

A background image featuring medical supplies: a magnifying glass, a syringe with a yellow plunger, several pills (white, blue, and red-and-white), and a pill blister pack. The image is dimmed to allow text to be read.

Drug Diversion by Healthcare Personnel: What Every Compliance Officer Needs to Know

KIMBERLY NEW

LUCAS OVERMIRE

Understanding Diversion



All facilities face this issue



Substantial safety, quality, regulatory compliance and legal risk



Mitigate risk with formal program, transparency and culture change

Regulatory Environment



University of Michigan-\$4.3 million

Effingham Health-\$4.1 million

Intermountain Healthcare - \$1 million

Mass General - \$2.3 Million Settlement

\$10,000 or more per civil violation including failure to keep appropriate records

Current Climate

“At a time when our country’s opioid crisis is ravaging communities across the country, hospitals...have a critical responsibility to ensure that controlled substances are tracked and safeguarded from theft or loss and are not diverted for illegal uses...This record-setting civil penalty is a proactive step that DEA Diversion and our partners in the U.S. Attorney’s Office can take to discourage other healthcare providers from engaging in such reckless behavior.”

Current Climate

"This case should alert all health systems – large or small – that complying with the Controlled Substance Act is not only their legal responsibility but also a matter of public trust."

illuminate, give
accountable ad
if any of the m
respons
able.

Culture: Ongoing Awareness, Education and
Accountability

DIVERSION

Diversion Prevention Program

Key Aspects of Program



Policies to prevent, detect and properly respond to diversion



Stakeholder collaboration



Method of auditing/transaction review



Prompt attention to suspicious data



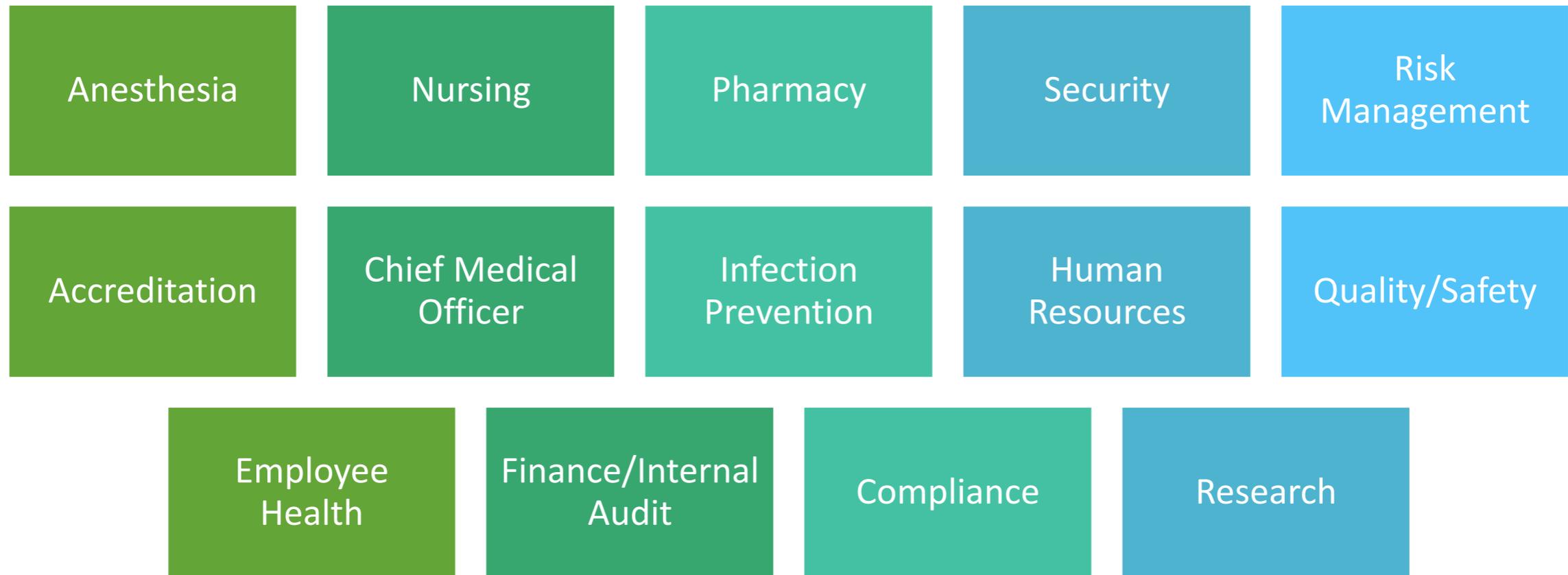
Collaborative relationship with external agencies



