

Morning Session Learning Objectives

- Create a compelling case to resource system-level teams focused on sterile compounding standards compliance and drug diversion prevention.
- Identify various methods to maximize the financial opportunity associated with billing for waste.



YOchsnerHealth

Unleashing System Support for Diversion Prevention and Sterile Compounding

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Agenda

Sutter Health Intro and Journey

Sutter Health Controlled Substance Diversion System Support

Ochsner Health Intro and Journey

Ochsner Controlled Substance Diversion System Support

Sutter Health Sterile Compounding System Support

Ochsner Health Sterile Compounding System Support

Lessons Learned

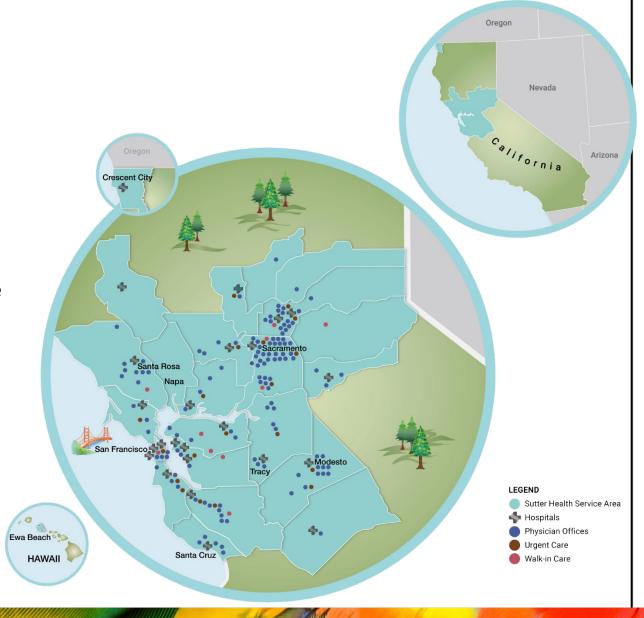
Key Takeaways

Q&A



Sutter Health

- 3.3M patients served in 2022 by:
 - 12,000+ physicians; 4,500 with aligned medical groups
 - 2,000+ Advance Practice Clinicians, 15,000+ nurses
 - 50,000+ employees
- Across an extensive healthcare ecosystem
 - 27 acute care campuses, 4000+ inpatient beds
 - 300+ clinics, ambulatory surgery centers, and urgent care
 - 12th largest home health organization with 700k+ visits
- Value-focused care
 - 400k+ in value-based care programs, including 100k members in Sutter Health Plus
 - High-quality care with top-decile performance in ambulatory and top-quartile in acute
- Growing academic programs
 - Training 196 residents and fellows annually



Sutter Health

Journey to
Controlled
Substance
Diversion System
Support

Key Areas of Focus & Impact

DEA
AUDIT/INSPECTION
TRAINING &
CHECKLISTS

STANDARD ESCALATION & INVESTIGATION PROTOCOLS

SPECIAL INVESTIGATIONS UNIT

EDUCATION & COMMUNICATION

CS WASTE TESTING
ANALYZER

Document Repository

POA, DEA, Biennials, Regulatory Reporting

STANDARD CS WASTE STREAM

CS POLICY VS. PRACTICE

AI DIVERSION
DETECTION
PLATFORM

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Ochsner Health

- Integrated not-for-profit health care system
- 46 Hospitals
 - U.S. News & World Report top 50 children's hospital
 - U.S. News & World Report best hospital in Louisiana
- 370 health and urgent care centers
- 37,000 Employees
- 4,700 employed and affiliated physicians
- 1.4 million patients treated in 2022



System Drug Diversion Prevention – Ochsner Health



Formal Drug
Diversion
Response Team
Established at
Ochsner
Medical Center



System
Compliance
Director Hired
to Lead Drug
Diversion
Prevention



System RN Auditor and Analyst Hired



System
Compliance
Specialist Hired



System RN Auditor Hired



System RN Auditor Hired



System RN Auditor Hired

2017

Sept 2019

Oct 2019

Mar 2020

Dec 2020

Dec 2021

Sept 2022

Standardized Policies and Procedures

- System Drug Diversion Prevention and Response Policy
- Yearly education of drug diversion prevention for frontline workforce members
- System policies for pharmacy, anesthesia, and nursing
- Drug and alcohol-free workplace policy that includes for-cause drug testing
- Conditions of employment process for workforce members

