



Medication Bagging Challenges: Where Do We Go From Here?

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Relevant Financial Relationship and Conflict of Interest Disclosure

- No one in control of the content of this activity has a relevant financial relationship or conflict of interest with an ineligible company.

Learning Objectives

- Define the differences between clear, white and brown bagging
- Identify regulatory, medication safety and patient care issues created by bagging practices
- Describe strategies to potentially mitigate medication safety risks with brown bagging

Provider-Administered Medications

Clinics, hospital outpatient departments, infusion services

Traditionally buy and bill plus an administration fee

Subject to strict regulatory requirements for acquisition, storage and handling

Frequently specialty medications

Buy and Bill Payment Structures

Medicare

- Average sales price + 6% + administration fee

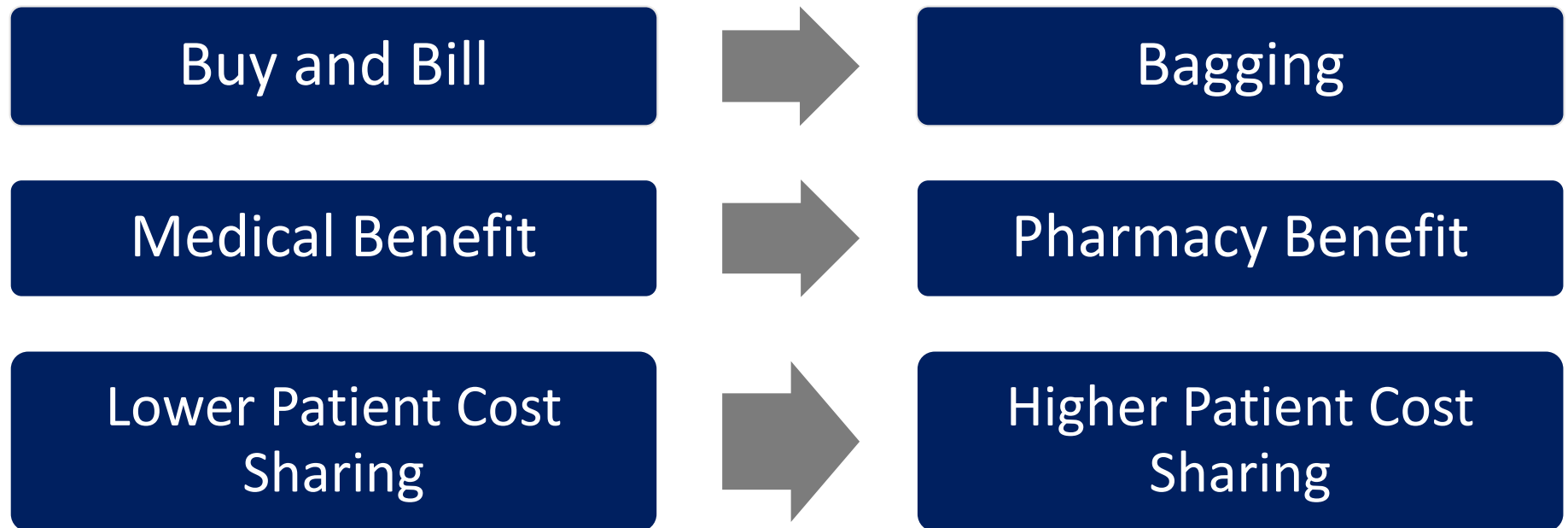
Medicaid

- Often acquisition cost + administration fee

Commercial

- Percentage of charges
- Negotiated rates

Drug Acquisition and Payment Shifts



Payer Rationale for Transitioning to Bagging

45% of specialty medication spend is on drugs administered by clinicians and reimbursed through the medical benefit

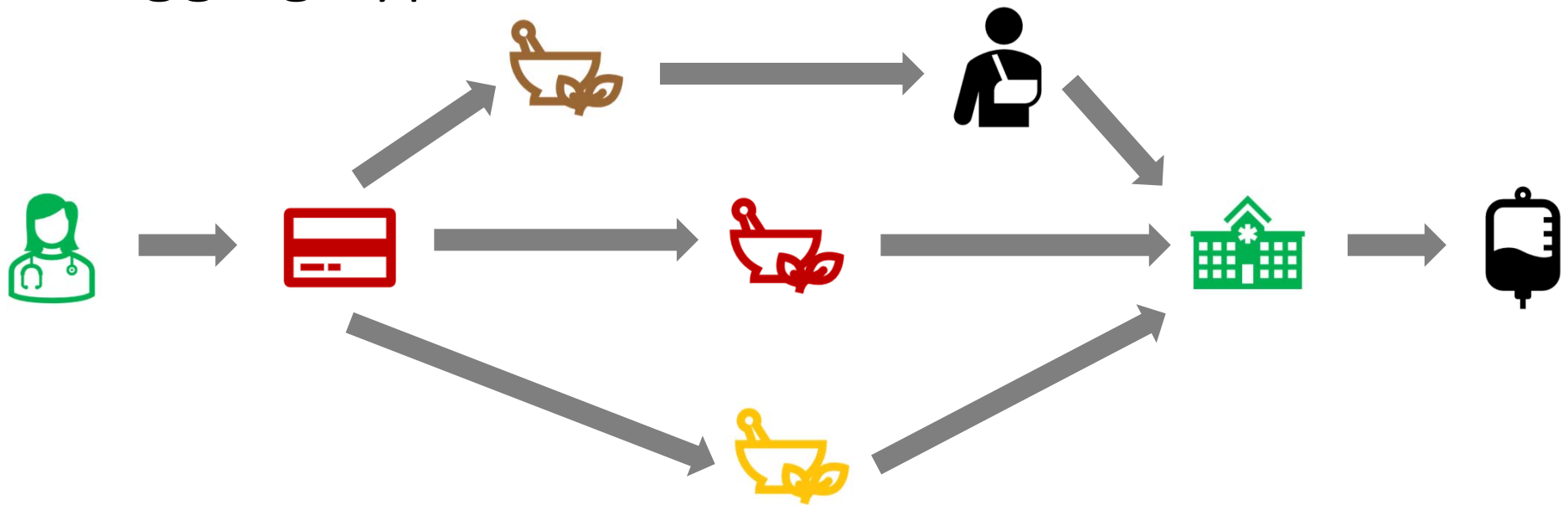
- By shifting the cost to the prescription benefit, payers purport that the drug acquisition costs are lower due to specialty pharmacy volume discounts
- Lower markup rates by clinic