Education for all staff



Diversion risk rounds



Developing a Proactive Program Oversight Committee Membership

Oversight Committee Functions



High level with ability to provide resources



Direct and support efforts



Subcommittees and workgroups may be helpful (ie, outpatient, anesthesia)



Annual goals-address gap analysis findings

Response Team Functions



Small team (Nursing, HR, Pharmacy, Supervisor)



Data driven suspicion (impairment handled per policy)



Problem solving (investigation of non-diversion CS issues)



Defined workflow/process-email group



Early structural component-must have as program ramps up

Diversion Prevention Specialist



Operations of program



Day to day accountability



Develops and provides:

Education
Surveillance/auditing
Policy development



Collaborates with internal and external stakeholders



Key Regulatory Considerations

Screening For Risk

21 CFR 1301.90 Employee screening procedures

- Obtaining certain information is vital to assess the likelihood of an employee committing a drug security breach
- Need to know is a matter of business necessity, essential to overall controlled substances security
- Conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry

Screening for Risk

21 CFR 1301.93 Sources of information for employee checks

DEA recommends that inquiries concerning employees' criminal records be made as follows:

- Local inquiries. Inquiries made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions.
- DEA inquiries. Inquiries furnished to DEA Field Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

Security from
Procurement
to
Administration
and Disposal

42 CFR §482.25(a) Standard: Pharmacy Management and Administration

- The pharmacy or drug storage area must be administered in accordance with accepted professional principles.
- The hospital's pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.

Controls and Safeguards

42 CFR §482.25(b) Standard: Delivery of Services

- In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.
- Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to:
- Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed.

Controls and Safeguards

42 CFR §482.25(b)(1) - Medications must be dispensed by the hospital in a manner that is safe and meets the needs of the patient:

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;

Security

42 CFR §482.25(b)(2)(i) - All drugs and biologicals must be kept in a secure area, and locked when appropriate.

- Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons
- If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained
- All controlled substances must be locked.



Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored?

Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.

Staff Reporting

21 CFR §1301.91 Employee responsibility to report drug diversion

- Reports of drug diversion by fellow employees is necessary and also serves the public interest at large
- An employee with knowledge of drug diversion from his employer by a fellow employee is obligated to report to a responsible security official of the employer
- Confidentiality for those reporting
- Employer shall inform all employees concerning this policy

External Reporting

21 CFR §1301.76 Other security controls for practitioners

- Registrants required to notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft.
- Also complete and submit to the Field Office, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss.

Theft and Loss



Diversion is theft, not loss



Updates every 30 days



For loss, no single objective standard, but instead view in context of a registrant's business activity and environment



When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances

Theft and Loss: Determining significance of loss



Actual quantity of controlled substances lost in relation to the type of business;



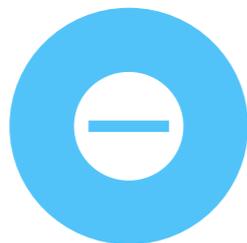
The specific controlled substances lost;



Whether the loss can be associated with access by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;



A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,



Whether the specific controlled substances are likely candidates for diversion;



Local trends and other indicators of the diversion potential of the missing controlled substance.

A hand holding a magnifying glass over a red question mark. The magnifying glass is held by a hand on the left side of the frame. The lens of the magnifying glass is positioned over a large, bold red question mark. The background is a solid grey color. The text 'Investigating Diversion' is overlaid in white, centered horizontally and partially overlapping the magnifying glass and the question mark.

