

Hospital Controlled Substance Diversion Monitoring Automation

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Presenters



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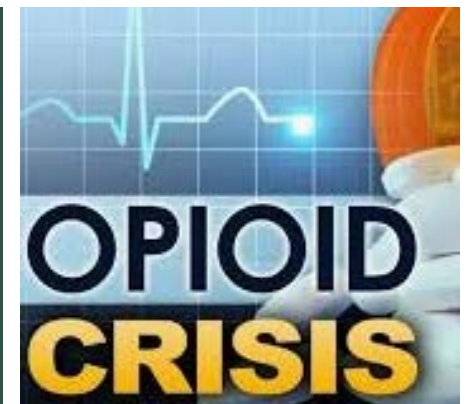
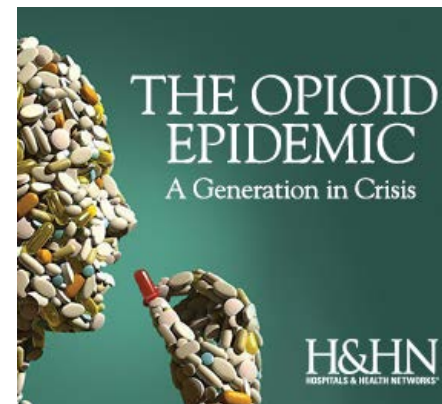
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Hospitals Role in Opioid Epidemic: *What Have We Learned?*

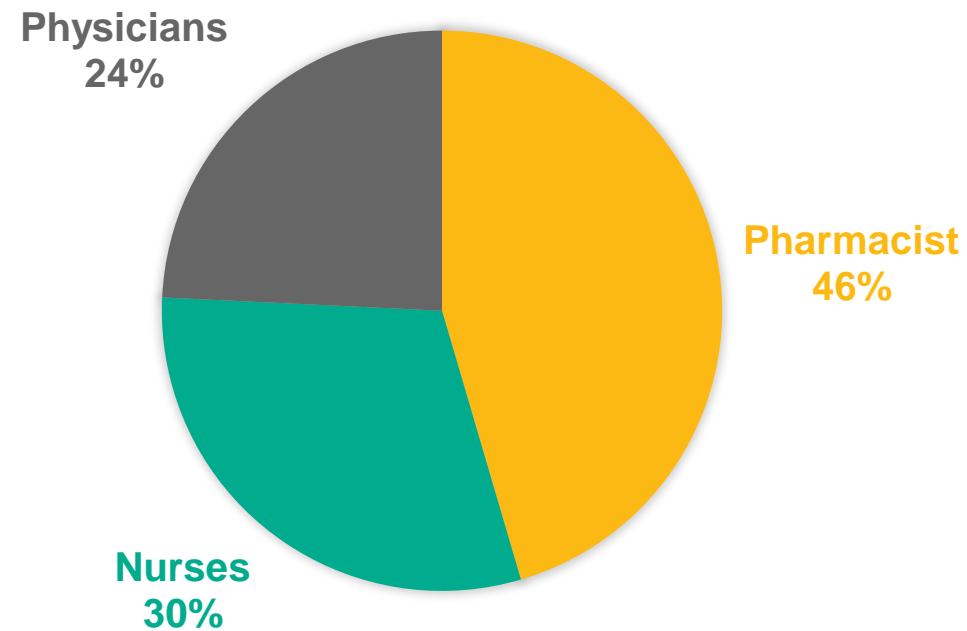
- National Institutes of Health released a new study demonstrating that 41% of US adults suffer from a painful health condition of these adults, 24.3% are prescribed opioids.
- 2016 - 15% of hospitalization were associated with a new opioid prescription. 43% of which were associated with an opioid claim after 90 days of discharge suggesting the development of potentially a new addiction to opioids after an acute hospitalization. JAMA (2016;176(7):990-997
- 8.5% of 2016 ED visits for pain (ages 18>) were given or prescribed opioids. Over 38% of adults over 65 years of age were given or prescribed an opioid. Centers for Disease Control (CDC)



Employee Diversions

Every 13 Minutes an American Dies From an Opioid Overdose

WHO'S DIVERTING?