Lower administrative costs due to vertical integration

Perceived improved drug utilization review and formulary process associated with PBM

Less likely to be impacted by drug shortages due to purchasing power

Bagging Types



Brown bagging – filled by PBM-preferred community or specialty pharmacy and dispensed to patient



White bagging – filled by PBM-contracted specialty pharmacy and sent to healthcare administration site



Clear/Gold bagging – filled by health system owned specialty pharmacy and sent to internal administration site

Medication Bagging Target Examples



Parenteral chemotherapy



Chemotherapy support medications



Immunomodulatory medications targeting rheumatoid arthritis, Crohn's disease

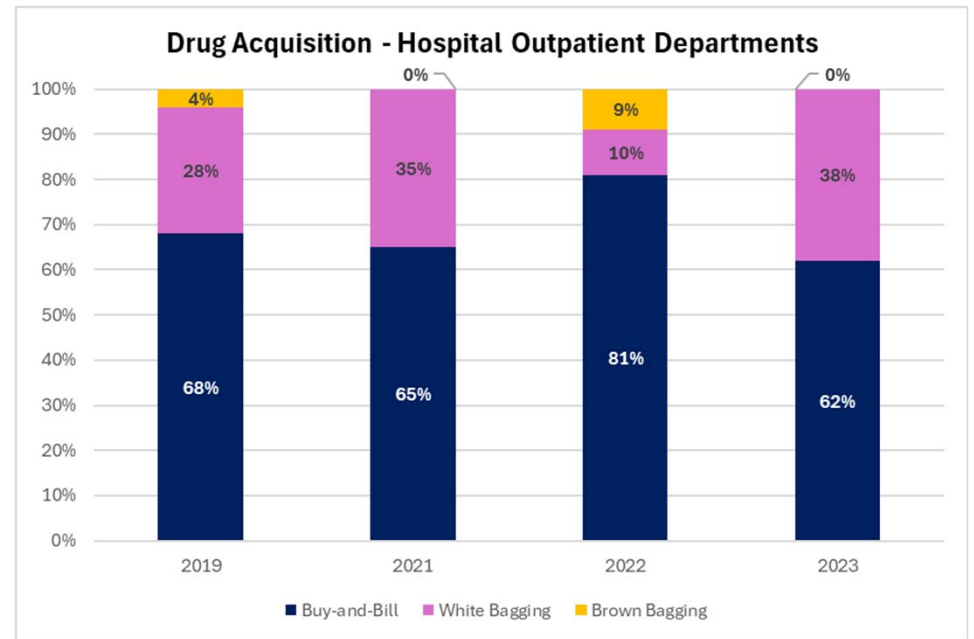
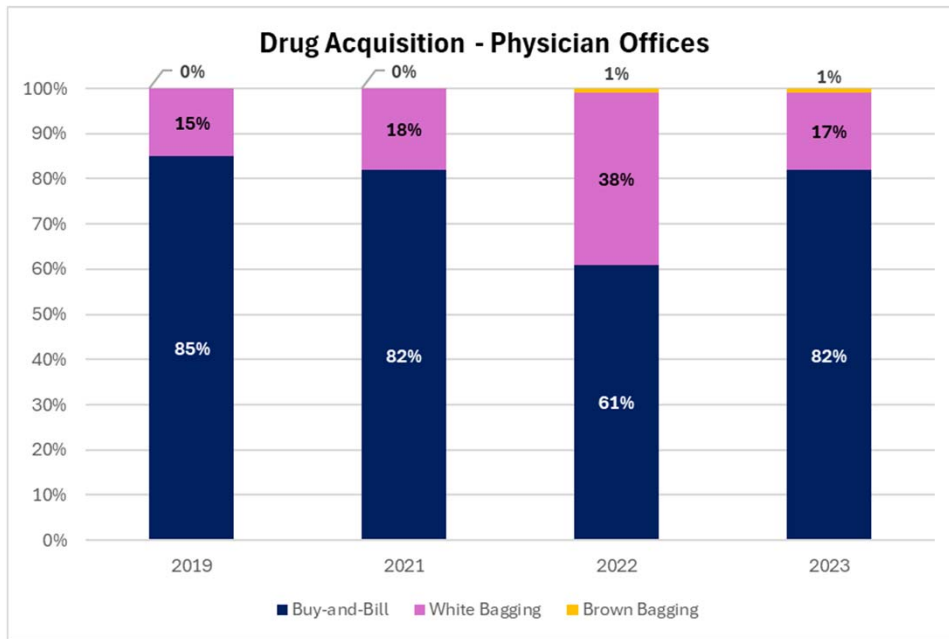