Investigating Diversion

Signs of Diversion

Removal of medication; no administration

Removal of medication when not needed

Removal for discharged patient

Removal of duplicate dose

Removal of/diversion from fentanyl patches

Removal of medication without order

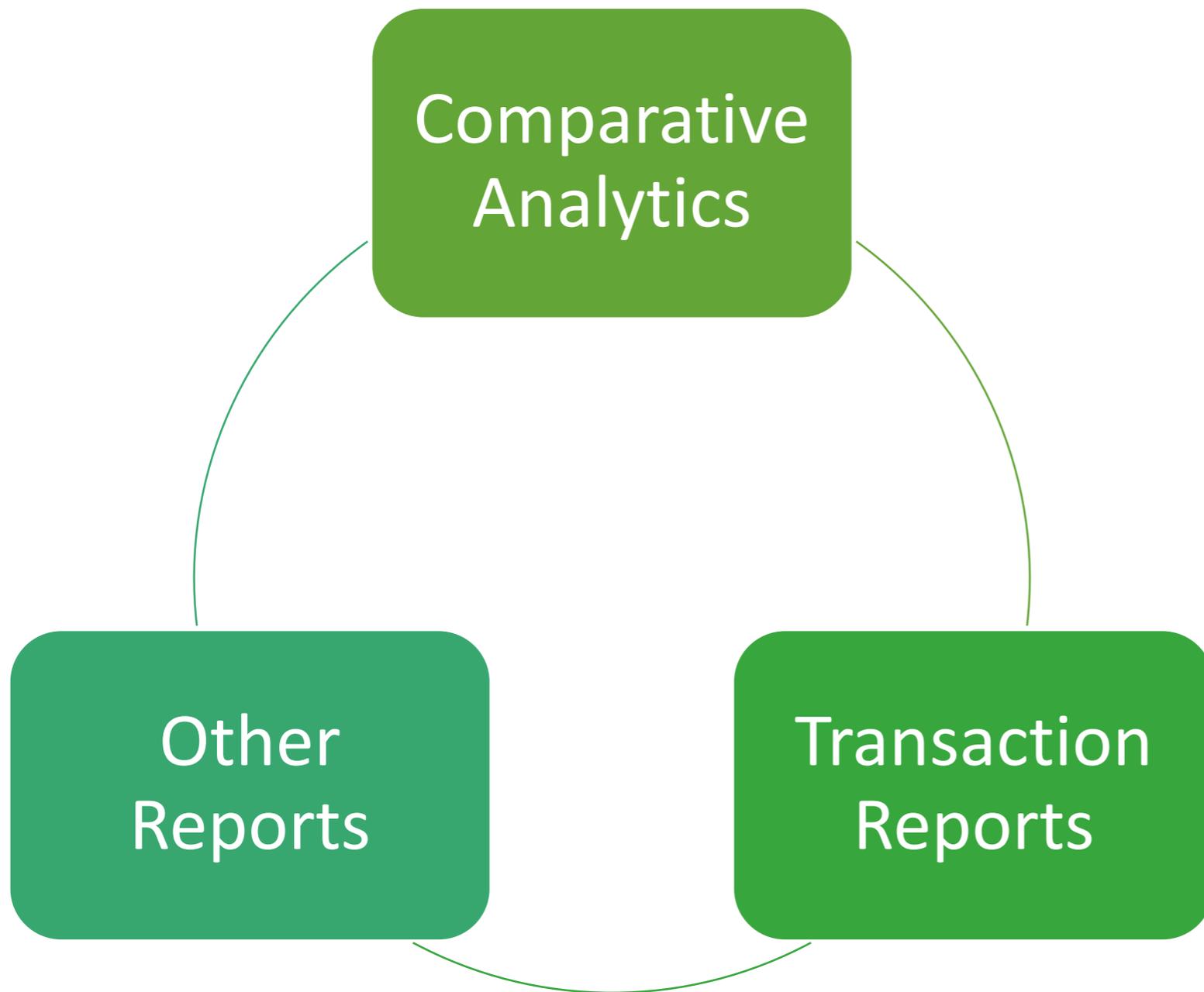
Diversion from waste

Frequent breaking of containers for injectables

Removal under sign-on of colleague

Removal of oral and injectable opioid at the same time

Tampering



Transaction
Audits

Comparative Analytics

Embedded with ADC Software	Commercially Available Basic	Commercially Available Next Gen
Dispensing Practices	Omnicell Analytics	BlueSight
Narcotic Surveillance	Pandora Analytics	Invistics
Proactive Diversion	RxAuditor	Protenus