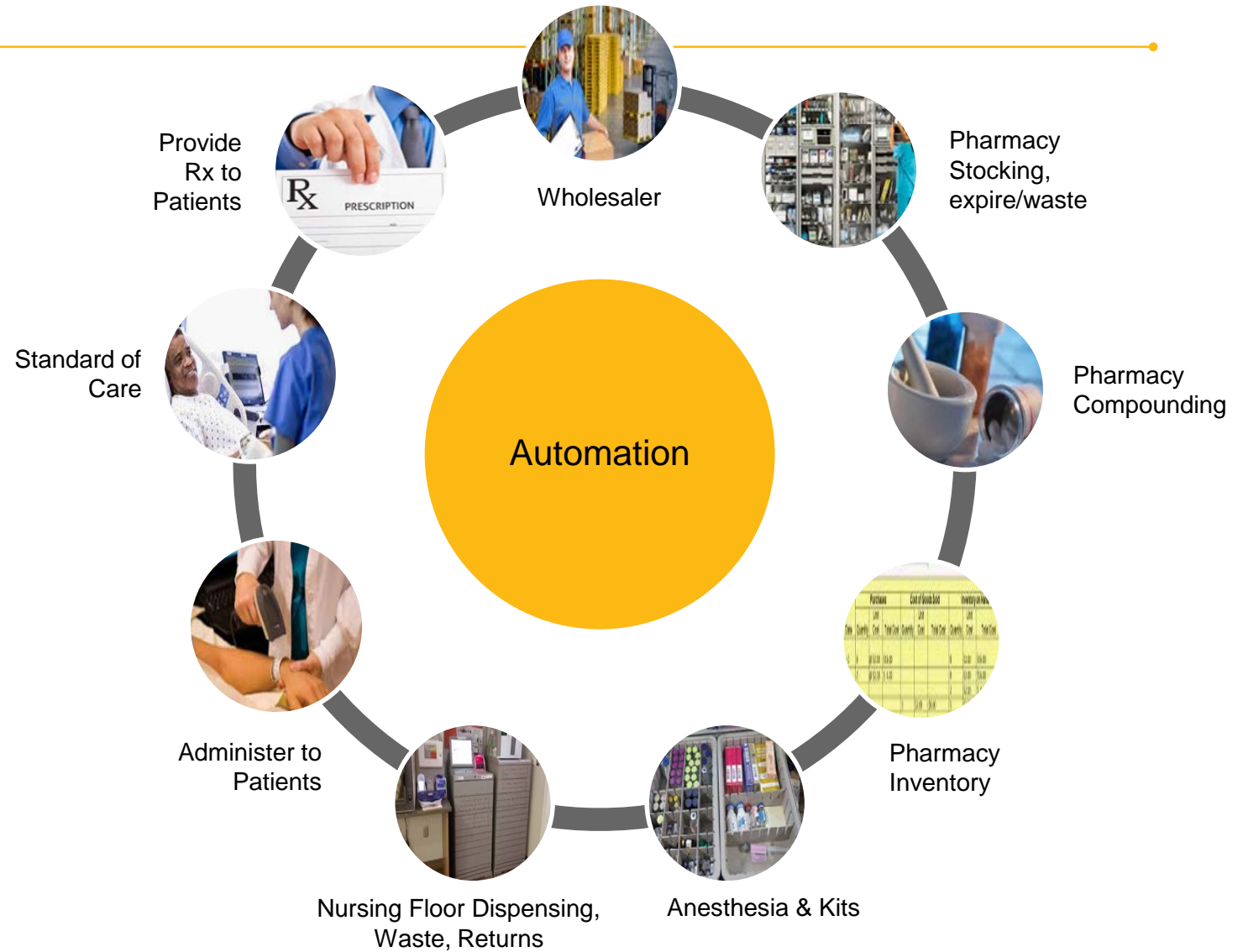
Polling Question

What have we learned from the Opioid Epidemic research?

- a. Opioids are bad
- b. Not to use opioids
- c. Hospital discharge scripts over five days can cause someone to be addicted



Current Vs. Future State



Future State

- Automated
- Integrated System
- Self Contained – Drill Down / Research
- No “Red Flags” except from Artificial Intelligence or manual areas
- Address Gaps (No BCMA, outside of ADC)
- Holistic from purchase to administration, sedation to discharge scripts




Polling Question

For hospital diversions what % of the diversion are nursing?

- a. 100%
- b. 50%
- c. 30%
- d. 1%





How to be Ready for Automation? Robust Preventative and Detective Controls

Order / Receiving Current State

- Reconcile Wholesaler Report to Automated Dispensing Cabinets (ADC) Stocking Report



McKesson
Dispensing Medicines

RETURN AUTHORIZATION

NY CITY DC #0010
PROXODON DRUG
1200 WY BLVD.
NY CITY, NY 10036
(QA # PRO00005)

Subtable

Batch	0001200007
Lot	3416380
Return P/N	10007

000110	001	002	1 of 1
Quantity	Amount	Stop	Page

SHIP TO:
 NY PHARMACY
 124 WY STREET
 NY CITY, NY 10036
 (QA # 000120005)
 P/N # 0000000000
 CTRL # 00012000000

SHIP TO:
 NY PHARMACY
 124 WY STREET
 NY CITY, NY 10036

Form: 000
 RA Valid Th: 01/15/12
 ODR Control #: 0001200007



Omnicell Transactions by Date

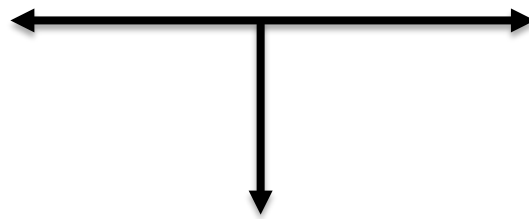
Date Range: [Redacted] Page 1

Omnicell
 Items: 000001170, 000001104 (1 selected)
 Transaction Type: RA
 Item Count at Level: 2
 Transaction Subtype: RA
 Product ID Type: RA

Date/Time	Item Description	Item ID	Type	Qty	BN	Charge ID	Patient Name	Pos ID	User Name
	Item 001 50mg/7ml, 2ml, vial	0001200007	RA	1	0	000001170	[Redacted]	[Redacted]	[Redacted]
	Item 002 10mg/7ml, 2ml, vial	0001200007	RA	1	0	000001104	[Redacted]	[Redacted]	[Redacted]

Order / Receiving Current State

- Review and Reconcile Daily Transfers To and From the Nursing Units



Polling Question

What should every hospital do to fight diversion?