Blood factors



IVIG

Infused Oncology Drug Sourcing



Bagging Impacts on Patients, Providers and Healthcare Organizations



Treatment Delays



Compromised Drug Integrity



Lost 340B Revenue



Uncompensated Patient Care



Higher Patient Cost

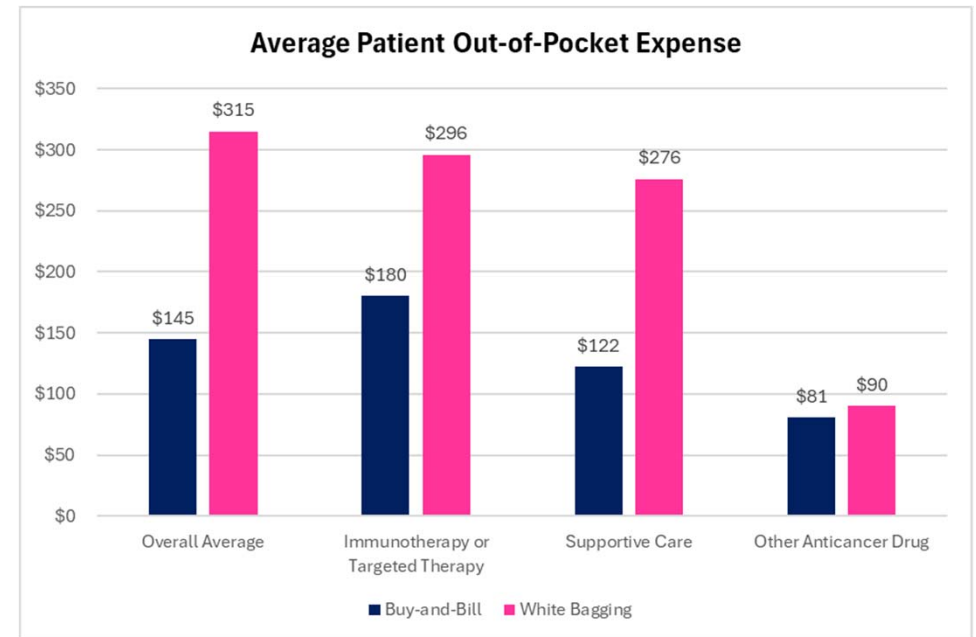
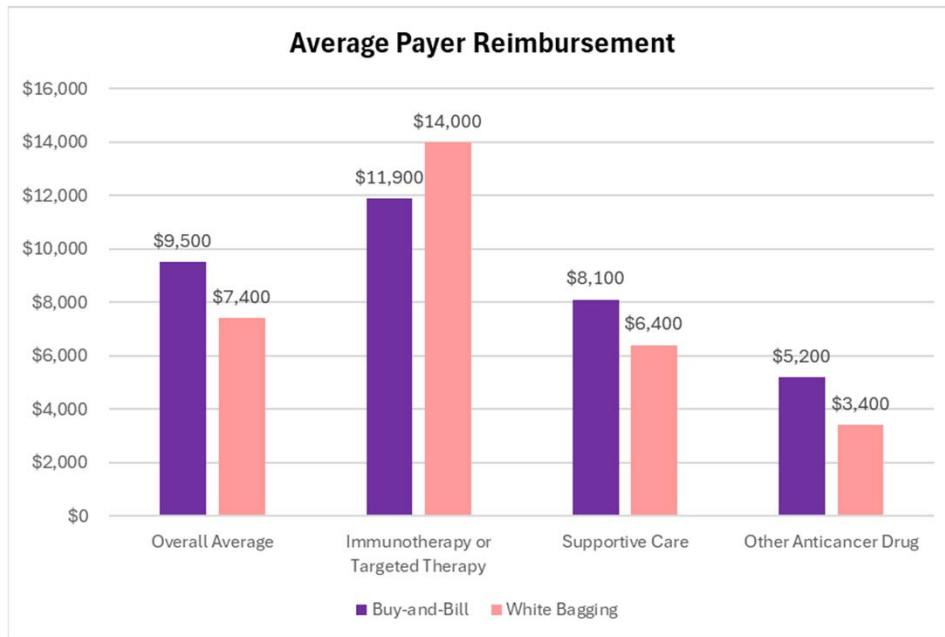


Drug Waste



Liability

Payer Reimbursement and Patient Cost Sharing



Bagging and Regulatory Considerations

Medication Management Standards and Bagging

MM.02.01.01: The hospital selects and procures medications

- 6. The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.
- 7. The hospital follows a process to select, approve, and procure medications that are not on its formulary

MM.03.01.05: The hospital safely controls medications brought into the hospital by patients, their families, or licensed practitioners.

- 2. Before use or administration of a medication brought into the hospital by a patient, their family or a licensed practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.

Medication Management Standards and Bagging

MM.05.01.17: The hospital follows a process to retrieve recalled or discontinued medications.