Pandora Analytics: Anomalous Usage Report

Group
Sub-Group
Members

Whispering Springs - Rx (P)

Anomalous Usage Group/Sort by: SiteID, NursingUnitID MedName/ Qty-WtdQty Desc, UserID

Selected Criteria:
 Date Period BETWEEN 4/2/2008 AND 6/30/2008
 Systems IN (Pyxis)
 Nursing Units IN (LD)
 StdDev > 0.5
 Transaction Types IN (WITHDRAWN)
 Med Classes IN (Controlled C-II; Controlled C-III; Controlled C-IV; Controlled C-V)
 Levels IN (Mild; Extreme)

Report Options:
 Weighted = False; Display = User Name

UserName	Trans Cnt	Qty	Wtd Qty	Pop	Mean	UIF	UOF	SDev
Site: ; NursingUnit: LD								
MOR10I Morphine Sulfate 10Mg 1Ml Vial				82	5	13.5	21	9.013
Brush, Janelle	69	69						
Jefferies, Fred	22	40						
Gaughan, Sandhya	18	18						
Schmid, Elizabeta	16	16						
Anderton,	15	15						

Report Criteria

Group: Site/Area

Sub-Group: Med

Group Members

Pandora Analytics: Anomalous Usage Report



UserName	Trans Cnt	Qty	Wtd Qty	Pop	Mean	UIF	UOF	SDev
Site: ; NursingUnit: LD								
MOR10I Morphine Sulfate 10Mg 1Ml Vial				82	5	13.5	21	9.013
Brush, Janelle	69	69						

RxAuditor: Rx Diversion Index

Station Name: cabinet (ADM) or group of cabinets (can be defined)

Med Group: For example, hydrocodone or oxycodone could be multiple strengths/formulations

Group Members

Statistical Outliers By Station											
5.0 or Greater Units of Standard Deviation Above Mean											
Station	Med Group	User Name	Count	Mean	Assurance Metrics						
					UAM	% TDC	TriageRx	TrendRx	ProjectRx		
ED	Oxycodone	Charming, Prince	18	2.430	6.058	9.375%		—	—	6.06	—
CICU	Propofol	Fiona, Princess	49	8.138	5.213	7.527%		—	—	5.21	—
4.0 - 4.9 Units of Standard Deviation Above Mean											
Station	Med Group	User Name	Count	Mean	Assurance Metrics						
					UAM	% TDC	TriageRx	TrendRx	ProjectRx		
TRAUMA	Propofol	Stepmother, Wicked	30	5.712	4.806	7.194%		—	—	4.81	—
PACU	Percocet	White, Snow	26	4.114	4.680	18.056%		—	—	4.68	—
MICU	Hydromorphone	Duck, Daisy	39	7.286	4.663	12.745%		—	—	4.66	—
CICU	Benzodiazepine	McQuack, Launchpad	12	2.119	4.659	13.483%		—	—	4.66	—
OB	Tramadol	Hook, Captain	11	2.129	4.645	16.667%		—	—	4.64	—
NEURO	Oxycodone	Godmother, Fairy	24	3.829	4.556	15.287%		—	—	4.56	—
SICU	Fentanyl	Cricket, Jiminy	19	3.458	4.514	7.631%		—	—	4.51	—
ED	Hydrocodone	Hood, Robin	9	2.265	4.484	5.844%		—	—	4.48	—

RxAuditor: Rx Diversion Index

UAM (units above mean):
commonly referred to as Standard Deviation

% TDC:
this user's percentage of total for the med in question

TriageRx:



- A. Drug Audit Report (Station) ✓ Left side of the triangle
- B. Drug Audit Report (Hospital) ✓ Right side of the triangle
- C. Daily Average Drug Audit Report (Station) ✓ Base of the triangle

TrendRx:
A snapshot of this user's activity over the last 3 months

ProjectRx:
A prediction of what this users' activity will score if they continue on this path

Mean:
Average removed for the group

Count:
total number removed (for the med listed)