- a. Reconcile and review CS transactions
- b. Hire more security
- c. Not have CS in the hospital



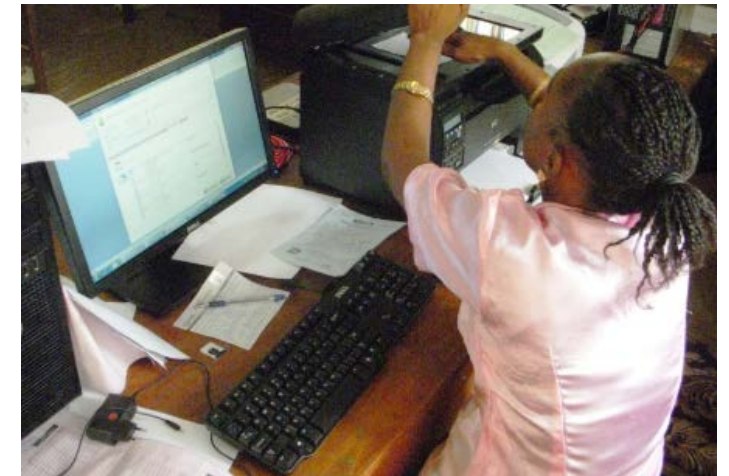
Order / Receiving Current State

- Manual Anomalous Usage Audits / Chart Reviews
- Diversion Task Force

Controlled Substance Anomalous Usage Audit
Time Period _____

Name of Employee _____ Name of Auditor: _____
 Has employee been on report previously for same controlled substance? Y/N Date Completed: _____
 Investigatory Meeting Required? Y/N
 The auditor shall review a minimum of 10 controlled substance dispenses from the identified high user unless there is <10, then 100% of dispenses shall be reviewed.

Location of Controlled substance removal (nursing unit)	Name of Controlled Substance	Does admin follow parameters of order? (correct dose, frequency)	Is dose selected from Omnicel appropriate for dose required	Date/ Time of narcotic removal from Omnicel	Date/ Time narcotic documented as given on MAR	Time nurse charted	Pre/Post Pain Score documented	If waste, document waste dosage, date and time	Name of waste witness	Are there any other narcs taken or admin at the same time?	Comments





A Health Systems Journey To Perfecting Preventative and Detective Controls

About Dignity Health / New CommonSpirit



- CommonSpirit Health
 - 139 Hospitals
 - \$28.4 Billion
- 150,000 employees
- 25,000 physicians

DEA Findings

Published

Department of Justice

U.S. Attorney's Office

Eastern District of California

SHARE 

FOR IMMEDIATE RELEASE

Wednesday, July 16, 2014

Dignity Health Agrees To Pay \$1.55 Million In Civil Penalties To Resolve Controlled Substances Act Claims

Poor
Recordkeeping

Failure to maintain
accurate records of
receipt

Failure to maintain
required inventory

The DEA audit identified numerous infractions in recordkeeping requirements with each infraction fined at \$10,000 / infraction.