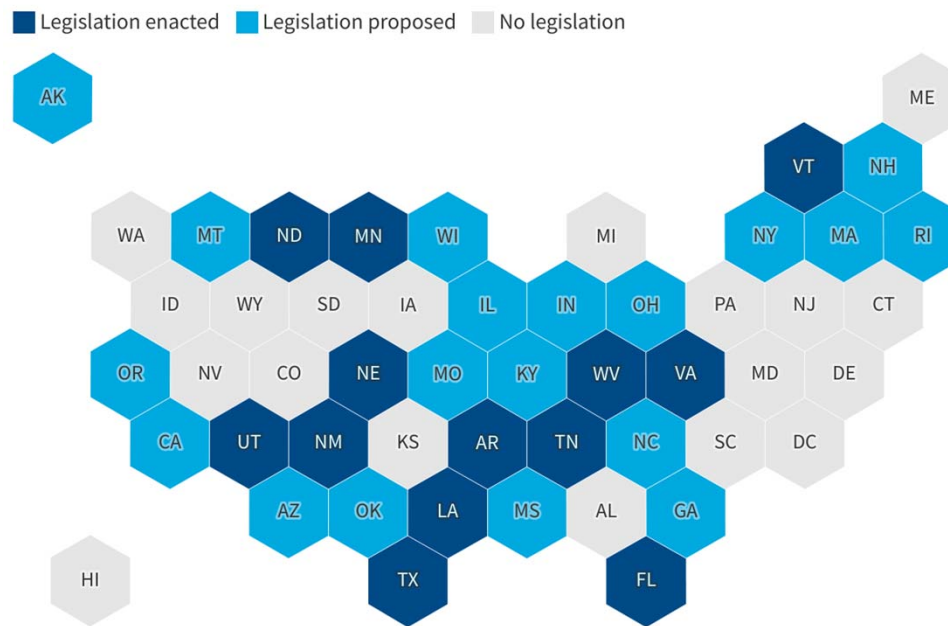
- 4. When required by law and regulation or hospital policy, the hospital informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA).

DSCSA Considerations

Drug Supply Chain Security Act (DSCSA)

- Requirements aimed to deter, detect, and remove potentially dangerous drugs from the supply chain
- Track and trace
- Patient-specific medication

Bagging Legislation



Source: American Society of Health-System Pharmacists; legislative sessions 2021-23 Map data: Telegrams/NPR

Illinois Proposed Legislation – SB3225

- Introduced February 3, 2023 by Cristina Castro
 - Health benefit plans (HBP) or pharmacy benefit managers (PBM) shall not:
 - Require a patient to obtain a clinician-administered drug from a pharmacy selected by the HBP or PBM
 - Require a patient to obtain a clinician-administered drug from a pharmacy selected by the HBP or PBM with the intent to have it transported to another site of service for administration
 - Offer financial incentives for patients to do one of the above
 - Deny or restrict coverage for a drug provided by a pharmacy, for provider administration, not specified by the HBP or PBM
 - Deny or limit reimbursement for the above
 - Assess higher fees to the patient for the above
 - Require an enrollee to use home infusion or use a site of service identified by the HBP or PBM
- Reassigned to the insurance committee on 1/10/24

Providers and Bagging Options

Accept all bagged medications

Deny all bagged medications and refer those patients to another location for administration

Deny certain types of bagging and refer those patients to another location for administration

Negotiate with insurers for buy and bill or clear bagging only

Strategy for Addressing Brown Bagging Concerns



445 bed hospital
30+ Outpatient clinics
7 onsite Ambulatory Pharmacies

Compliance

MM.03.01.05 The hospital safely controls medications brought into the hospital by patients, their families, or licensed practitioners

Before use or administration of a medication brought into the hospital by a patient, their family or a licensed practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.

UI Health Hospital Policy TX 3.11

B. Outpatient Use of Patient's Own Medications

1. As a rule, medications that are to be administered to patients in the clinics should be obtained from the Hospital pharmacy.
2. The use of the patients' own medications will be allowed if the medication cannot be obtained by the Hospital pharmacy, such as due to health plans restrictions. In these cases, medications should be sent directly to the Hospital pharmacy by the outside specialty pharmacy. They should not be brought to the clinic by the patient or mailed to the clinic from an outside source unless required.
3. Prior to administering the medication(s) to the patient, the Hospital pharmacist will, to the best of his/her ability, ensure its integrity and that it is the medication ordered for the patient.
4. The person administering the medication should document in the patient's medical record that the medication was obtained from an external source and given to the patient.

Prior to administering the medication(s) to the patient, the pharmacist will ensure its integrity and the medication is ordered for the patient

For safety purposes, a pharmacist must conduct the Outside Medication Verification process

Descriptions We Use at UI Health (UIH)

- Patient supplied medications
- Outside medications
- Brown, white, clear & gold bagged medications

Scenarios

For Future appointments:

- Medication is delivered (via mail) to clinic directly
- Medication is delivered to the Medication Assistance Program Clinic (MAP) embedded inside the Specialty Care Building pharmacy

For Same Day appointments:

- Medication is brought in by patient
- Medication is dispensed from in-house pharmacy