Statistical Outliers By Station										
5.0 or Greater Units of Standard Deviation Above Mean										
					Assurance Metrics					
Station	Med Group	User Name	Count	Mean	UAM	% TDC	TriageRx	TrendRx	ProjectRx	
NEURO	Oxycodone	Mouse, Minnie	67	11.035	5.121	10.652%		— 3.20		5.12
4.0 - 4.9 Units of Standard Deviation Above Mean										
					Assurance Metrics					
Station	Med Group	User Name	Count	Mean	UAM	% TDC	TriageRx	TrendRx	ProjectRx	
ICU	Oxycodone	Duck, Donald	97	14.217	4.932	9.888%		— — 4.93		—
BEH	Benzodiazepine	White, Snow	16	2.610	4.908	14.953%		— — 4.91		—
PACU	Fentanyl	Charming, Prince	17	3.819	4.574	4.239%		— — 4.57		—
MED/SURG	Morphine	McDuck, Scrooge	15	2.406	4.419	19.481%		— — 4.42		—

Transaction Reports

ADM	Report Name
Acudose	Station Details (by User)
Knowledge Portal*	All Transaction Activity Detail
Omnicell	Transactions by User
Pandora ⁺	Activity
Pyxis	All Device Events
RxAuditor ⁺	Detail Report
*Pyxis Only ⁺ Acudose, Omnicell, and Pyxis	

Pyxis Recommended Criteria

Date Range	Whatever is needed, up to ~60 days*
Devices	All
Med Classes	All
Meds	All
Transaction Types	All
Users	<select user of interest>

*Transaction data beyond 60 days can be sent from BD Carefusion Knowledge Portal report

Pyxis Transactions (CSV format)

Several Columns Deleted for ease of viewing; turned on auto filter

Manually Added Columns: administration amount, administration time, comments, amount missing

	A	G	I	J	L	M	O	P	AI	AJ	AL	AO	AP	AQ	AR	AS	AT	AU
1	UserNa	Device	MedID	MedDescription	M	Transaction	Quantit	QtyUO	ID	Patient	TransactionDateTim	Ses	Se	admin amount	admin time	comments	unacco	ted for
2	Duck, Don	ICU	63710719	oxyCODONE IR (Roxicodone) 5 mg T	2	Remove		1 Tab	2101976112	MERMAID	10/3/2018 9:43	#####	####					
4	Duck, Don	ICU	63700124	acetaminophen (Tylenol Extra Strer U		Remove		2 Tab	2101976112	MERMAID	10/3/2018 9:43	#####	####					
6	Duck, Don	ICU	63612378	fentaNYL (Sublimaze) 100 mcg/2 mL	2	Remove		1 Inj	2101985311	BEAR, BAL	10/3/2018 14:19	#####	####					
8	Duck, Don	ICU	63612378	fentaNYL (Sublimaze) 100 mcg/2 mL	2	Remove		1 Inj	2101985311	BEAR, BAL	10/3/2018 15:03	#####	####					
10	Duck, Don	ICU	63604177	ondansetron (Zofran) 4 mg/2 mL (2 t U		Remove		1 Inj	2101985311	BEAR, BAL	10/3/2018 15:43	#####	####					
12	Duck, Don	ICU	63710719	oxyCODONE IR (Roxicodone) 5 mg T	2	Remove		1 Tab	2101953095	BEAGLE, B	10/3/2018 16:14	#####	####	5mg	1615	pain score 4; ordered for pain score 1-3		
13	Duck, Don	ICU	63612378	fentaNYL (Sublimaze) 100 mcg/2 mL	2	Waste		50 mcg	2101985311	BEAR, BAL	10/3/2018 17:13	#####	####					
15	Duck, Don	ICU	63603096	HYDRomorphone (Dilaudid) 1 mg/1	2	Remove		1 Inj	2101968010	SMITH, JO	10/4/2018 11:31	#####	####			whole dose wasted 1: 1mg		
17	Duck, Don	ICU	63710719	oxyCODONE IR (Roxicodone) 5 mg T	2	Remove		2 Tab	2101968010	SMITH, JO	10/4/2018 11:33	#####	####	10mg	1134	pain score 8; by another RN		
19	Duck, Don	ICU	63747281	albuterol-ipratropium (Duoneb) (3 t U		Remove		1 Soln	3041686514	CATCHER,	10/4/2018 13:47	#####	####					
20	Duck, Don	ICU	63603344	ketorolac (Toradol) 30 mg/1 mL (1 m U		Remove		1 Inj	3041686514	CATCHER,	10/4/2018 14:13	#####	####	30mg	1415	pain score 5		
22	Duck, Don	ICU	63604177	ondansetron (Zofran) 4 mg/2 mL (2 t U		Remove		1 Inj	3041683214	DEVIL, CRI	10/4/2018 15:43	#####	####			no admin; is he caring for this patient?		
24	Duck, Don	ICU	63607477	diazePAM (Valium) 10 mg/2 mL (2 m	4	Remove		1 Inj	3041641741	GOOSE, M	10/4/2018 16:39	#####	####	2.5mg,2.5mg	1643,1717			
26	Duck, Don	ICU	63603096	HYDRomorphone (Dilaudid) 1 mg/1	2	Remove		1 Inj	3041641741	GOOSE, M	10/4/2018 16:39	#####	####	0.5mg,0.5mg	1644,1654	pain score 10 each time		
27	Duck, Don	ICU	63603096	HYDRomorphone (Dilaudid) 1 mg/1	2	Remove		1 Inj	3041641741	GOOSE, M	10/4/2018 17:09	#####	####	0.5mg,0.5mg	1710,1744	pain score 7,5		
29	Duck, Don	ICU	63607477	diazePAM (Valium) 10 mg/2 mL (2 m	4	Waste		1 mL	3041641741	GOOSE, M	10/4/2018 17:48	#####	####			waste		