DEA Settlement



Culture Prior to DEA Agreement

**Pharmacy System
Leadership was
“Advisory”**

**Regulation compliance
focus (vs. prevention and
detection controls)**

**Relied on PIC
license for effective
controls**

No System Requirements

Impact Throughout System



Additions to daily duties for PIC and staff



Additions to daily duties for Nursing



New System oversight and accountability



External and Internal audits

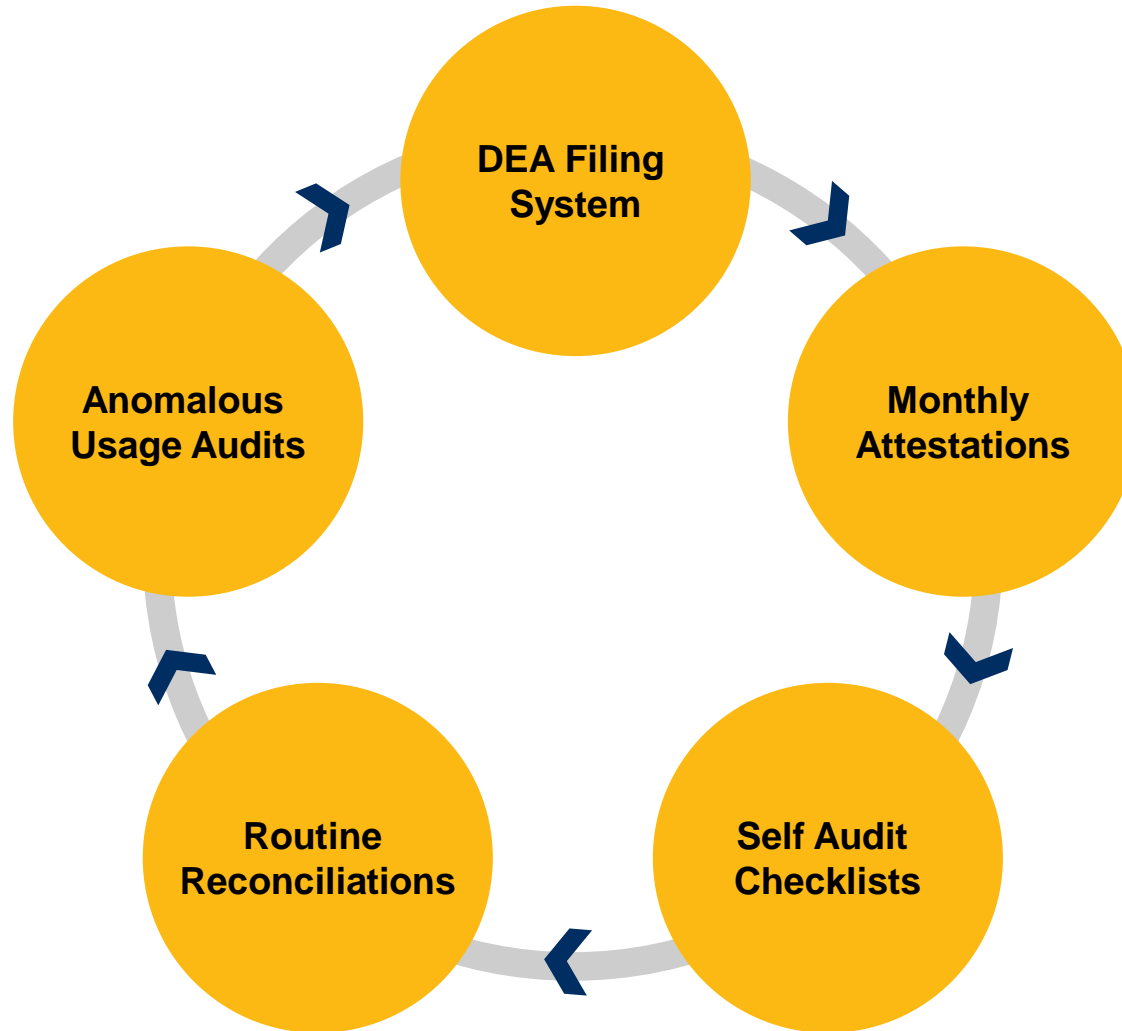


New Key Performance Indicators (impact to Hospital Presidents Incentives)



Added staffing to entire organization

DEA Agreement Required Control Highlights



After DEA Agreement – Reconcile, Audit, Review

Completion of Monthly Self Audit Checklists

Dignity Health

Controlled Substance Compliance Audit

Facility Compliance: Corrective Action Needed? Yes No

Reviewed By: _____
 COO Signature: _____
 Review Date: _____
 Spoke With: _____

Auditor's Findings:

