

Attachment 8

ADDS QUESTIONNAIRE

Vendor name: Becton Dickinson
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1. In what specific patient care settings would this ADD be used? Pyxis MedStation ES System (ADDS) are compatible with a variety of care settings, and are routinely and effectively used throughout health systems (acute care), which include ambulatory surgery centers, nursing homes, rehab facilities, and long term acute care. Some of these settings can involve remote locations. Becton Dickinson has had specific questions brought to us from a large California metropolitan fire department medical team specifically asking about controlled drug acquisition, perpetual inventory, storage and accounting, as well as management of other non-controlled medications. Our responses address remote settings within health systems (acute care) and settings specific to emergency management services (EMS). EMS locations could include, ambulances both stationary and in transit as well as all locations where emergency medical technicians provide care.

What are the security requirements for the remote location to ensure that medication access is limited to authorized providers? Authorized access to medications in the Pyxis ES System can be assured through a software-based centrally managed user privilege system that can store a pre-configured, electronically stored list of authorized users, including bioID data such as fingerprint images. The system would allow medication access only to authorized users. Authorized users use fingerprint and UserID combinations to gain access to the system. Pyxis ES (ADDS) cabinets are encased in steel boxes with locking drawers, which also provide a level of security. In the case of EMS response teams, the above security capabilities can suitably prevent unauthorized access in the central storage area (such as a firehouse) and treatment areas such as remote locations.

2. How will Pharmacists review medication orders? For pharmacist to review medication orders, the orders need to be made available to a pharmacist in advance of administration to the patient. In an acute care environment where a health information system (HIS) is present, medication orders are computer-entered into a health information system by a physician and then electronically forwarded to the pharmacist for review. The pharmacist approval would then need to go through an electronic interface to the ES Pyxis cabinet (ADDS) allowing the controlled release of the medication to the caregiver. In EMS environments, EMT/ambulance response and treatment circumstances typically do not allow prospective medication ordering by physician, or review by a pharmacist. In these settings, emergency medical technicians work under a pre-set therapy protocols from staff physicians, and through base-radio contact. Medication orders are typically reviewed in retrospect by trained medical professionals – which in some cases may be pharmacist for quality audits.

Is there an interface or other method that allows for prospective review, or is this only retrospective? The Becton Dickinson Pyxis ES System (ADDS) has interface capabilities which allow the system to import pharmacist-approved physician orders from an HIS. Once in the system, these orders are sent to the cabinets which restrict access to ordered medication only. For prospective review of medication orders, a physician's medication order must be computer-

entered into an HIS, and pharmacist then checks the order in the same system. Once the pharmacist check is complete, order information can be sent over an interface to a central Pyxis server. The Pyxis server sends messages to the (ADDS) cabinets, allowing access to specific medications. These interface capabilities allow for prospective review of medication orders by a pharmacist in acute care settings where an HIS is present. This process is typically in an acute care setting. In an EMS setting, field emergency situations preclude physician ordering into an HIS system and prospective review by a pharmacist may not be possible. Since the ordering and administration information may only be captured via manual documentation, retrospective review would be relegated to a manual process.

3. What specific features are available through the technology to ensure that the correct medication was removed per the provider's medication order? In a health System setting, the Pyxis Enterprise system "profile" capability allows medication removal from the Pyxis cabinet (ADDS) to be restricted to medications ordered by a physician for specific patient. This capability requires prospective medication ordering by a physician (CPOE) and prospective order review and checking by a pharmacist. Specifically, this process involves: 1) Medication orders entry into a HIS by a physician, 2) Pharmacist checking of the medication order in the HIS 3) Order transmission across an interface into the Pyxis ES System (ADDS) 4) Order transmission to the Pyxis cabinet 5) Nurse access becomes limited to secure individual storage compartments (Pyxis smart Cubie) that open one at a time, restricting access to the medication orders once the cabinet drawer opens. In EMS settings, emergency medical technicians work under a pre-set therapy protocols from staff physicians, and through base-radio contact. An HIS system is typically not present, orders are typically not computer entered, and in some cases samples of orders are reviewed in retrospect by trained medical professionals – which in some cases may be pharmacist, for quality audits.
4. What are the security features of the technology?
 - a. We support positive identification in order to access the MedStation device. There are two forms of positive identification that are supported:
 - i. BioID
 - ii. Barcode scan of user badge
 - b. Once the MedStation device is accessed, users can only access the medications that have been configured for that user and only for patients configured for that device.
 - i. In a profile system, pharmacists must approve a medication order prior to the nurse having access to that medication for that patient (exception for override medication(s) configured by the hospital)
 - ii. Users can be assigned roles that have associated privileges. A user can have multiple roles depending on the facility and responsibility (staff nurse at one facility vs. nurse manager at another)
 - c. Once all criteria have been met to access the medication, there are different drawer types available to store medications. The drawer types below focus only on those that provide single line item access for the user.
 - i. Single dose MiniDrawer
 1. One pocket exposes only one dose of the medication in that pocket