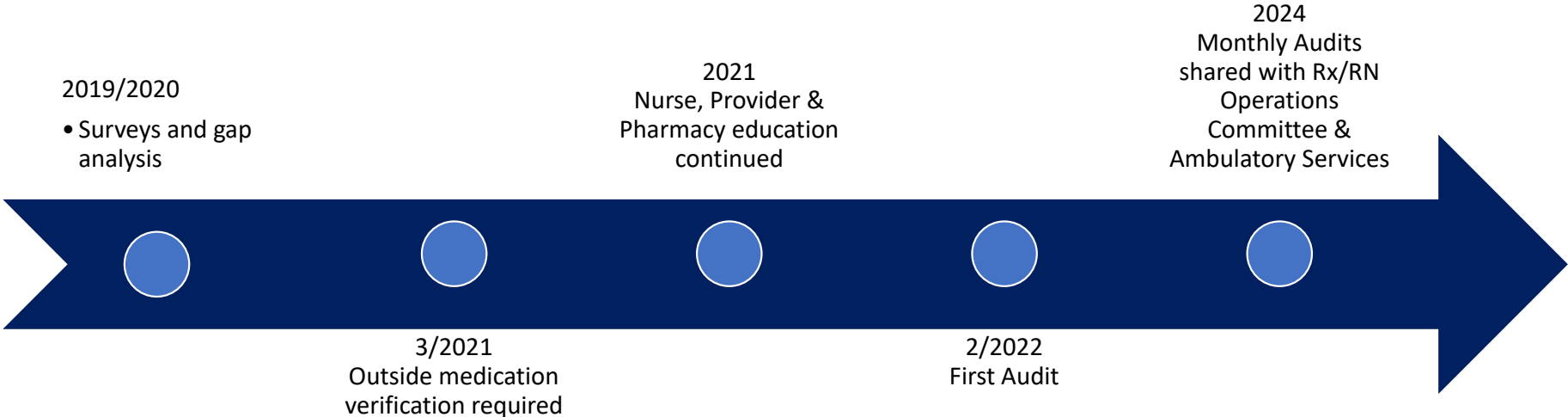
All scenarios:

- Nurse or patient must bring patient specific medication to pharmacist for verification prior to administration in clinic
- Must be prescribed by UI Health Provider only

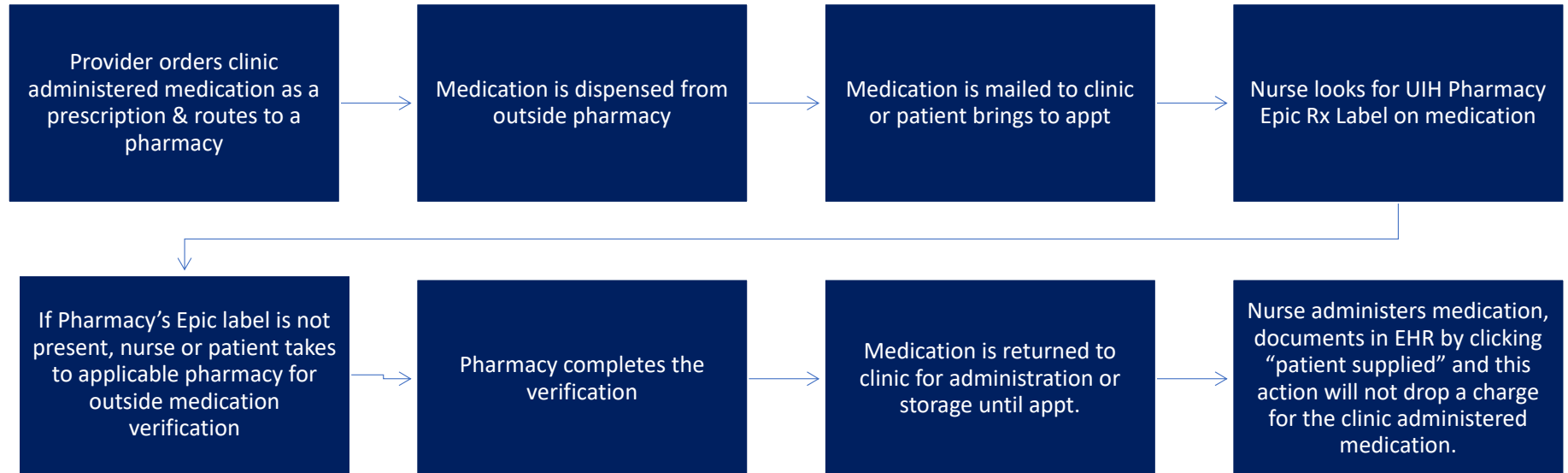
Partnership: Ambulatory Nursing and Pharmacy

- Rx/RN Operations Committee
 - Identified potential risks and compliance gaps
- Workflow process design was a collaboration between Ambulatory Nursing and Pharmacy
- Developed audit model and implemented