Ochsner		Ochsner Health Checklist for Reasonable Suspicion of Drug/Alcohol Abuse				
	Employee:	DOB:Dept:				
	the leader provide rea	e suspicion of drug and/or alcohol abuse during work duty should be carefully documented by This form is used to document the person's behavior, appearance, and/or actions which asonable suspicion for being under the influence of drugs and/or alcohol. Please include all aformation, and add any additional facts or circumstances.				
	1. <u>Na</u>	ture of Incident / Cause for Suspicion Absenteeism / tardiness / Unusual or Insufficiently substantiated absence Admission to being under the influence of alcohol ordrugs Apparent drug or alcohol intoxication Conviction or pleading guilty to possession of drugs or drug paraphernalia Arrest for drug-related offense Narcotic counts show missing narcotics Nursing documentation does not support administration of narcotics Observed & substantiated Drug Usage while on duty Observed / reported possession Observed / ported possession Observed abnormal or erratic behavior Other (flagrant or reckless violation of safety, serious misconduct, fighting, argumentative/ abuse language, etc.) Pattern of absence of patient pain relief, even after medication administered Workplace Injury				
	2. Bel	navioral Indicators				
		Extreme aggressiveness or agitation Inappropriate verbal responses Other erratic or inappropriate behavior Physical Abuse Verbal Abuse Withdrawal, lack of responsiveness				
	3. Ph	/sical Signs or Symptoms Bloodshot or watery eyesDilated or constricted pupils or unusual eye movementDisheveled appearance / out of uniform / Unusual appearanceExcessive sweating or clamminess of skinExtreme aggressiveness or agitationFlushed or very pale faceHighly excited or nervousOdor of alcoholOdor of Marijuana				

Advanced Diversion Analytics Software

- Centralized by Corporate Compliance Diversion Team
- Integration of automated dispensing cabinet dispenses and electronic medical record administrations
- Automated 1:1 dispense to administration tracking for controlled substances
- Utilizes Predicative Analytics and Machine Learning to:
 - Identify outliers based on community trends and patterns
 - Proactively exposes areas of anomalies











Local Response Team

Ad hoc and monthly meetings

Local Nursing Local Pharmacy

Local Anesthesia

Risk/Legal

Employee Relations

Compliance & Privacy

Security



Standardized Meeting Structure

- Typically, 30 minutes 1 hour
- Discrepancies unresolved in 24 hours review
- Waste within 30 minutes review
- ADC and Pharmacy Safe counting compliance review
- Proactive monitoring and escalations review
- Audits scored in meeting:
 - Re-Randomize
 - Schedule for Follow-up Review
 - Informal Coaching
 - Formal Coaching
 - Intervention

Yearly Quality and Assurance Projects

- Risk Rounds
- Accountability Reviews
- ADC Pocket Reviews
- Biometrics Audit
- Pharmacy Technician Delivery Audits
- Pharmacy ADC "Sell" and "Send" Audits
- Retail Pharmacy Audits and Response Team

Sutter Health Journey

Sterile Compounding System Support

- Sterile Compounding Coordinator reports to Vice President of Pharmacy
- 1 FTE for Sutter Health Enterprise
- Financial case solidified on insource vs outsource compounding
- Business case with USP Compliance designated person(s) mandate

Key Areas Focus

- Align initiatives to organization strategic plan
- Drive multi-modal compounding standardization
- Lead compliance compounding committee effort
- Develop quality program structure
- Forecast and proactively strategize for regulatory changes

Compliant Cleanroom Standardization

- Gap Analysis of 43 compounding areas
- Completed \$145M construction project
- "Prototype" design and equipment
- Continuous evaluation of "prototype" design
- New construction oversite and prototype optimization
- *NEW* Allergenic extract compounding area design