2. Once one dose is removed, system will pop open the next pocket in that tray exposing another dose of that medication
- ii. Multi dose MiniDrawer
 1. One pocket exposes multiple doses of that medication in that pocket
 2. Once all doses are removed, system will pop open next pocket in that tray exposing more doses of the medication
- iii. CUBIE
 1. Multiple CUBIEs can be loaded with the same exact medication and used in a sequential draining method
 2. Can configure one dose or multiple doses to be stored within a CUBIE pocket type

How is user access maintained and by whom?

- a. MedStation ES:
 - a. Supports the use of Active Directory; Active Directory is typically managed and maintained by the hospital IT department
- b. MedStation 4000 and earlier versions:
 - a. User management is supported within the console application
 - b. Users can be managed and maintained by whoever has the appropriate privileges to do so. Typically, this has been an activity supported by pharmacy
 - c. There are settings to help with user management and maintenance such as user templates (standardize privileges) and inactivity notifications

Who has the ability to remove medications?

- c. Users can be configured in the system to only perform certain transactions for a particular group of medications – for example, respiratory therapists can only remove respiratory medications

5. **How are remote devices restocked?** To restock Pyxis ES System (ADDS) cabinets in remote settings in health System environment, the following steps would be involved in restocking remote automated dispensing devices, fully using the Pyxis ES capabilities:
 - a. Generating refill reports for remote stock areas for drugs have fallen below their PAR level.
 - b. Medications below PAR are then removed from the secure CII Safe Pyxis System and bar code checked.
 - c. Using Pyxis ES Mobile dock, medications would be filled into secure Cubies using a bar code verification process. This process will embed medication ID into the microchip on-board the Cubie.
 - d. Secure transport of the locked Cubies to the remote automated dispensing cabinet
 - e. Bar code based placement of filled Cubies into the remote automated dispensing station (the chip syncs with the Pyxis ADD cabinet assuring accurate filling)
 - f. Routine monitoring of refill process through transaction reporting.
(Note – some of the above products are in development stages and general availability may vary)

In an EMS setting, steps a, b and c could be completed per the above process. Since Pyxis Mini has not yet been modified to work in a mobile vehicle. Until modifications are complete steps d, e and f would work as follows:

- d. Medications removed from the secure CII Safe or Pyxis System pending refill would be bar code checked on removal and placed in secure transfer containers and taken to the fire trucks and ambulances.
- e. Double-locked boxes would be opened and medications would be placed in the boxes.
- f. Medications would be added to the manual written inventory in the vehicle.

If the medication is transported after being checked by the pharmacist, what features are available that provide detection of a tampered container? In a health system environment, Cubies used for secure transport cannot be opened by unauthorized people without traumatic damage to the Cubie structure (tamper evident). Upon arrival at the Pyxis ES cabinet, the Cubies can be scanned by authorized users and appropriate drawers in the Pyxis ES cabinet (ADDS) will open, allowing placement of the Cubie and electronic syncing of the Cubie contents to the Pyxis ES cabinet. The Electronic sync accurately communicates the Cubie contents eliminating the possibility of miss-filling error. Additionally, reporting capabilities provide a chain of custody record of medication removal from the central storage area, and refill into the remote ADD unit. For controlled drugs, CII Safe serves as the central repository and perpetual inventory management system. Once a narcotic is removed from CII-safe, the CII Safe system monitors for the corresponding remote Pyxis ES cabinet (ADDS) replenishment event to form a closed loop monitoring system, all of which is reportable. In an EMS environment, Cubie transport would not be available for medications stored in mobile trucks or ambulances. Once Pyxis cabinets (ES Mini) has been modified to work in this environment, Cubies could be used as a secure transport method

6. Can controlled substances be stocked? Yes

If so, what additional security features are available?