Timeline

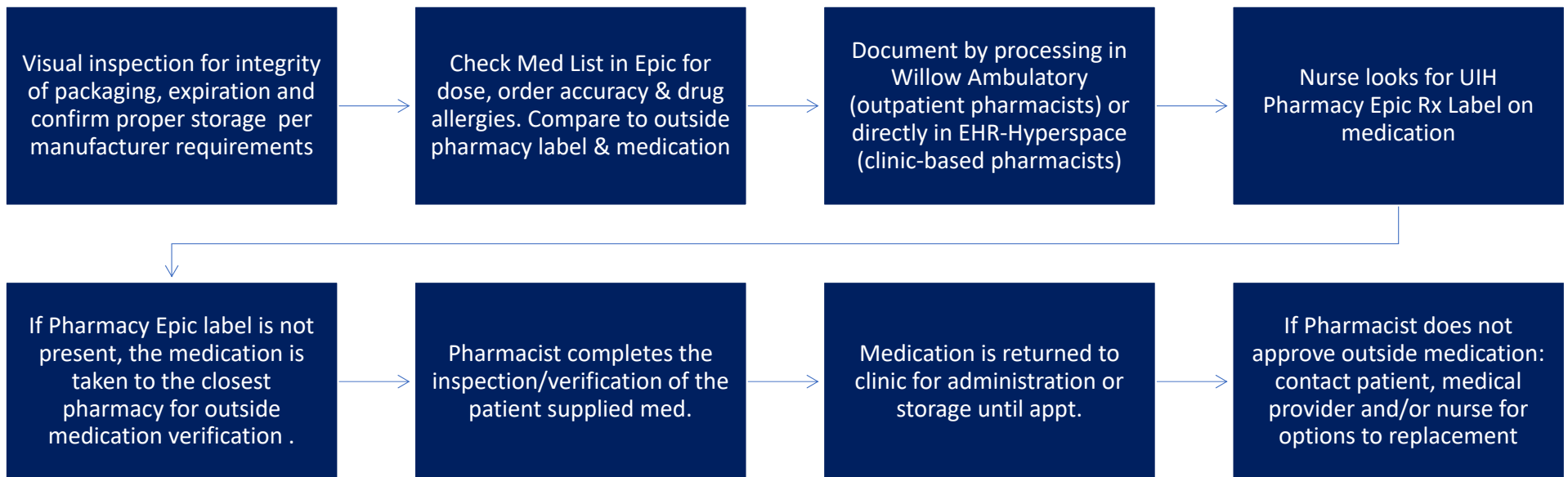


Clinic Nursing Workflow

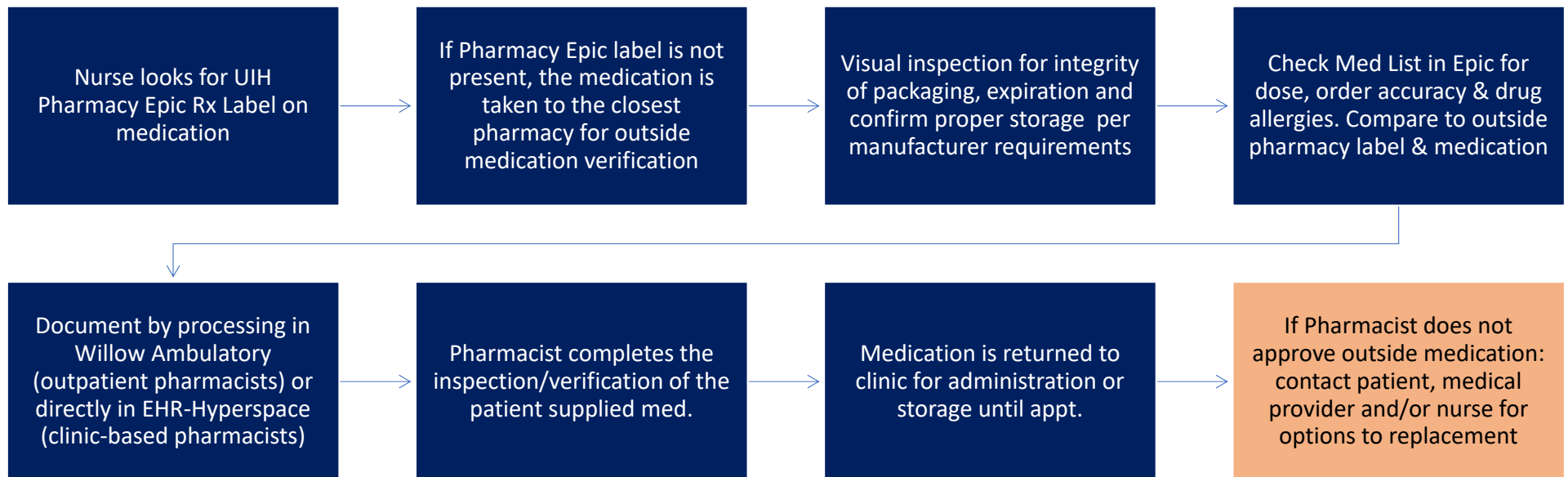


A screenshot of an EHR medication administration form. The form includes fields for Priority (set to Routine), Exception Code, Rate (ml/hr), Administer Over, and Phase of Care. A red box highlights the "Patient Supplied" checkbox, which is checked, and the "1 doses" field. A red arrow points to this area with the text "Make sure to enter patient supplied!". The form also has "Next Required" and "Accept/Cancel" buttons.

Outpatient Pharmacy Workflow



Outpatient Pharmacy Workflow



Outside Medication Verification Label


Rx filled at UIH Pharmacy

UIC WOOD ST PCC OP PHARM...
312-996-6887
840 S Wood St, Rm 163, CHICAGO, IL 60612

Test, Maptestpt Rx #: 20037535-02
1/1/2000 Filled On: 12/18/2020
Synagis 100 MG/ML injection
Generic: palivizumab
Inject 15mg/kg intramuscularly once monthly

Shannon Murphy, MD
No refills remaining
Initial Review: SO

Qty: 1 mL
RPh: SO




Outside medication verified by UIH Pharmacy

UIC WOOD ST PCC OP PHARM...
312-996-6887
840 S Wood St, Rm 163, CHICAGO, IL 60612

Test, Maptestpt Rx #: 20037547-02
1/1/2000 Filled On: 12/18/2020
OUTSIDE MEDICATION VERIFICATION
Medication: Synagis 100 mg/mL, Indication: Inject 15mg/kg
intramuscularly once monthly, NDC: 60574-4113-01, Lot: LP0122, Exp:
04/2022

Shannon Murphy, MD
No refills remaining
Initial Review: SO

Qty: 1 vial
RPh: SO



The outside medication is processed in the same manner as a prescription.
Turn around time will depend on same day (Waiter) or future appt (24 hours).