Sutter Medical Center of Sacramento. Photo Credit: Sutter Health



Sutter Health Journey

Sterile Compounding System Key Areas Focus

- Servant Leader
 - Subject matter expert
 - Multi-disciplinary engagement for compounding needs
 - Establish quality, safety standards
 - Inspire compounding excellence culture
 - Develop operational standard practice
 - Develop Enterprise Sterile Compounding Certification: In Person Boot Camp Training



Sutter Memorial Modesto Medical Center. Photo Credit: Sutter Health

Develop "Recipes" to Standardize

- IV Workflow technology standardization
- Master Formulation Recipe Committee & Standard Structure
- Compounding Compliance Team (CCT) Collaboration Committee
- Hazardous Drug Risk Mitigation List & Evaluation
- Standard policy and template procedure
- Track Environmental Monitoring, Review and Trending
- Personnel and Environmental Media Insource to Shared Microbiology Laboratory
- Compounding PPE and equipment supply standards
- Centralized peer assessment
- Mock Survey and Continuous Readiness
- Dashboard, metrics, and reporting

USP Compliant Cleanrooms at Ochsner Health



Point person to drive cleanroom strategies: System Director – Sterile Drug Compounding Operations to support strategic and DAILY functions



44 cleanrooms system side



Over 20 cleanrooms constructed since the initial release of USP <800> and counting

Gayle and Tom Benson Cancer Center



Photo Credit: Ochsner Health

Ochsner - The Grove



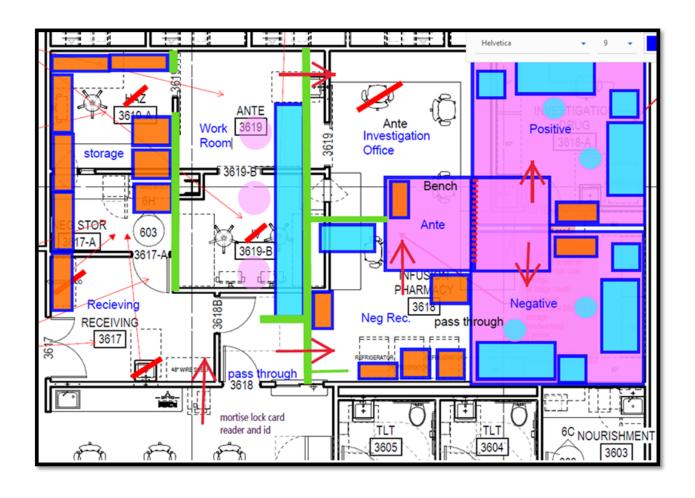
Standardization of Cleanrooms

- Hire a specialized cleanroom construction company to handle the building of your cleanrooms
- Start with creating a standardization list of what your cleanrooms are going to consist of:
 - Engineering
 - Information systems
 - Minimum standards for your rooms (ante, positive buffer, negative buffer, and negative receiving)
 - Room aspects that are specific to you and you're your staff's preference
 - Buildout materials and components

When Building a New Cleanroom

- Start with understanding projected volumes for the next five to ten years
- For a chemotherapy infusion center
 - How many patient chairs are you going to need?
 - How many positive pressure and negative pressure hoods are you going to need?
 - o Does your full chemotherapy suite need a minimum of two negative pressure hoods
- What size rooms are you going to need?
 - Ante
 - Positive buffer
 - Negative buffer
 - Hazardous negative storage/receiving
 - Non-hazardous storage room
 - Pharmacy workspace
- Be able to provide standard pharmacy space requirements based off compounding needs

