

# **Attachment 1**

Questions	imgRx/ MedifriendRX	Cubex, LLC.	AscribeRx	Omnicell, Inc.	Asters Inc.	Arxium Innovative Pharmacy Solutions	Becton Bickinson	MedAvail Technologies , Inc.	Pharmacist Bardas	PharMerica
1. In what specific patient care settings would this ADD be used?	Community clinics	SNFs	Hospitals, SKFs, Assisted Living, Jails, Multi-doctor offices	Anywhere prescriptions need to be secured/ accounted LTC, ALF, adult day care, hospice, PACE, EMT/ fire dept.	Pick up of patient-specific finished prescriptions by RPH	Remote clinic where main pharmacy is associated with clinic	Acute health care system - ambulatory, nursing home, rehab, and LTC	Tailor to each scenario: hospital emergency, clinics, surgery center, retail, employer, LTC	Ambulatory surgery centers	LTC/skilled settings
What are the security requirements for the remote location to ensure that medication access is limited only to authorized providers?	Secure to prevent unauthorized access	Bio-id with fingerprint	Locked room, unique user names, licensed personnel, camera, electronic tracking	Hierarchy for access	Security cameras, biometric ID, pin, login with pin, photo, signature	Locks on every cabinets; authorized users have key	Authorized access, lists of user, bio data like fingerprint, user IDs, ADDS encased in steel	Medication from robotic device facilitated by a real time RPH	Secured area location	Only PharmMerica can grant access to an authorized provider
2. How will the pharmacist review medication orders?		As order is sent to the pharmacy	RPH conducts prospective view; machine then fills order	RPH enters approved order into system and real-time access the cabinet	By RPH at pharmacy	Faxed or scan of the rx from the clinic; RPH reviews/ approves	Electronic interface	RPH views through pharmacy management system	Consultant RPH audits	
Is there an interface or other method that allows for prospective review, or is review only retrospective?		Yes		All prospective except, override, ekit or emergent first dose.	N/A		Yes to import dr/rph approved orders into HIS except for EMT/field emergency	Electronic or scanned prescriptions	Only retrospective	Retrospective; for narcotics, RN must contact the pharmacy prior to dispensing upon RPH approval

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3. What specific features are available through the technology to ensure that the correct medication was removed per the provider's medication order?		Microchips for medicines; Bio-id verification	ACRS chip - to establish a unique identifier for each canister of medication; f/u scan of medicine	Safety Stock software and barcode technology	N/A	Barcode for prepackaged medicine	Profiles system of Pyxis	Predetermined prepackaged medicines; verification by barcode; human loads packages to be stocked on robot	Only RNs	Barcoding
4. What are the security features of the technology?		Bio-id, witness, passcode, divergence/discrepancy avoidance & notification, double lock access	Monitor users and unique passwords, policies, training, password lockout, secured room	Safety Stock, barcodes, alarms, notification, locks, pharmacy notified, data encrypted	Secure access, audit tracking 100%, photo, signature, ID verification, secure prescriptions, auto return to stock	User security for restock and dispensing	BioID, barcode scan of user badge; For user access only for patients; roles assigned to users; different drawers available for storage	10-gauge steel, touchscreen, audio/visual, data and power monitoring systems	Nurse administrators and RPHs have console privileges	Barcoding, biometric
How is user access maintained and by whom?		Pharmacy	Pharmacy/authorized personnel	PIC		Super user with key	ES -active directory; 4000 and earlier versions-user management within console	Pharmacy staff deploying robot; access user cards	RNs and RPHs	Pharmacy is notified of intrusion
Who has the ability to remove medications?	After consultation	Authorized users	Authorized users - electronic and video monitor	RPH/intern to restock, return and maintain; nurse to administer	Pharmacy staff	Super user with key	Users configured by the system for certain actions	Access user cards	RN administrator and RPHs	Licensed RNs and pharmacy staff