Omnicell Recommended Criteria

Date Range	Whatever is needed, up to at least 7 years
Omni	All
Item Control Levels	All
Transaction Types	All
Users	<select user of interest>

Note: you may want to request a “Report Abbreviation Key” with any reports requested, which will define fields that may otherwise be unclear

Omnicell Transactions (XLS format)

Several Columns Deleted for ease of viewing; turned on auto filter

Manually Added Columns: administration amount, administration time, comments, amount missing

	A	B	D	G	H	I	Q	R	S	U	V	Y	AA	AB	AC	AD	AE
1	pat	omni s	xact date	xf	xfers	qty	user name	witnes	was	rx_name	pat_nar	str_unit	loginpos	admin amt	admin time	comments	amt missing
2	H0006	OCICU	2018121606113700	I	I-UN	1	Duck, Donald			MAGNESIUM SU 1GM/100ML 100ML BAG	GOOSE, M GM		N				
3	H0006	OCMS	2018121520003500	I	I-UN	2	Duck, Donald			ACETAMINOPHEN 325MG TAB	CRANE, I MG		N				
4	H0006	OCMS	2018121520493600	I	I-UN	2	Duck, Donald			oxyCODONE/APAP 5-325 MG 1TAB	MUDDLEFTAB		N				
5	H0006	OCMS	2018121920330900	I	I-UN	1	Duck, Donald			oxyCODONE/APAP 5-325 MG 1TAB	SMITH, J TAB		N				
6	H0006	OCMS	2018122001510000	I	I-UN	1	Duck, Donald			oxyCODONE/APAP 5-325 MG 1TAB	HEADLES TAB		N				
7	H0006	OCMS	2018122001552500	W	W-WS	1	Duck, Donald	Mouse, M	1	oxyCODONE/APAP 5-325 MG 1TAB	HEADLESS TAB		N			whole dose waste	
8	H0006	OCMS	2018122003275900	I	I-UN	2	Duck, Donald			oxyCODONE/APAP 5-325 MG 1TAB	MERMAID TAB		N				