- a. Blind Count – which asked the user to count the remaining number of medication in the storage pocket without informing them of the prior count.
- b. Witness required options – requiring a second authorized person to witness either a medication removal return or waste.
- c. Routine inventory
 - i. Accessed/Non-accessed inventory
- d. Enforce waste upon remove workflows when necessary
- e. Undocumented waste
- f. Menu timeout/open drawer timeout
- g. Clinical Data Category to gather reason for override

7. How would patient consultant occur? For patient consultant to occur, as is the case in retail pharmacy settings, the pharmacist would have to be immediately available and have had a chance to review the order prior to the medication delivery or administration. In the case of EMS environments, EMT/ambulance response and treatment circumstances consultant by a pharmacist is not possible since they are not present. In these settings, where emergent

condition precludes emergency medical technicians often provide the needed patient consultation.

8. How would the ADDS remote user interact with the pharmacists? In acute care settings, the physician has the ability to enter the medication order into the HIS, and of the pharmacists has access to the HIS, which provides a method for interaction. In the case of EMS environments, EMT/ambulance response and treatment circumstances consultant by a pharmacist is not possible since they are not present. In these settings, where emergent condition precludes emergency medical technicians often provide the needed patient consultation.

9. What technology options exist?

In the EMS settings, where EMT's need additional medical or pharmacy-related assistance, they contact a physician via radio for additional guidance.

10. How would the pharmacist detect drug diversion for medications stocked in the ADDS?
What reports are available to allow the pharmacist to monitor safe use of the ADDS technology?

Please provide examples of these reports

- a. Discrepancies are created if the count is incorrect between removals with Blind Count or Verify Count enabled for the pocket
- b. Initiating the resolution of a discrepancy depends on user privileges; a witness is required for this process
- c. Discrepancy reports can be filtered by open, closed or all
- d. Other reports:
 - i. CIISafe Compare
 1. CIISafe manages controlled substances for pharmacy
 2. Compare report reflects where a refilled or loaded quantity does not match the quantity removed to be delivered from pharmacy
 - ii. CIISafe Proactive diversion search
 1. Shows those users above average for CS removals
 - iii. Migration Summary
 1. Monthly summary of all transactions (including discrepancies) for each controlled substance
 2. Includes running total for each transaction type and ending balance for the month
 - iv. MedStation All Station Events reporting
 1. Any transaction type can be filtered as a report by user or device
 - a. Overrides
 - b. Removes
 - c. Cancelled transactions
 - d. Wastes
 - e. Undocumented wastes
 - v. User modifications
 - vi. Temporary patient activity
 - vii. CS inventory counts – review compliance with policies and procedures

11. What specific law changes are recommended to support the use of this remote ADDS technology.

1. Authorize fire stations / and other public emergency response providers that administer controlled substances and other drugs as a part of their legal emergency response capabilities to legally order them.
2. Require these providers to maintain an electronic or manual perpetual inventory, and legally prove through electronic and manual documentation the dispensation of each dose, and provide waste documentation every amount of drug container that exceeded the dose administered to the patient authorized and verified by two caregivers.
3. Set regular inspection intervals for controlled drug management.
4. Require these providers to report to the Board and DEA any and all losses of controlled drugs which cannot be accounted for.

Please submit completed questionnaire to Debbie Damoth by FAX at (916) 574-8618 or by email at Debbie.damoth@dca.ca.gov by 5pm Feb. 10th



Migration Summary Report

Pyxis Corporation
Torrey Pines Road
San Diego, CA 92065

Grouped by: Schedule
Sorted by: Med

Report Parameters

Date Range: 05-01-2004 00:00:00 to 06-16-2004 23:59:59	Stock Type: Accessible And Secured	Schedule: ALL
Activity: Include Meds With No Tx Activity	Med Status: Exclude Inactive Meds	