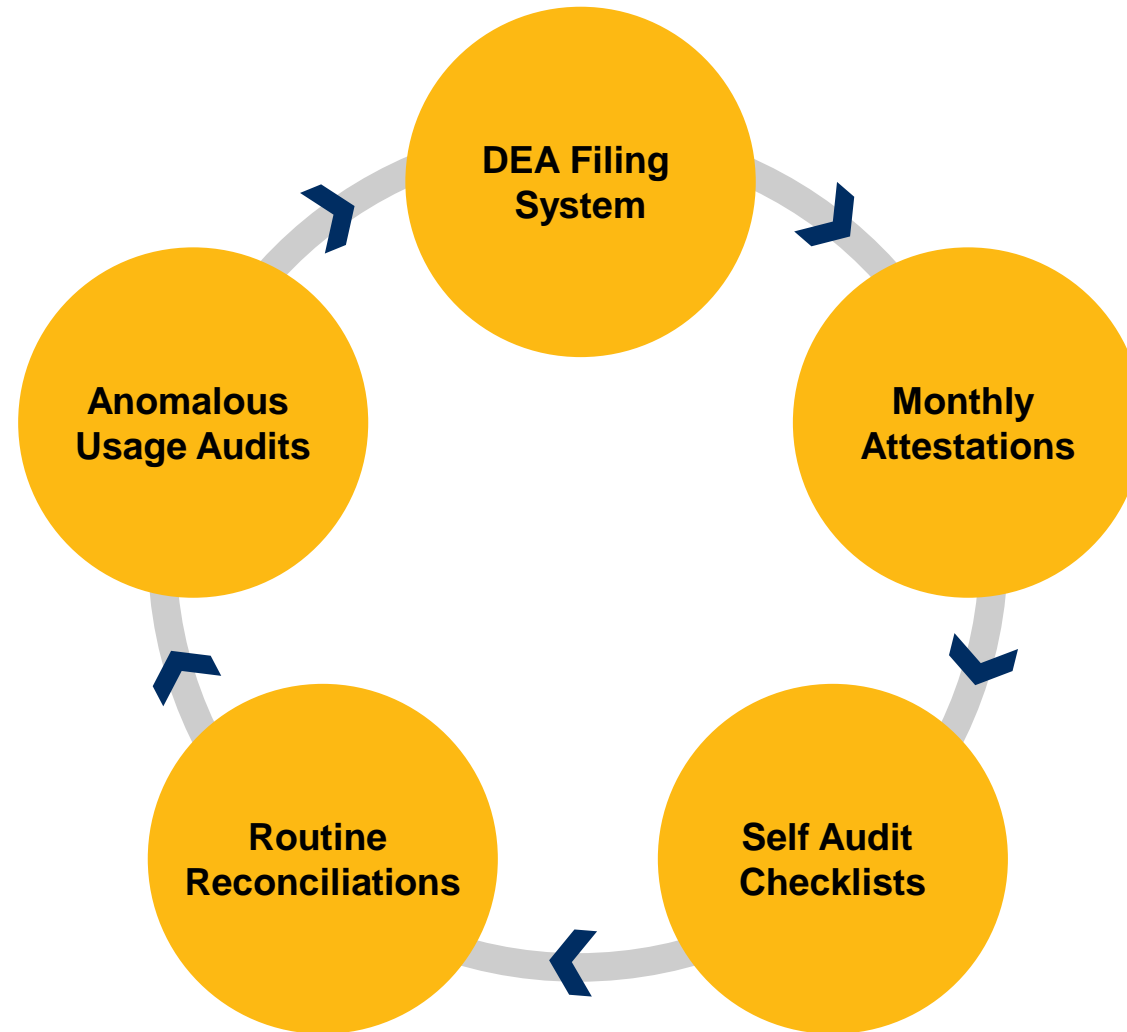
Revised 05-08-19
 Review the contents of the controlled substance record-keeping file for the following:
 (Keep only 3 years of documentation for these current files on site; 3rd year may be remote with Board of Pharmacy Off Site waiver - remaining 4 yrs may be stored offsite.)

Record Keeping Requirements *Describe reason for NO answers

01.	Are the below records filed neatly, clearly labeled and chronologically in the designated controlled substances record-keeping box / file, readily retrievable ; and all remote storage areas are noted with a "placeholder" designation?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
	1. CII-CV Invoices (CII's separated)		
	2. Unused DEA 222 Forms		
	3. Executed DEA 222 Forms – (separate file)		

Diversion Detection - Inpatient			
32.	Are diversion screening reports (anomalous use) issued to nursing managers on a monthly basis or reviewed within pharmacy? (IP)	YES <input type="checkbox"/>	NO <input type="checkbox"/>
32a.	Were the outliers referred to nursing or pharmacy for review, based on the established criteria? What percentage of outliers were referred? _____ (estimate)	YES <input type="checkbox"/>	NO <input type="checkbox"/>
32b.	Are diversion screening reports (anomalous use) tracked and returned to pharmacy within 14 days; and results reviewed based on criteria? (IP)	YES <input type="checkbox"/>	NO <input type="checkbox"/>
33.	Is there an audit trail for weekly discrepancy resolution review , unacceptable reasons are evaluated and these documents retained on file? (IP)	YES <input type="checkbox"/>	NO <input type="checkbox"/>
33a.	Has CNO been sent the monthly summary statistics for discrepancy resolution?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
33b.	Are CII-CV transfers to the floors and transfers back from the floors are reviewed for all items and reconciled to ensure what was removed was stocked or properly returned. CSM Exception report is printed daily	YES <input type="checkbox"/>	NO <input type="checkbox"/>
33c.	Are anesthesia kits and PCA controlled substances removals from CSM reconciled for these transactions?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
	Are used anesthesia kits reconciled to the medical record anesthesia administration documentation through a defined process ?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>
33d.	Are used anesthesia kits tracked, monitoring and accounted for?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
33e.	Are all anesthesia kits tracked, monitoring and accounted for?	YES <input type="checkbox"/>	N/A <input type="checkbox"/>
33f.	Are non-significant non-theft controlled substances losses track and trended and maintained on file? (if you have more than 4 per month)	YES <input type="checkbox"/>	NO <input type="checkbox"/>

DEA Agreement Required Control Highlights



Anomalous Monthly Audit

- Distributed to nursing managers by the 10th of the following month
- Nursing reviews 10 removals/outlier
- Return due back to pharmacy in 14 days
- Track return rate