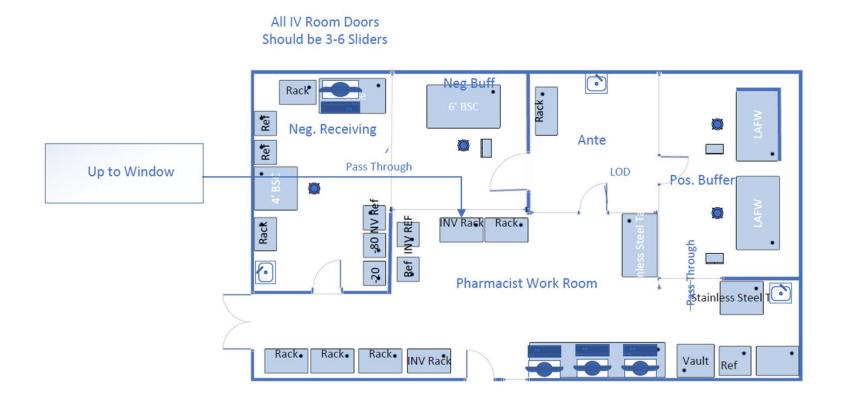
Understand How Construction Can Go Wrong





Minimize Your Risk

Simple diagrams will help your cleanroom architect perfect YOUR cleanroom workflow



Standardization of Reporting

Centralized view to drive corporate level support



Standardization of Reporting

- How will your facilities receive notifications of temperature, pressure, and humidity variations
 - Text message
 - Daily email
- WHEN will they receive temperature pressure, and humidity variations
- What is the time delay on emergency alerts

Room		Low Limit	High Limit	Time Delay
	Temperature	60 F	72 F	300 sec
Ante Room	Humidity	0	65	900 sec
	Pressure	0.02	0.059	900 sec

Lessons Learned

- Support from multiple areas of the organization is key
- Develop a reporting structure that works for your organization, there is not one right answer
- Engage leaders early in developing the solution to the problem
- Your timeline may not be the organization's timeline
- Consistency, persistence, and resiliency are keys to achieving efficient, standardized, compliant programs
- Communicate and educate early and often

Key Takeaways

- There is a critical link to patient safety in the areas of sterile compounding and drug diversion
- Standardize Controlled Substance System Policies and Education as early in the process as possible
- Al platforms provide LARGE amounts of data
 - Expect 1-2 years to work out the non-diversion practice/policy variations
 - Expect the data to identify the unexpected
- Compliance, safety, quality is a journey not a destination
- System support structures align operations with higher reliability outcomes/solutions
- Match efforts to organization strategic goals
- Do not mistake a low visibility pharmacy specialty area with low organizational impact

Questions?





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This educational session is enabled through the generous support of the Vizient Member Networks program.









Optimization for Pharmaceutical Billing

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Eyal Yazdi, MBA, Associate Director of Pharmacy Business Operations, Yale New Haven Health System, New Haven, Conn.

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National Health Care Expenditures

	Personal Income	Health Care Spend Per Capita*	Gross Domestic Product** (\$ Billions)	National Health Care Spend (\$ Billions)	Prescription Drug Spend (\$ Billions)
2013	\$44,586	\$9,121	\$16,692	\$2,879	\$265
2022	\$65,423	\$12,591	\$25,461	\$4,400	\$397
2030	\$84,961	\$19,405	\$36,535	\$6,808	\$565
Average Trend (2022 to 2030)	3.3%	5.5%	4.6%	5.6%	4.5%

- In 2022, Centers for Medicare & Medicaid Services (CMS) reported National Healthcare Expenditures grew 3.2% to \$4.4 trillion in 2022, or \$13,413 per person, and accounted for 17.2% of Gross Domestic Product (GDP).
- National Health Care Spend will rise at a rate of 5.5%, and is expected to reach \$6.8 Trillion by 2030, a 55% increase from 2022. CMS expects individuals to be spending 23% of their personal income on health care in 2030.
- Hospital expenditures grew 4.4% to \$1,323.9 billion in 2021, slower than the 6.2% growth in 2020.
- Prescription drug spending increased 7.8% to \$378.0 billion in 2021, faster than the 3.7% growth in 2020. In 2021 & 2022, prescription drugs were 9% of the national health care spend. CMS is projected drug spend to remain at approximately 9% by 2030

https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html Accessed 8/10/2023

^{*}Per Capita: For each person; in relation to people taken individually.