Not Approved for Clinic Administration

Wrong temperature storage:
Deliveries left at front desk too long
Package is lost or did not arrive to clinic
Patient stored room temperature medication in refrigeration

Medication or dose change in Epic does not match the outside medication

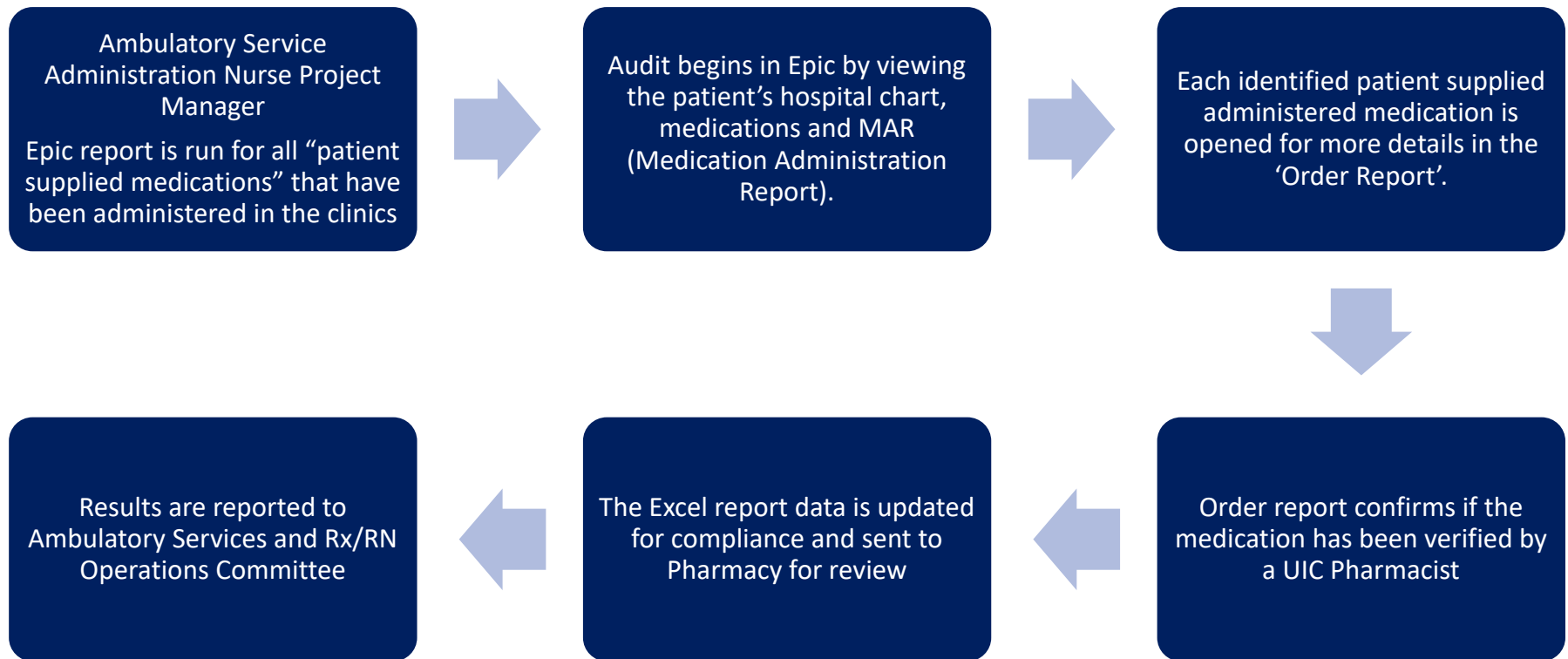
Dosage form is not appropriate for use (SDV was used as MDV)

Missing medication order in Epic

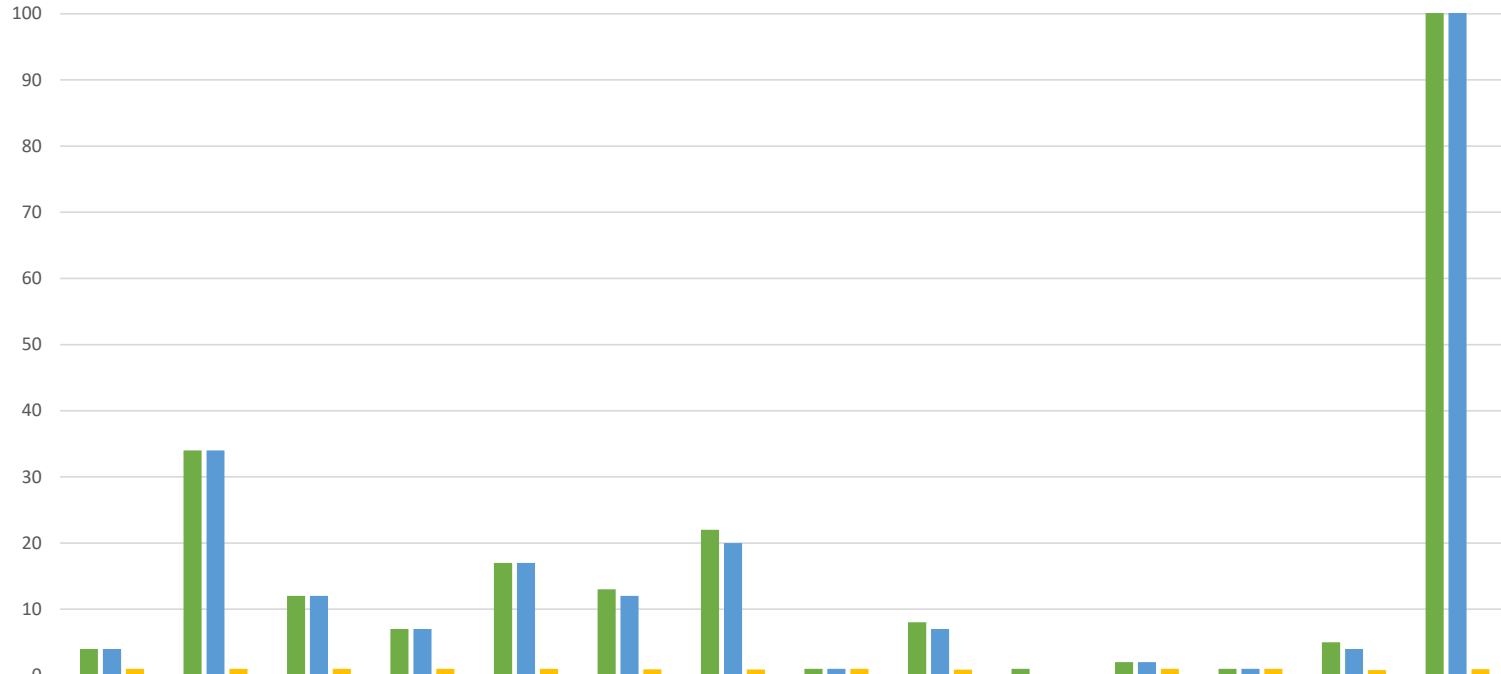
Patient reasons:
Tampered with medication
Time between receiving the medication at home vs appt date was too long