Audit Process for Controlled Substance Anomalous Usage Report

1. The Pharmacy Department utilizes PandoraVia as its diversion software
2. The Pharmacy Department runs a Controlled Substance Anomalous Usage report to identify the highest users for controlled substance dispenses in a defined time period. The pharmacy will run this report monthly and as requested by a department director/manager.
3. The Pharmacy Director or Designee will review the Anomalous Usage reports and identify the significant high users by placing an asterisk (*) next to the user's name. Omnicell Removal Reports or PandoraVia Dispensing Reports for the last 30 days will be generated for the users identified who significantly exceed removals (2 or more standard deviations).
4. The Nursing Manager will review a minimum of 10 removals for the identified high users. For users who remove less than 10 controlled substances, 100% of all removals will be reviewed.
5. The pharmacy department designee or nursing manager or designee will review the controlled substance removal reports generated on these high users for the following:
 - Date/Time of removal of the narcotic/controlled substance from the Omnicell
 - Location of the Omnicell the removal occurred at
 - The name of the narcotic/controlled substance removed
 - The time RN documents administration of the narcotic/controlled substance to the patient
 - The narcotic/controlled substance removed will be verified against the physician order- including verification that the medication/dose are appropriate based on the pain scale if appropriate.
 - The actual time the RN documented (charted) the administration of the controlled substance in the eMAR (the electronic time-stamp) and the time between the documentation of administration and the actual time of documentation of administration will be calculated (if significantly different)
 - If the narcotic/controlled substance is being administered for treatment of pain – the pain assessment prior to the administration and the re-assessment after the medication has been given and the times documented vs the electronic time stamp (the time the RN charted the administration)
 - All wastage documentation will be reviewed – including that the correct amount is wasted, the date/time of the wastage (at removal or quantified time after removal) and that all wastage has been witnessed and the co-signing RN initials will be noted. Trends can be identified by running the Omnicell Witness Buddy Report.
 - The auditor will also note if the RN has removed multiple narcotics at the same time
 - The Nursing Manager shall notify the Pharmacy Director immediately if questionable practices (e.g. undocumented controlled substances) have been identified.
 - A RN with questionable controlled substance practices will be subject to an investigatory meeting per Policy: _____
 - The Nursing Manager audit reports are to be returned (scan or fax) to the Pharmacy Director within 14 days.

Anomalous Usage Audit Form

- Nursing completes audit form within 14 days of receipt
- Pharmacy monitors and tracks

Controlled Substance Anomalous Usage Audit											
Time Period _____											
Name of Employee _____					Name of Auditor: _____						
Has employee been on report previously for same controlled substance? Y/N					Date Completed: _____						
Investigatory Meeting Required? Y/N											
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Strategies & Goal