^{**}Gross Domestic Product: The total value of goods produced and services provided in a country during one year.

Regulatory Considerations



- Cost Update and Mark Up Structure
- Unclassified HCPCS
- Waste Documentation and Billing JW Modifier
- 340B Billing JG/TB Modifier
- New Technology Add On Payment
- Prudent Buyer
- Price Transparency
- Multi Dose Vial Billing Structure
- Self Administered Drugs
- Packaged Drugs
- Research Billing Management
- Free Drug Management VFC/MAP

More than revenue.....



Pharmaceutical Revenue Cycle Collaboration



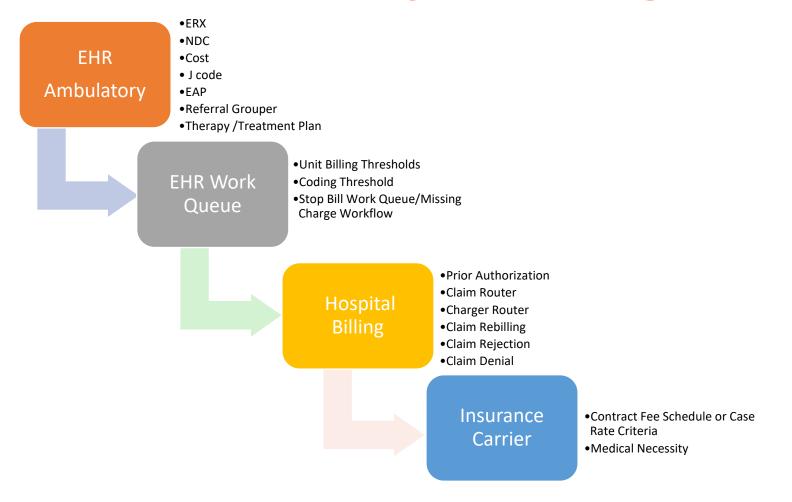
Pharmaceutical Charge Capture & Billing Cycle



Billing and Revenue Cycle Governance



Pharmaceutical Revenue Cycle Management



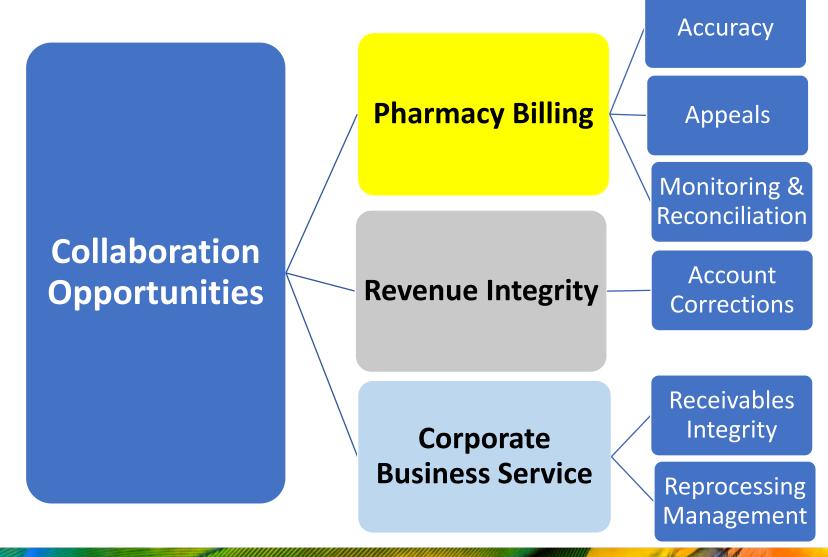
Program Success

- 600,000 records exported per month
- Current billing accuracy 99.9%

Fiscal Year	Avg Claims Reprocessed per Month
2020	25
2021	6
2022	5

Data provided from Yale New Haven Health internal database, Fiscal Year 2020 - 2022