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5. How are remote devices restocked?	Supplier, RPH, pharmacy technician	At pharmacy by pharmacy technician & verified by RPH	Pharmacy permittee; RPH verifies, affixes label and placed tamper evident seal	RPH/inter, tech using Safety Stock and barcode.	Pharmacy staff with pharmacy manager sign off		Procedures for restocking - reports, mobile dock, secure transport, barcode	Pharmacy staff deploying robot	RN	Via secure tote from pharmacy
If the medication is transported after being checked by the pharmacist, what features are available that provide for detection of a tampered container ?	Supplier, RPH, pharmacy technician	Verified, released in secure tote for delivery	Locked tote opened by licensed user	Checked at pharmacy; recommend pedigree or manifest			Cubies tamper evident structure	Robot stocks; secured tote also used		Barcode
6. Can controlled substances be stocked?		Yes	Yes	Yes	Yes		Yes	No	Yes only for CS now	Yes
If so, what additional security features are available?	Images captured, scanning	Its own Cubie	Electronic and video monitor; policies and procedures	Safety Stock, barcode, two RN witness, blind count and flags, end of shift count	Can configure ID verification and/or rx held by RPH	Match NCD number and quantity	Blind count, witness, routine inventory, enforce waste, undocumented waste, menu time out, data for override		See above	Any discrepancy requires further research
7. How would patient consultation occur?		Not required in health care facility 1707.2(a)(3) and 4074(d)	Telephone, video conference or writing	Pursuant to laws, video or Skype	Counseling received before rx receipt; patients call for counsel and rx is released by RPH	Technician at the clinic and RPH at the pharmacy via Skype	Retail-RPH has to be available; Emergency - not possible	Real-time via audio/video feed while the robotics are selecting the medicine	Not required when MD present	When prompted by RN staff

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8. How would the ADDS remote user interact with the pharmacist? What technology options exist?		Phone, could watch the actual screen	Video, internet camera, kiosk, phone	Real time interface unless ekit/ first dose requires override. Controlled substance manager-analytic software; video feeds	Phone, video consult	Video conferencing	Acute care-physician enters information & RPH reviews; Emergency-not available	Audio/video communication to call RPH on duty or back up telephone	RPH audits monthly	Clinical support for after hours and routine consultant RPH
9. How would the pharmacist detect drug diversion for medications stocked in the ADDS?		Discrepancy occurrence; alert; review and resolution; at cabinet; cloud	electronic and video tracking, alerts	Report to PIC via email; alarm, controls locked, blind counts, witnesses		Reports show who restocks and dispensed for patient and time period.	EMT - contact physician via radio guidance	Receive/ check the medicines	Audits, discrepancy reports, transactions compared to CDR and HER	Email to the pharmacy if unauthorized user or discrepancy

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What reports are available to allow the pharmacist to monitor safe use of ADDS technology?		Many; discrepancy unresolved, C2 report and the resolved discrepancy, C3 report	Activity reports with many parameters	Discrepancy , null, dispensing error, Safety Stock, med override, waste, return, dispensing practice	Reports for 100% tracking of rxs		Various-discrepancy, CII inventory, CII diversion, monthly transactions, overrides, removes, cancelled, wastes, user modification, patient activity, inventory	Discard bin emptied, dispensed packages, package summary, package details, physical access all doors, physical access failed, quarantined harvest packages, stocking, removed, who removed it, packages dispensed, details of stocked, details of stocking reiects		Daily transaction reports

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10. What specific law changes are recommended to support the use of this remote ADDS technology?	4186 - amend to allow operation not under the clinic license; 4119.1 - board has discretion to allow ADDS in any licensed health facility	Clarification to CA Prac Act 1261.6 - allow RN or PHY personnel to exchange Cubies	Allow placement of ADDS without advanced Board approval; add by Board vote and not regulation; language to allow pharmacy staff/ authorized personnel to load sealed canisters to machines	Regulations for ALF, residential, EMT/fire; nurses authorized to restock and held accountable ; EMT/fire to restock and held accountable ; working with other boards to establish accountability	Update 1713 to include all rxs and ADDS to be placed in remote pharmacy. Allow for licensing of technology .	Remote dispensing systems are approved on state level.	Authorize fire stations/EMT to administer controlled substances and order to them; require these fire/EMT maintain perpetual inventory and legally prove each dispensed dose; inspections for controlled substances; require report loss to DEA and Board	1713 - amended for new and previously dispensed rx and placement outside of a pharmacy; 4186 amend to expand locations and appropriate patient settings; 4105.5 amend to allow ADDS to dispense directly to the patient and to add requirements that address patient counseling and expand locations	Laws should take into account the electronic recording of controlled substances.	

Currently approved for use under Section 1261.6