Acudose Recommended Criteria

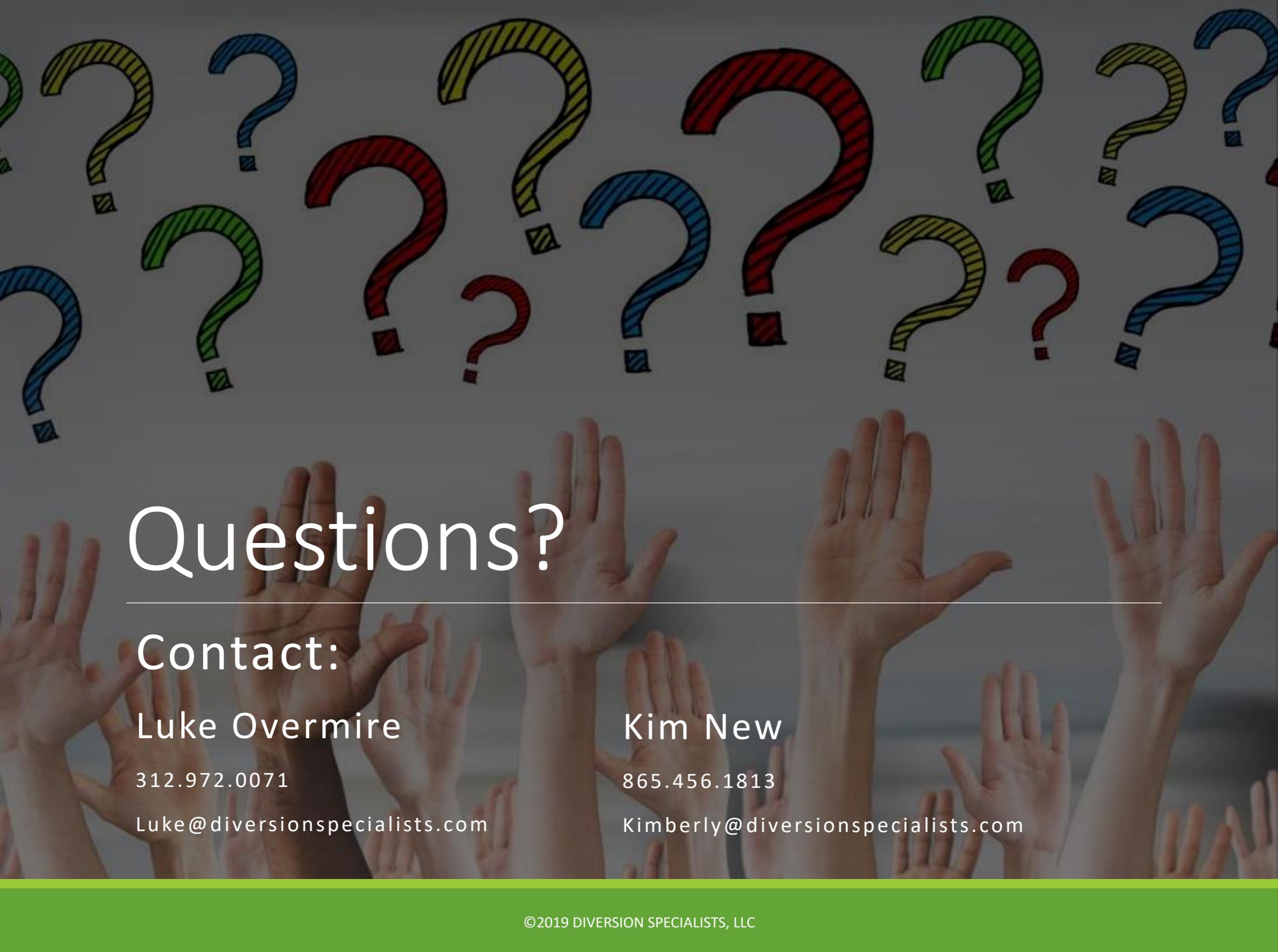
Date Range	Specify date range
Station	All
From DEA Code to DEA Code	Rx (to) 5
Transaction Types	All
Users	<select user of interest>

Acudose Transactions (XLS format)

Several Columns Deleted for ease of viewing; turned on auto filter

Manually Added Columns: administration amount, administration time, pain score, order info, comments, amount missing