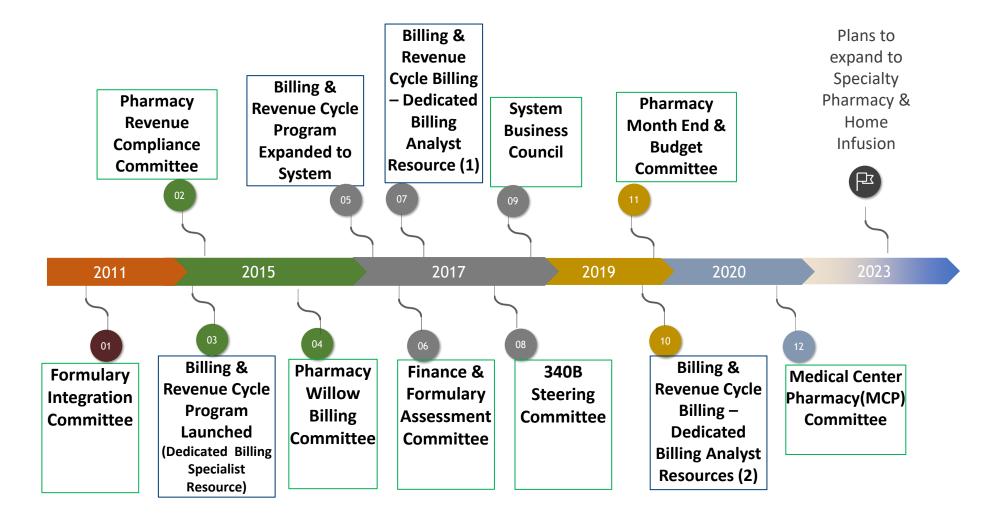
Key Takeaways



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Lessons Learned and Timeline







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Billing for Waste – JW Modifier Background

- Created in 2003 to report the amount discarded from single use vials/packages
 - Use was left to each Medicare Administrative Contractor's (MAC) discretion
- January 1, 2017: providers required to report the JW modifier on all claims that bill for separately payable drugs under Medicare Part B with unused and discarded amounts from single-dose containers
- JW modifier is often omitted on claims, and has led to incomplete data describing quantities of discarded amounts and the associated Medicare payments
 - Lack of waste?
 - Incorrect billing?
 - Missed opportunity?

Drugs and Biologicals, Wastage and/or Discarded Amounts (Modifier JW). Moda Health. Retrieved August 3, 2023, from https://www.modahealth.com/pdfs/reimburse/RPM015.pdf

Federal Register (n.d.). Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies. Govinfo.gov. Retrieved August 3, 2023, from https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf





Billing for Waste – OSUWMC Journey

- Many private payer contracts reference CMS billing requirements and payment structures
 - Opportunity to bill ALL payers for waste
- Hesitation within revenue cycle and pharmacy operations leadership dating back to 2015
- Technicians not given access to document waste until 2019 after leadership turnover
 - Implemented in non-oncology infusion centers
- Resident audits to quantify opportunity throughout the system in 2020
- COVID-19 vaccine initiative diverted focus

Regulatory Change

- Infrastructure Investment and Jobs Act requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.
 - Bad data/difficult to implement
- CY 2023 Medicare Physician Fee Schedule (PFS) final rule
 - Required to report the JW modifier for all separately payable <u>drugs with discarded drug</u> <u>amounts</u> from single use vials or single use packages payable under Part B
 - Required to report the JZ modifier for all such drugs to attest when there were no discarded drug amounts from single dose vials

Federal Register (n.d.). Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies. Govinfo.gov. Retrieved August 3, 2023, from https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf





Billing for Waste - Timeline

- January 1st: JW modifier required
- July 1st: JZ modifier required
 - Claims that do not report the JW or JZ modifier may be subject to provider audits
- October 1st: Claims that do not report the modifiers will be returned as un-processable

Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Cms.gov. Retrieved August 3, 2023, from https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf



Project Accelerate

- Tapped to chair multidisciplinary team for rapid implementation in October 2022
- Small pilot in November 2022
 - Review claims in December
- System go-live January 1, 2023

Implementation Planning

- Medical record build
- Identify separately payable drugs procured in single dose vials
- Compounding automation custom interface
- Denials / patient responsibility
- Vial sizes / formulary edits
- Staff education tip sheet
 - Documentation in medical record



