

Attachment 3

ADDS QUESTIONNAIRE

Vendor name Cubex

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1. In what specific patient care settings would this ADD be used? What are the security requirements for the remote location to ensure that medication access is limited only to authorized providers?

The Cubex solution is used in Skilled Nursing Facilities (SNF) as a secure automated First Dose/ Emergency Kit.

The Cubex unit in the SNF has a bio-id that is programmed with the fingerprints of the authorized providers ensuring only the proper users are able to access the medications in the Cubex.

2. How will the pharmacist review medication orders? Is there an interface or other method that allows for prospective review, or is review only retrospective?

A pharmacist will review orders as they are sent to the pharmacy for filling.

Yes, Cubex has an interface with Framework, QS1, Prodigy, and other long term care pharmacy information systems so a pharmacist can have a prospective review of the patient's prescription. After the review of the patient's prescription and determination of no adverse drug interactions, the patient profile is sent from the pharmacy information system to the Cubex.

3. What specific features are available through the technology to ensure that the correct medication was removed per the provider's medication order?

Each Cubie in the Cubex solution is programmed with a microchip for a specific medication. This chip tracks NDC, lot number, expiration date, facility name, unit in the facility if there are more than one at the location, location in the Cubex down to a specific drawer and location in said drawer, and quantity of each medication in each Cubie.

After pharmacists' prospective review for any drug interaction, the programming ensures when a nurse uses his/her bio-id fingerprint to access patient specific medication in the Cubex, only the drawer and Cubie lid of the correct medication is opened.

4. What are the security features of the technology? How is user access maintained and by whom? Who has the ability to remove medications?

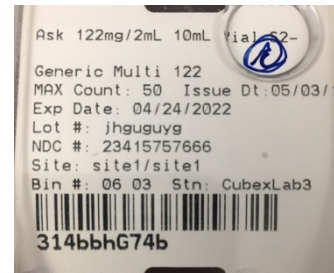
Security features include: Bio-id fingerprinting, witness, authorization passcode, divergence/discrepancy avoidance and notification, double lock access.

Authorized user access is maintained and monitored by pharmacy. However, the facility, if granted permissions by the pharmacy, can help maintain active users.

Only authorized users of the system can remove medications.

5. How are remote devices restocked? If the medication is transported after being checked by the pharmacist, what features are available that provide for detection of a tampered container?

Cubex programmable removable pockets are restocked at the pharmacy by a pharmacy technician and verified by a pharmacist before being removed from the Cubie Replenishment Station (CR Station). Once the pharmacist has verified the medication in the Cubie is consistent with label in the Cubie, the tamper evident programmed removable pocket is released from the CR Station and placed into a secure tote for delivery.



6. Can controlled substances be stocked? If so, what additional security features are available?

Yes, controlled substances can be stocked as each medication will have its own Cubie. The Cubex units are DEA compliant with double locks and are in medication rooms at the facility. Additionally, the Cubex solution security system is created specifically for controlled substances. Thus no additional features are present.

7. How would patient consultation occur?

1707.2 Notice to Consumers and Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility** licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

4074. Drug Risk: Informing Patient; Providing Consultation for Discharge Medications

(d) A health facility shall establish and implement a written policy to ensure that each patient shall receive information regarding each medication given at the time of discharge and each medication given pursuant to subdivision (a) of Section 4056. This information shall include the use and storage of each medication, the precautions and relevant warnings, and the importance of compliance with directions. This information shall be given by a pharmacist or registered nurse, unless already provided by a patient's prescriber, and the written policy shall be developed in collaboration with a physician, a pharmacist, and a registered nurse. The written policy shall be approved by the medical staff. Nothing in this subdivision or any other provision of law shall be construed to require that only a pharmacist provide this consultation.

****Note that: (f) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Public Health under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.**

8. How would the ADDS remote user interact with the pharmacist? What technology options exist?

The remote authorized user would interact via phone. However, if required, the pharmacist could be allowed to watch the actual screen while the remote user is accessing the Cubex.

9. 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 ADDS technology? Please provide an example of these reports.