Establish/sustain compliance with DEA



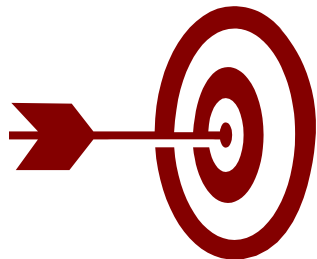
Immediate detection



Immediate investigation

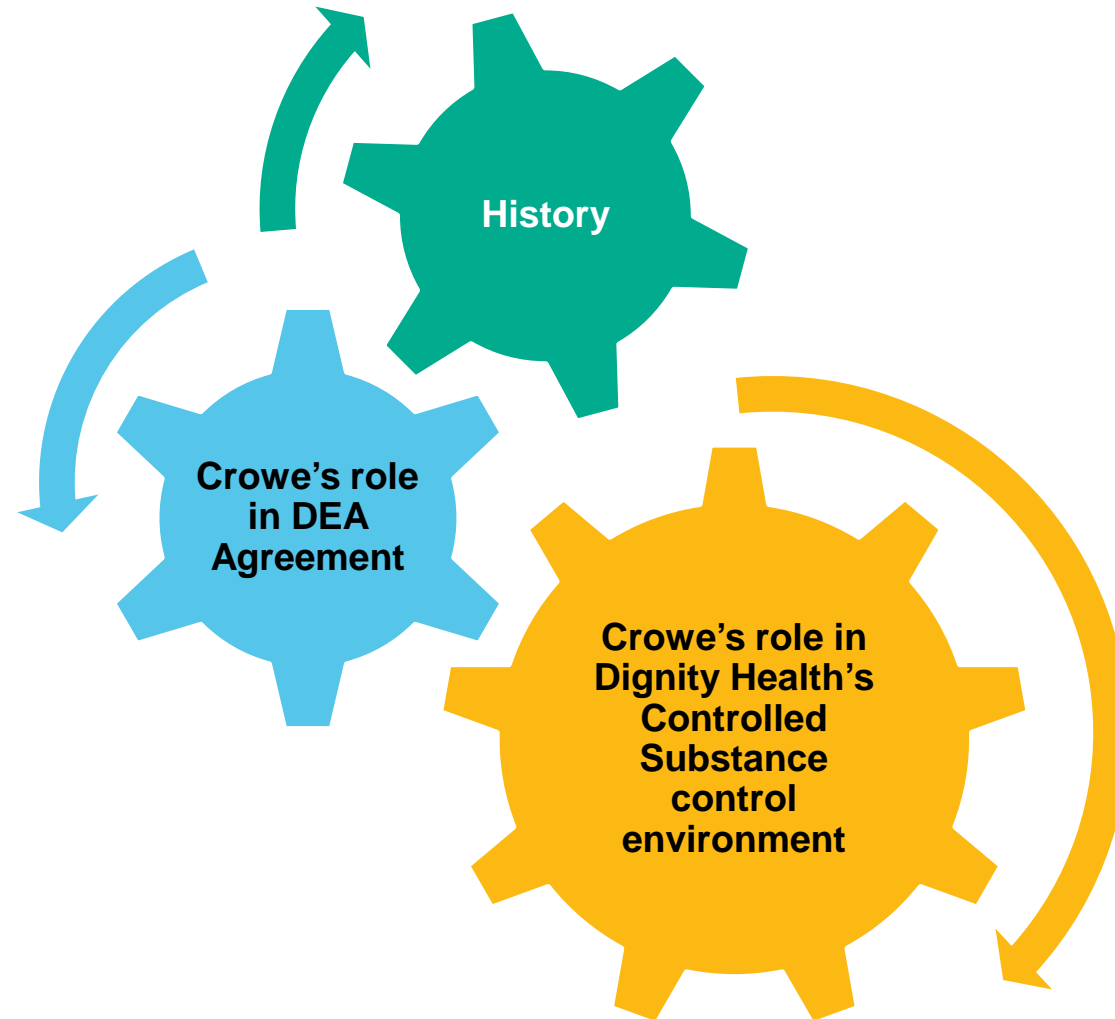


Immediate reporting



No penalties from the lack of management of controlled substances

Dignity Health Partnership with Crowe



Polling Question

What does every hospital need to do to be ready for automated CS controls?

- a. Invest in more IT equipment
- b. Have robust manual controls in place
- c. Take an IT course



Dignity Health Partnership with Crowe – Steps Toward Automation

CYCLE COUNT RECONCILIATION SUMMARY
BEGINNING CYCLE COUNT DATE: 20181101
ENDING CYCLE COUNT DATE: 20181201

Pharmacist-In-Charge: _____ Pharmacist-In-Charge Signature: _____ Date: _____

FACILITY	BEGINNING CYCLE COUNT DATE TIME	BEGINNING CYCLE COUNT QUANTITY	ADDITION		SUBTRACTION			DISCREPANCY (D)	ENDING CYCLE COUNT QUANTITY	ENDING CYCLE COUNT DATE TIME	ENDING CYCLE COUNT VARIANCE
			STOCK	RETURN	DISPENSE	EXPIRED	WASTE				
FACILITY A	201811010700	9,687	3,882	110	2,856	235	0	1	10,587	201812051337	0

Purchase and Stock Reconciliation

FACILITY	INVENTORY TRANSACTION STOCK	PURCHASE PER MCKESSON REPORT	PURCHASE PER VENDOR B REPORT	PURCHASE PER VENDOR C REPORT	PCA / DRIP / EPIDERAL ADJUSTMENT	PURCHASE AND STOCKING VARIANCE
FACILITY A	3882	-3687	-130		-65	0

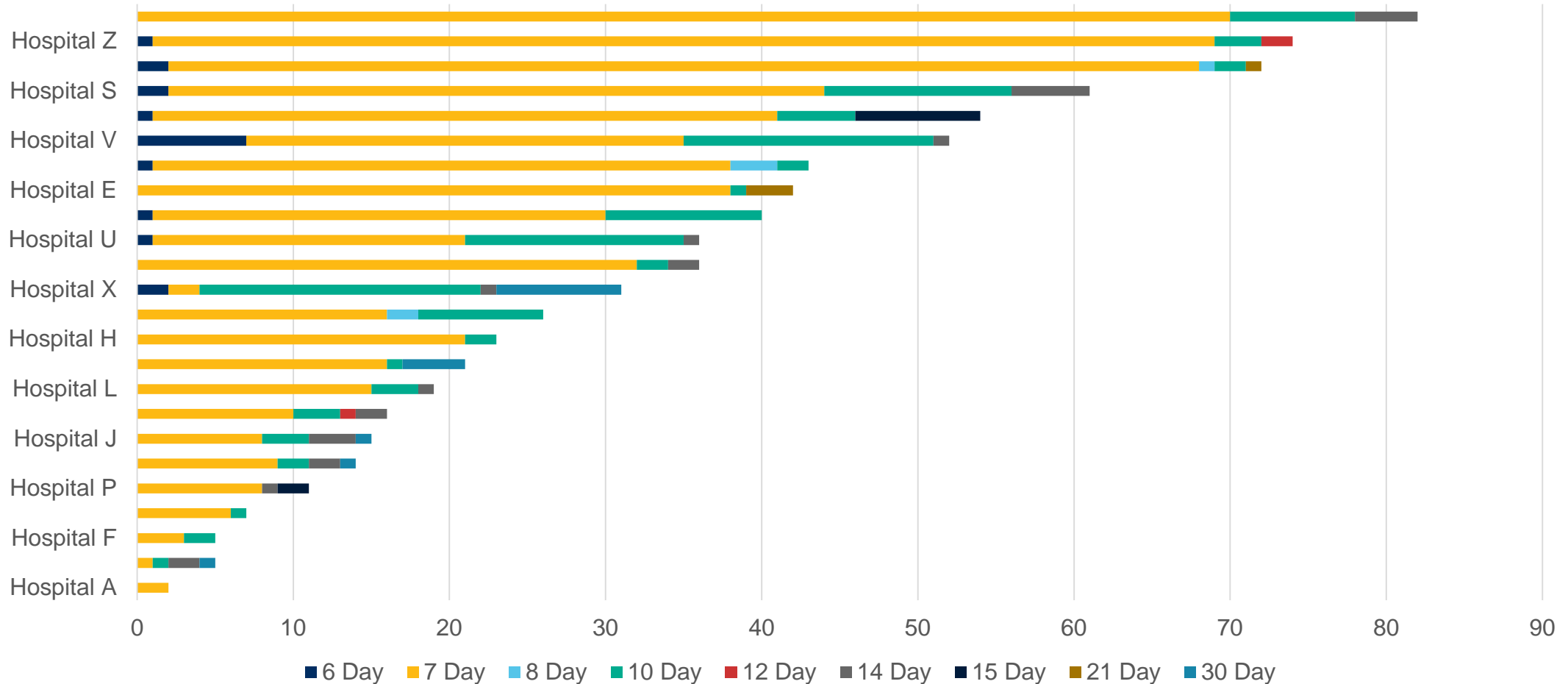
VARIANCE EXPLANATION (ENDING INVENTORY VARIANCE, PURCHASE AND STOCKING VARIANCE AND DISCREPANCY (D) TRANSACTIONS):