OSUWMC Billing for Waste (BFW) Tip Sheet

Purpose:

a. To comply with a CMS requirement to report discarded amounts of drugs beginning 1/1/23

Definitions:

- a. Single Dose Vial (SDV): a single-unit container for articles or preparation intended for parenteral administration only. It is intended for single use. A single-dose container may not always be labeled as such and should be assumed to be single-dose unless stated to be a multiple-dose container (or says single patient use, bulk vial)
- Multi Dose Vial (MDV): as labeled by the manufacturer, a container that is formulated for removal of portions of the contents on multiple occasions up to 28 days after first entry because it contains antimicrobial preservatives (or shorter as specified by manufacturer)

General Process:

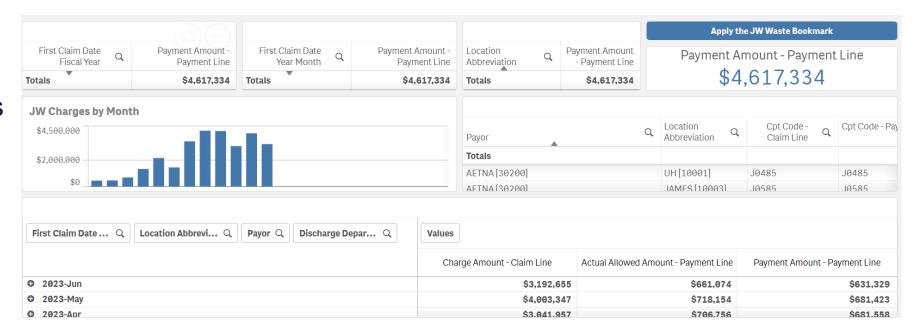
- a. Determine whether the medication is eligible for billing for waste
 - Inpatient ONLY SDVs where the 'Waste' button is present in Dispense Prep. The
 waste button shows up on the right-hand side AFTER the vial is scanned
 - IHIS is unable to make this a hard-stop so the technician needs to look for the Waste button when completing Dispense Prep
 - ii. If there is no Waste button, no changes should be made to current compounding practices





Monitoring

- Claims dashboard
 - Refreshes daily
 - JW charges
 - JW line payments
- Interactive analysis
 - Business Unit
 - Location
 - Drug
 - Payor
 - Denials



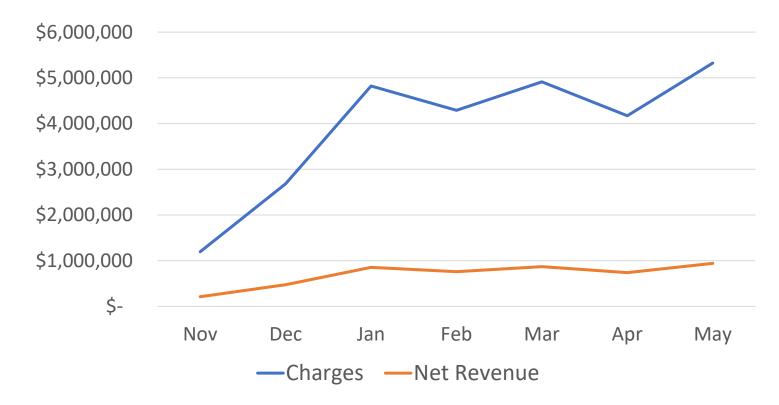
Data provided from The Ohio State University internal database, July 2022-June 2023.

Lessons Learned

- Incomplete data related to which drugs are provided in single dose vials
 - Wholesaler reports
 - Third-party drug information vendors / medical record
- Inventory impact related to increasing the number of vial sizes in stock
- Culture change surrounding waste and perceived inefficiency
- Need to plan for dispensing "exceptions"
 - Lost or returned doses
 - Re-dispensing

Key Takeaways

Financial opportunity was larger than anticipated!



Data provided from The Ohio State University internal database, Nov. 2022-May 2023.

Questions?





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