Pharmacists utilizing a Cubex Solution have multiple ways to detect and track potential diversion.

DISCREPANCY OCCURANCE

Every transaction or "touch" to the system is tracked by the software and stored in the cloud. Cubex tracks quantity amounts for every transaction, e.g.: initial stocking, subsequent restocks, issue, waste, return, and cycle count (audit).

Additionally, with the countback or blind countback feature enabled, the software can require a manual count either confirming an amount based on the current software count shown on the screen (countback) or asking the user to provide a count without knowing what the software believes to be correct. In either case, if the count provided by the user doesn't match the current software count, the system will immediately flag a "Discrepancy (DI transaction type on all relevant reports)." This count discrepancy is immediately stored in the cloud for review and resolution by a system administrator.

A software feature called Discrepancy Notation can also be enabled requiring the user who caused the discrepancy to immediately notate what occurred (pill dropped, vial broken, unknown, etc.). These notes are stored in the cloud with the discrepancy transaction.

DISCREPANCY ALERT

Immediately, at the cabinet, with the software feature enabled, Cubex can notify anyone who comes to the cabinet that a discrepancy (or discrepancies, if more than one) is outstanding with an alert banner.

DISCREPANCY REVIEW & RESOLUTION

Review and resolution of any discrepancy can be either directly at the Cubex cabinet or from any web browser via myqlink.net (for those with specific user privileges).

AT THE CABINET

At the cabinet, once the discrepancy occurs, a Discrepancy Reviewer can discuss what occurred with the user who caused the discrepancy and make notes that are stored in the cloud.

A Discrepancy Resolver must then, based on the information provided, determine whether to resolve the discrepancy based on the information provided or do more research. If they determine the cause of the discrepancy and account for it, they can resolve the DI.

Final resolution of all discrepancies requires a Witness. The Cubex software will not allow the Review, Resolver, or Witness to ever be the same as the person who initially caused the Discrepancy.

THROUGH MYQLINK.NET (The "Cloud")

Resolution of Discrepancies from myQLink.net are performed almost identically to those at the cabinet.

Though numerous reports can be used to track the entire history of any item within the Cubex, controlled substance discrepancies are primarily tracking using the Discrepancy Unresolved, C2 report and the Resolved Discrepancy, C3 report. (see attached)

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

We would recommend clarification to CA PracAct 1261.6 allowing a nurse or pharmacy personnel to exchange the individual Cubies as they are programmed to only go into a specific location by the pharmacy creating a superior option to a manual tackle box for security and patient safety.

Please submit completed questionnaire to Debbie Damoth by fax at (916) 574-8618 or by email at debbie.damoth@dca.ca.gov by **5 p.m. Feb. 10.**