Item ID _____ Description _____

Reason _____

Dignity Health Partnership with Crowe – Steps Toward Automation

of Opioid Discharge Scripts > 6 Days



Key Takeaway from Dignity Health's Experience. . . .

!! IMPLEMENT !!

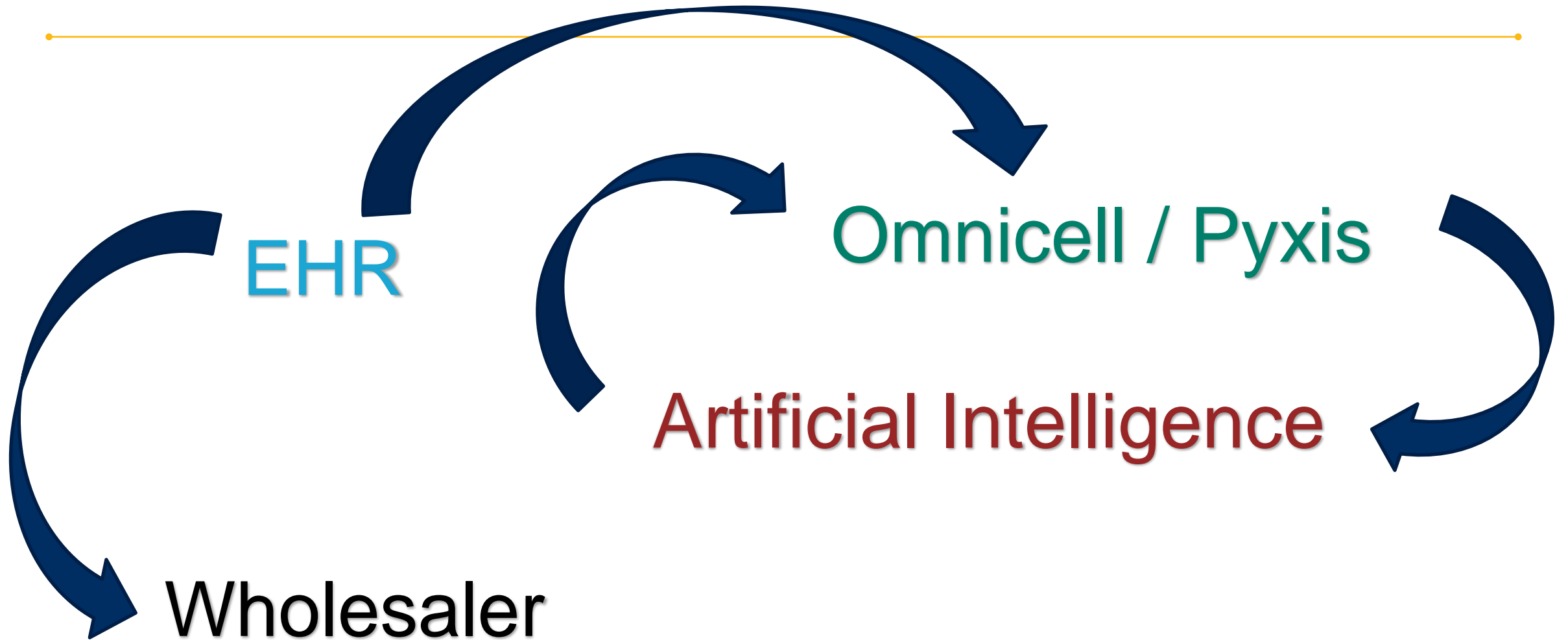
!Prevention and Diversion control Processes!

Be Ready for Automation!



Automated Solutions

Future State:



Thank you

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