	B	C	D	E	F	G	J	K	L	N	Q	Y	Z	AA	AB	AC	AD	AE	AF	AG	AA
1	STATI	Event Type	Trans	Medication	User	Patient	Event Date Time	Can	Discr	Waste	Witne	Admin Time	Pain	Order	Comm	Missing					
2	ICU	Profile Dispense	0.000	LORAZEPAM 2MG/ML 2 MG VIAL	By Duck, Rose		4/28/2019 9:50:43 AM	*****	TRANSACTION			CANCELED	N/A								
12	ICU	Profile Dispense	2.000	OXYCODONE (IR) 5 MG TABS (0	By Duck, Tulip		4/16/2019 12:51:35 PM					0 mg	12:53	10	TID prn pain						
14	ICU	Profile Dispense	2.000	OXYCODONE (IR) 5 MG TABS (0	By Duck, Marigo		4/16/2019 5:37:00 PM					0 mg	17:38	8	TID prn pain						
36	ICU	Profile Dispense	1.000	GABAPENTIN 400 MG CAPSULE	By Duck, Grass		4/16/2019 8:37:17 AM														
44	ICU	Profile Dispense	1.000	GABAPENTIN 400 MG CAPSULE	By Duck, Grass		4/18/2019 8:48:09 AM														
51	ICU	Profile Dispense	1.000	CLONAZEPAM 1 MG TABS (51079-0882-	By Duck, D Daffodi		4/10/2019 9:10:15 AM					1 mg	9:48	N/A	QID	Pulled over 30 min prior to administration					
52	ICU	Profile Dispense	1.000	GABAPENTIN 100 MG CAPSULE (00904-	By Duck, D Daffodi		4/10/2019 9:10:26 AM					100 mg	9:48		TID	Pulled over 30 min prior to administration					
55	ICU	Profile Dispense	1.000	TRAMADOL HCL 50 MG TAB (68382-031	By Duck, D Daffodi		4/10/2019 9:11:07 AM					50 mg	9:48		BID	Pulled over 30 min prior to administration					
61	ICU	Profile Dispense	1.000	ONDANSETRON HCL 4mg/2ml 1 EA VIAL	By Duck, D Daffodi		4/10/2019 10:31:06 AM					4 mg	10:34		One	One time order					
63	ICU	Profile Dispense	1.000	CLONAZEPAM 1 MG TABS (510	By Duck, Daffoc		4/10/2019 12:26:18 PM					1 mg	12:36		QID						
64	ICU	Profile Dispense	1.000	GABAPENTIN 100 MG CAPSULE	By Duck, Daffoc		4/10/2019 12:26:27 PM					100 mg	12:36		TID						
65	ICU	Profile Dispense	1.000	morPHINE SULFATE 2MG per 1M	By Duck, Daffoc		4/10/2019 3:29:19 PM					1 mg	15:35	9	Q 12 prn pain 8-10						
66	ICU	Profile Dispense	1.000	CLONAZEPAM 1 MG TABS (510	By Duck, Daffoc		4/10/2019 5:15:27 PM					1 mg	17:28		QID						
67	ICU	Waste	1.000	morPHINE SULFATE 2MG per 1ML INJ 2 M	By Duck, D Daffodi		4/10/2019 7:06:22 PM					Waste Me Mouse Minnie			Delayed waste over 3 hr 30 min						
68	ICU	Profile Dispense	1.000	CLONAZEPAM 1 MG TABS (51079-0882-	By Duck, D Daffodi		4/12/2019 8:46:44 AM					1 mg	9:31		QID	Pulled 45 min prior to administration					
69	ICU	Profile Dispense	1.000	GABAPENTIN 100 MG CAPSULE	By Duck, Daffoc		4/12/2019 8:46:53 AM					100 m	9:31		TID						
76	ICU	Profile Dispense	1.000	CLONAZEPAM 1 MG TABS (510	By Duck, Daffoc		4/12/2019 11:55:07 AM					1 mg	12:18		QID						
77	ICU	Profile Dispense	1.000	GABAPENTIN 100 MG CAPSULE	By Duck, Daffoc		4/12/2019 11:55:23 AM					100 m	12:18		TID						
79	ICU	Profile Dispense	1.000	TRAMADOL HCL 50 MG TAB (68	By Duck, Daffoc		4/12/2019 12:21:19 PM					50 mg	12:22		Q 8 hr						
80	ICU	Profile Dispense	0.000	CLONAZEPAM 1 MG TABS (510	By Duck, Daffoc		4/12/2019 5:48:16 PM	***	*****	DISCREPANCY CREATED -- EXPECTED 7, END QTY 1 -- RESOLVED											



Questions?

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