Unresolved Discrepancies, C2

02/08/2017 9:19:18 am

Pacific Standard Time

Date Range: 2/9/2016 - 2/8/2017

Cabinet Range: -

Item Range: -

Issue Date/Time	User Name	Witness Name	Patient Name	Cab-Bin	Item Description	Type	Auto Pending	On-Hand Before	Cntnr On-Hand Before	Found	Discrepancy	Issued/ Restocked	Units	Contnr	Sched	Dept	Doctor	
04/06/2016 10:35:09 pm	Nalock, Aaron	Hertzeg, Adam	Howard, Annette	Med Flex 2000-02 04	AMBIEN 5MG	B	False	16.00	6.00	10.00	-6.00	-2.00	TAB				4	
04/07/2016 7:10:28 am	Vitter, Anton			Med Flex 2000-02 04	AMBIEN 5MG	P	False	8.00	-6.00	14.00	6.00	0.00	TAB				4	
04/18/2016 7:43:07 am	Ruzinkskiya, Ashley			Med Flex 2000-02 04	AMBIEN 5MG	P	False	0.00	-1.00	1.00	1.00	0.00	TAB				4	
04/18/2016 8:20:46 pm	Parquette, Ben	Bill Chamberlik	Fleason, Bill	Med Flex 2000-02 04	AMBIEN 5MG	B	False	1.00	1.00	0.00	-1.00	0.00	TAB				4	
07/26/2016 2:59:49 pm	White, Braden			Med Flex 2000-02 04	AMBIEN 5MG	P	False	12.00	2.00	10.00	-2.00	0.00	TAB				4	
08/05/2016 12:59:12 am	Drake,wood Chelsea	Chris Henderman	Pachiarz, Cora	Med Flex 2000-02 04	AMBIEN 5MG	B	False	10.00	-2.00	12.00	2.00	-1.00	TAB				4	
03/27/2016 8:02:14 pm	Baldinattii, Damon			Med Flex 2000-02 06	ATIVAN 0.5MG TAB	P	False	29.00	1.00	28.00	-1.00	0.00	TAB				4	
04/19/2016 9:24:59 pm	Marshall, Danielle	Dave Clarkson	Powers, Desmond	Med Flex 2000-02 06	ATIVAN 0.5MG TAB	B	False	22.00	1.00	21.00	-1.00	-2.00	TAB				4	
03/12/2016 7:52:36 am	Fairclough, Dolly			Med Flex 2000-02 03	DURAGESIC 25MCG/HR PATCH	P	False	3.00	1.00	2.00	-1.00	0.00	PATCH				2	
03/12/2016 9:53:38 pm	Binghamton, Doren			Med Flex 2000-02 03	DURAGESIC 25MCG/HR PATCH	P	False	2.00	-1.00	3.00	1.00	0.00	PATCH				2	
05/01/2016 10:44:45 pm	Owens, Gillian			Med Flex 2000-02 03	DURAGESIC 25MCG/HR PATCH	P	False	8.00	1.00	7.00	-1.00	0.00	PATCH				2	
05/01/2016 10:48:18 pm	Capracotta, Jackson			Med Flex 2000-02 03	DURAGESIC 25MCG/HR PATCH	P	False	7.00	-1.00	8.00	1.00	0.00	PATCH				2	
06/15/2016 7:27:44 am	Burkshire, Jimmy			Med Flex 2000-02 03	DURAGESIC 25MCG/HR PATCH	P	False	6.00	-1.00	7.00	1.00	0.00	PATCH				2	
06/16/2016 6:53:48 am	Bedson, Jason			Med Flex 2000-02 03	DURAGESIC 25MCG/HR PATCH	P	False	7.00	1.00	6.00	-1.00	0.00	PATCH				2	
																2		

Resolved Discrepancies, C3

02/08/2017 10:46:24 am

Pacific Standard Time

Date Range: 12/1/2016 - 2/8/2017

Cabinet Range: -

Item Range: -

Issue Date Time	Cabinet Name	Item	Description1	Resolve Date/Time	UserName	Witness	Patient	Resolver	Resolve Witness	Type	Qty On Hand Found	On Hand Displayed	Discrep Units ancy	Con tainer	Sched Dept	Doctor	Reason
12/01/2016 8:08:23 pm	CubexRx:08 04	602010300 00103	TEMAZEPAM 7.5MG CAP	12/5/2016 11:28:18 am	Burkshire, Jimmy	Aaron Nalock	Fleason, Bill	avitter: Anton Visser	bchamberlik: Chamberlik, Bill	B	-2.00	10.00	11.00	-1.00 CAP	4		Count Error two counts back
01/13/2017 9:40:00 pm	CubexRx:01 18	571000600 00305	LORAZEPAM 0.5MG TAB	1/16/2017 6:23:26 am	Owen, Gillian	DFair: Dolly Fairclough	Fleason, Bill	avitter: Anton Visser	bchamberlik: Chamberlik, Bill	B			0.00		4		Count Error two counts back
01/14/2017 2:09:13 am	CubexRx:01 18	571000600 00305	LORAZEPAM 0.5MG TAB	1/16/2017 6:24:09 am	Bedson Jason	bwhite: Braden White	Baldinatti, Damon	avitter: Anton Visser	bchamberlik: Chamberlik, Bill	B	-1.00	14.00	18.00	-4.00 TAB	4		Count Error two counts back