Audit Process



January FY24 Patient Supplied Medication Verified by Pharmacy

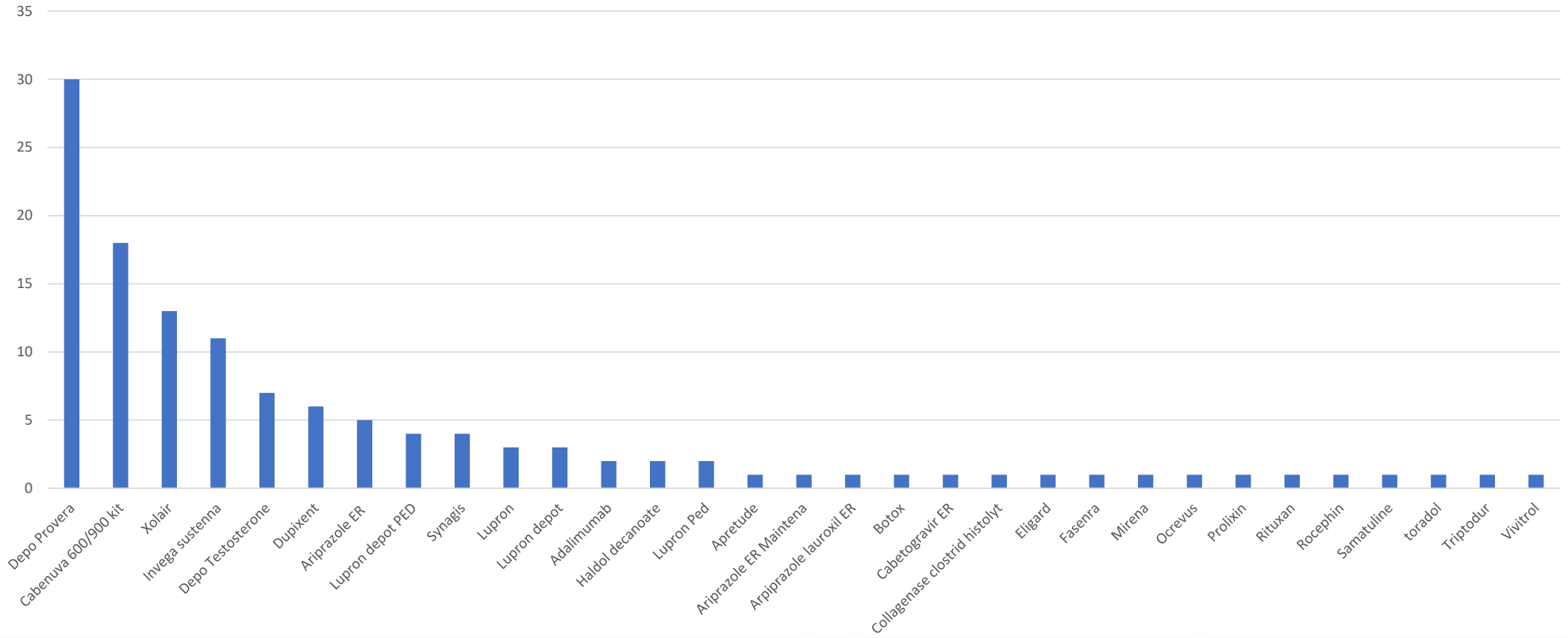


	ASA Float	CWH	CYC	DERM	FCID	LH	NPI	NSC	NWC	PCP	PGUV MAC	SC	SCB Urology	TOTAL
Total Medications	4	34	12	7	17	13	22	1	8	1	2	1	5	127
Verified Pharmacy	4	34	12	7	17	12	20	1	7	0	2	1	4	121
Pharmacy Compliance	100%	100%	100%	100%	100%	92%	91%	100%	88%	0%	100%	100%	80%	95%

■ Total Medications ■ Verified Pharmacy ■ Pharmacy Compliance

Types of Medications

January 2024



Lessons Learned

- Re-training and continuous education is key
- Non-revenue generating service: Additional time and work for pharmacies
- Monthly Audit process is manual & tedious.
 - Based on accuracy of nursing documentation
- Different processes for infusion drugs
 - Infusions are documented in a different manner by oncology pharmacy (WIP)
 - Injectables are verified and documented in (WAM)
- Revisit Epic capabilities for more efficient pharmacist verification workflow

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