Schedule II Meds

Med Name (Med ID)	Inv Type	Start Count	Subtractions						Additions				Discrepancy Resolution	Net Change	Final Balance	
			Send	Rx	Waste	Sale	Used In Cmpd	Move Out	Receive	Return	Made Into Cmpd	Move In				
ALFENTANIL HCL INJ 2 ML (5001201)	A	459	0	0	12	0	0	0	0	0	0	0	0	0	-12	447
	S	100	0	0	0	0	0	0	0	0	0	0	0	0	0	100
ALFENTANIL HCL INJ 5 ML (5001235)	A	500	0	0	0	0	0	0	0	0	0	0	0	0	0	500
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALFENTANIL HCL INJ 10 ML (5001268)	A	510	0	0	0	0	0	0	0	0	0	0	0	0	0	510
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BELLADONNA-OPIUM 30MG - 15A (5004296)	A	482	0	0	0	0	0	0	0	0	0	0	0	0	0	482
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BELLADONNA-OPIUM 60MG - 16A (5004320)	A	411	0	0	0	0	0	0	0	0	0	0	0	0	0	411
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CODEINE PHOSPHATE INJ 60 MG (5009998)	A	575	0	0	0	0	0	0	0	0	0	0	0	0	0	575
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CODEINE SULFATE TAB 30 MG (5009964)	A	688	0	0	0	0	0	0	0	0	0	0	0	0	0	688
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
D-AMPHETAMINE SULFATE 5 MG (5012653)	A	527	0	0	0	0	0	0	0	0	0	0	0	0	0	527
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FENTANYL 0.025MG/ML in 1/2NS (35)	A	502	0	0	0	0	0	0	0	0	0	0	0	0	0	502
	S	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CII Safe

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Migration Summary Report

6/16/04 4:34:19PM



Proactive Diversion Report

Sorted By: Doses Per Day

General Hospital
10020 Pacific Mesa Blvd
San Diego, CA 92121

Report Parameters

Date Range: 02/21/2016 00:00:00 to 02/23/2016 23:59:59	Location: ALL
Med: ALL	Schedule: ALL
Std Dev's: More than 2 Standard Deviation's Above the Mean	

<u>User</u>	<u>Days</u>	<u>Doses</u>	<u>Doses Per Day</u>	<u>Std Dev's Above the Mean</u>
MSUser, Nurse596	1	32	32	+ 5
MSUser, Nurse73	2	54	27	+ 4
MSUser, Nurse44	2	47	24	+ 3
MSUser, Nurse8	1	21	21	+ 2
MSUser, Nurse597	2	37	19	+ 2
MSUser, Nurse66	2	34	17	+ 2
MSUser, Nurse214	1	17	17	+ 2

<u>Usage</u>			
Sum of All Matching Doses :	1,768	Mean :	5.82544
Sum of All Matching Doses/Day :	1,106.833	Std Dev :	5.13113

<< End of Report >>

Inventory Verification

Provides a list of all inventory at one or more stations. You can use this report to verify that controlled-substance inventories have occurred or to see who has used the inventory function.

Fri Oct 31, 2008		INVENTORY VERIFICATION		17:49				
— build # 01.0.0.014 —								
REPORT SETUP PARAMETERS FOR MISSION HOSPITAL 654 UNIVERSITY AVE SAN DIEGO, CA 92121								
START TIME	:	10/30/2008	00:00					
END TIME	:	10/31/2008	17:49					
SORT MODE	:	BY STN/USER						
STATION	:	ALL STATIONS						
MED NAME	:	ALL MEDS						
MED CLASS	:	ALL CLASSES						
USER NAME	:	ALL USERS						
*** Only a partial report of the last day can be generated ***								
Med Classes:	1 = Misc. Controlled A, 2 = Controlled C-II, 3 = Controlled C-III, 4 = Controlled C-IV, 5 = Controlled C-V, C = PRN PROFILE, M = Non-controlled B, R = RESPIRATORY MEDS, U = Non-controlled A							
LOCATION:		MS4000						
Med Name		Med ID	Class	Drawer	Bag	End	Date	Time
Brand Name		Alt ID						
USER: User, Demo (DEMOUSER)								
rabies immune globulin (20U) 150 units / 1 mL VIAL		IN065HERAB	U	1-1	2	2	10/31/2008	17:45
IN065HPAB		25085157						
furosemide 20 mg / 2 mL INJ.		FUR020IV	U	1-2	30	30	10/31/2008	17:45
LASIX		2504435						
glyburide (10mg/2tab) 5 mg tablet		GLYB10TB	U	1-4	20	20	10/31/2008	17:45
DIABETA, MICRONASE		2508026						
ibuprofen 200 mg TABLET		IBUPR200	U	3-1	0	2	10/31/2008	17:45
NOTRIN		2508551						
**** DISCREPANCY in above transaction - EXPECTED 0, FOUND 2 ****								
RESOLUTION:								
Resolved By:	User, Demo	(DEMOUSER)	Reason:	Auto Resolved			10/31/2008	17:45
acetaminophen 325 mg TABLET		APAP325TB	U	3-2	50	50	10/31/2008	17:45
TYLENOL		2508949						
*magnesium sulfate 500 1 GR / 2 mL INJ.		MAG501	U	3-3	10	10	10/31/2008	17:45
*MAGNESIUM SULFATE		2503465						
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Profile Override

