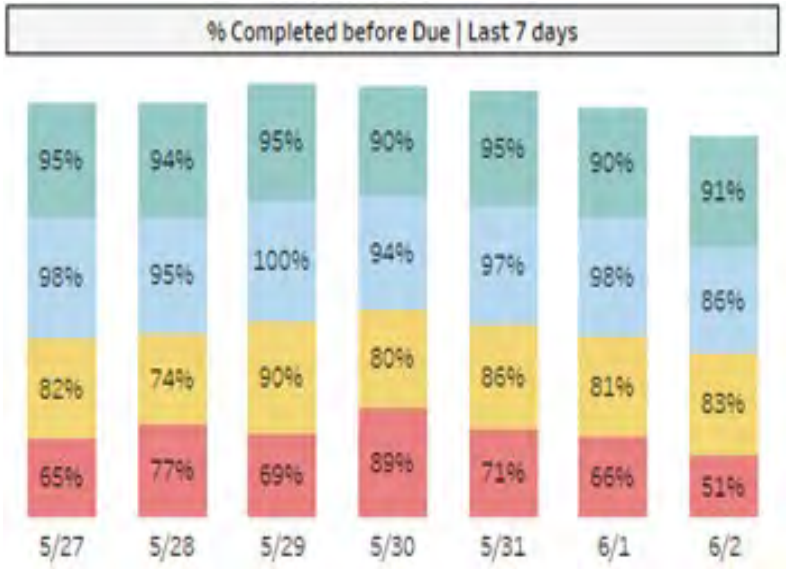
- Evaluate error root cause using pharmacist comments and manual image capture review.

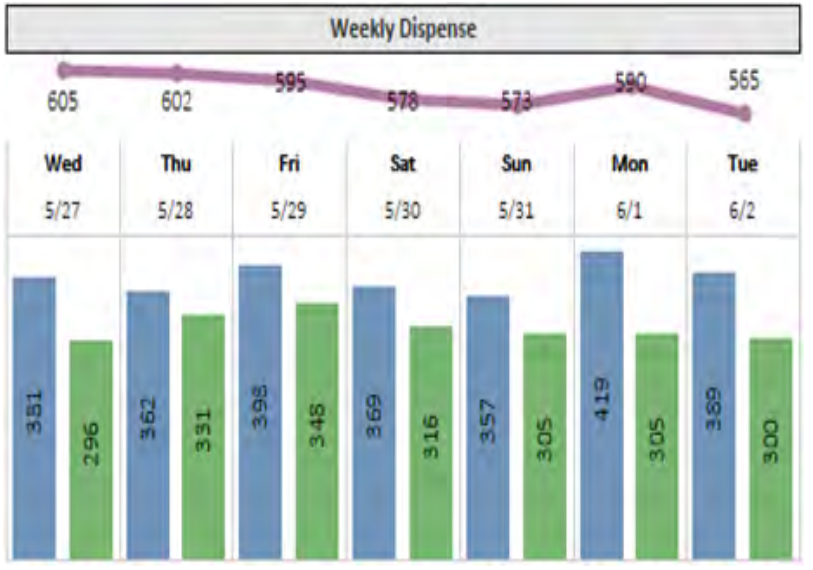
**Findings (pending)**

- Error type characterization; Cost Analysis
- Master Formula Additions/Corrections in EMR to maintain regulatory compliance – compounding log

# Daily & Weekly Staff Engagement




**Turquoise**= Cartfill
**Yellow=** First Dose/STAT
**Light Blue**= Scheduled Dispenses
**Red=** Redispenses
**Daily Total Avg=** ~383 IV products

**Goals**
Cartfill (>95%)=**92.86%**
Scheduled Dispenses (>95%)=**95.43%**
First Dose/STATs (>90%)=**82.29%**
Redispenses (N/A)=**70%**

**Purple=** Daily Census
**Blue=** Daily Total Dispenses
**Green=** Previous 5 Day Average

# Applying Data Analytics

- Staff Education Training Program – onboarding and continuous
- Cartfill Model Assessment
- Technician Workload and Workflow Assessment
- Sterile Compounding Committee

# In Conclusion

**IVWS implementation is critical to sterile compounding safety**

**Project Kickoff & Planning**

- Design workflows and system configuration to meet regulatory standards

**Implementation**

- Phasing in image capture can help reduce bottlenecking
- Strong communication channels are essential for prompt resolution of challenges

**Ongoing Quality Improvement**

- Routine review of metrics can help optimize workloads and minimize waste

# TEST QUESTIONS

1. ISMP recommends the syringe pull-back method as a reliable method for checking accuracy of a sterile compound
    A. True
    B. False

2. Which of the following are key elements of IV Workflow Software implementation?
    A. Workflow Design
    B. Compounding Log Development
    C. Staff training plan & competency assessment
    D. All of the above

3. Data analytics can help track productivity and identify opportunities for waste reduction in a sustainable manner
    A. True
    B. False

# TEST QUESTIONS

1. ISMP recommends the syringe pull-back method as a reliable method for checking accuracy of a sterile compound
    A. True
    B. **False- it is NOT reliable!**

2. Which of the following are key elements of IV Workflow Software implementation?
    A. Workflow Design
    B. Compounding Log Development
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    D. All of the above

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   B. False

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   **A. True**

   B. False

# Reference List


1. Eckel et al. Multicenter study to evaluate the benefits of technology-assisted workflow on i.v. room efficiency, costs, and safety, *American Journal of Health-System Pharmacy*, 2019.
2. ISMP. Maximize benefits of IV workflow management systems by addressing workarounds and errors. Acute Care ISMP Safety Alert! Acute Care Edition, 2017; 22:1-4.
3. ISMP. ISMP guidelines for safe preparation of compounded sterile preparations. 2013 [original publication], 2016 [revised].
4. Haston-Leary M and Eckel S. The Selection Process for IV Workflow Technology. Pharmacy Purchasing & Products Magazine. January 2018.
5. ISMP. 2019-2020 targeted medication safety best practices for hospitals. 2020.
6. California Code of Regulations. Title 16 Section 1735.2(e). Compounding Limitations and Requirements.
7. California Code of Regulations. Title 16 Section 1735.3. Recordkeeping for Compounded Drugs.


# Transformation of Sterile Compounding Services

## Implementation of IV Workflow Software & A Quality Improvement Program

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