Lists all Profile Override transactions that occurred during the specified time frame. Review this report to be sure that overrides are removed per hospital policy (urgent and emergent), to be sure an order exists for the medication removed, and to monitor the timeliness and accuracy of order entry.

Mon Nov 03, 2008	PROFILE OVERRIDE	14:37							
- build # c7.0.0.019 -									
REPORT SETUP PARAMETERS FOR MISSION HOSPITAL 654 UNIVERSITY AVE SAN DIEGO, CA 92121									
START TIME : 10/30/2008 00:00 END TIME : 11/03/2008 00:00 ORDER LEAD TIME: 4 Hours ORDER LAG TIME : 4 Hours SORT MODE : BY PATIENT STATION : ALL STATIONS MED NAME : ALL MEDS MED CLASS : ALL CLASSES USER NAME : ALL USERS PATIENT NAME : ALL PATIENTS									
*** Only a partial report of the last day can be generated ***									
Med Classes: 1 = Misc. Controlled A, 2 = Controlled C-II, 3 = Controlled C-III, 4 = Controlled C-IV, 5 = Controlled C-V, C = PRN PROFILE, M = Non-controlled B, R = RESPIRATORY MEDS, U = Non-controlled A									
PATIENT: MOORE, Tiffany X (4815758G)									
Activity	Qty	Med Name Brand Name	Med ID Alt ID	Class	Drawer	Reg	End	Date	Time
LOCATION: MS4000									
RETURNED TO BIN	- 1	TYLENOL #3 30 mg / 325 MG TABLET(S) acetaminophen/codeine	JSCYLL3 2502826	3				10/31/2008 17:29	
		By: User, Demo (DEMOUSER)	Room/Bed:						
		Order Number: OVERRIDE							
----- Order History for this Patient: 10/31/2008 13:29 to 10/31/2008 21:29 ----- No data found ----- End of Order History for this Patient -----									
PATIENT: JOHNSON, Diane X (4816059F)									
LOCATION: MS4000									
For Official Use Only									

System Surveillance Options

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		
MEDSURG	Hydromorphone	DEBLASIO, YOLANDA	134	16.735	6.110	16.341%	▲	— 5.51	6.11	—	
MEDSURG	Meperidine	DEBLASIO, YOLANDA	44	6.524	5.331	16.058%	▲	— 4.74	5.33	—	
4.0 - 4.9 Units of Standard Deviation Above Mean											
Station	Med Group	User Name	Count	Mean	Assurance Metrics						
					UAM	% TDC	TriageRx	TrendRx	ProjectRx		
MEDSURG	Percocet	DEBLASIO, YOLANDA	50	6.733	4.754	24.752%	▲	— 4.10	4.75	—	
3.0 - 3.9 Units of Standard Deviation Above Mean											
Station	Med Group	User Name	Count	Mean	Assurance Metrics						
					UAM	% TDC	TriageRx	TrendRx	ProjectRx		
ICU	Fentanyl	BURKE, ANTHONY	13	1.611	3.937	44.828%	▲	—	3.94	—	
ICU	Tramadol	HAMMOND, BRANDY	10	2.675	3.911	9.346%	▲	—	3.91	—	
ICU	Morphine	HULL, DOROTHY	23	6.320	3.753	4.852%	▲	—	3.75	—	
MEDSURG	Morphine	DEBLASIO, YOLANDA	41	10.149	3.745	8.595%	▲	5.16	4.93	3.74	3.0360

- Classifies controlled substance outliers by statistical risk in descending order
- TriageRx triangulates the users controlled substance activity by analyzing house-wide, by care area and daily average usage by days worked compared to their peers.
- Help prioritize internal audits based on user activity