School Based Emergency Medicine Class D Clinic

REQUIRED FOR COMPLIANCE

NM Board of Pharmacy Approved Policy and Procedure Manual

Table of Contents	Page
Security	3
Equipment	3
Sanitation	3
Licensing	3
Formulary	3
Drug Storage	4
Temperature	4
Packaging and Repackaging	4
Dispensing and Distribution	4
Supervision, duties of the consultant pharmacist	4
Labeling and Relabeling	5
Samples	5
Drug Destruction and Returns	5
Drug and Device Procurement	5
Records	5
Forms	Page
School Based Emergency Medicine Class D Clinic (SBEM CDC) Pharmacy Policy and Procedure sign off	6
SBEM CDC Perpetual Inventory for Epinephrine auto-injector	7
SBEM CDC Perpetual Inventory for Albuterol MDI with spacers	8
SBEM CDC Temperature log	9
SBEM CDC Quarterly medication inspection/ Out of temperature range	10
SBEM CDC Transfer Drug Form	11
•	
NM Board of Pharmacy Self-Assessment Form	12
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- A. Security: Emergency medications must be stored in a secondary, secure but unlocked, tamper evident container. This container must be in a restricted area but readily accessible to trained personnel.
 - a. A current list of trained school personnel authorized to administer emergency medicine will be maintained and available for inspection.
 - b. Access to the drug storage container shall be limited to trained and authorized personnel.
- B. Equipment: The clinic shall have the necessary equipment for the safe and appropriate storage of drugs [albuterol metered dose inhaler (MDI), and/or epinephrine auto-injector]. The following items shall be in the clinic:
 - a. Reference materials: an updated reference source, appropriate to each practice site, either electronic or paper version.
 - b. One copy of the most recently published New Mexico Board of Pharmacy laws, rules and regulations and available revisions, either electronic or paper version.
 - c. Regional poison control center's telephone number.
 - d. Secondary unlocked but secure (tamper evident) container must be used to store the medication.
 - e. Thermometer appropriate to monitor drug storage area temperature.
 - f. Class D clinics carrying epinephrine auto-injectors shall have a sharps container.
 - g. Class D clinics carrying albuterol MDIs shall have spacers.
- C. Sanitation: Albuterol MDIs and/ or epinephrine auto-injectors shall be kept in manufacturer's original packaging until time of use. Medications must be maintained in clean, orderly and sanitary conditions.
- D. Licensing: All School Based Emergency Medicine clinics shall maintain current NM Board of Pharmacy class D clinic licensure. The license allows for administration of School Based Emergency Medicine by qualified personnel. Applicant shall submit required application and fee to the NM Board of Pharmacy office. A copy of the current Class D clinc registration and consultant pharmacist's license shall be posted in the drug storage area.
- E. Formulary: Class D clinic shall only stock albuterol MDI and/or epinephrine auto-injector.
- F. Drug Storage: Space for the storage and utilization of drugs shall have proper ventilation, lighting, temperature controls and adequate security as specified in this manual. The drug storage area shall be kept clean and orderly at all times.

- a. Medication shall be stored in the manufacturer's original packaging until the time of administration, and in a secondary, secure but unlocked tamper-evident container. A list of the contents, including expiration dates, must be posted on the outside of the container. Expiration dates shall be monitored to ensure stock is in date to facilitate a timely replacement of short dated drugs.
- b. Unusable and/or unwanted drug will be placed in a secure quarantine area and held for destruction. Removal options are transfer to another licensed clinic, return to the legitimate source of supply (i.e. wholesaler), or to a reverse distributor. Remaining portions of used albuterol MDI and/or epinephrine auto-injector may be destroyed by the consultant pharmacist.
- c. All medications will be stored at controlled room temperature (68-77°F)¹. The daily temperature log shall be completed on school days. In addition, proper drug storage temperature shall be maintained when school is not in session.
 - i. Epinephrine auto-injector shall be protected from light. The contents shall be inspected through the clear window of the auto injector quarterly with proper storage conditions, and upon temperature excursions outside the range of 59-86°F. The solution should be clear; if it is discolored or contains particulates, replace the unit.
- G. Temperature monitoring in a clinic with albuterol MDI and/or epinephrine auto-injector: The daily temperature log shall be completed on school days. In addition, proper drug storage temperature shall be maintained when school is not in session. A thermometer shall be maintained in each Class D clinic to monitor and maintain proper drug storage area temperature. The thermometer shall have the capability to record daily highs and lows with memory of such in order to review temperatures of non-school days. Alternatively, a thermometer with capability to electronically notify a designated person of out-of-range temperatures will suffice, if designated person takes corrective action.
- H. Packaging and Repackaging: No packaging or repacking occurs at Class D clinics
- I. Dispensing and Distributing: No dispensing or distributing occurs at Class D clinics
- J. Supervision: duties of the consultant pharmacist
 - a. Review records at least annually. This review shall include a review of the Self-Assessment Form, receipt, disposition records, and storage records. This annual review does not require an on-site visit by the consultant pharmacist.
 - b. Oversee the removal of unused or unwanted albuterol MDI and/or epinephrine autoinjector. Removal options are transfer to another licensed clinic, return to the legitimate source of supply (e.g. wholesaler) or to a reverse distributor. Remaining portions of used dangerous drugs may be destroyed by the consultant pharmacist.
 - c. Review albuterol MDI and/or epinephrine auto-injector administration records within 72 hours of administration. This review shall be documented and available for inspection by the NM Board of Pharmacy at the licensed location for 3 years. Review shall include

¹ Controlled room temperature as defined by USP, <695>, packaging and storage requirements

- verification of compliance with procedures and protocols, including administration by properly trained personnel.
- d. Ensure required records are available for inspection at the licensed location for three years, including a log of activities and communications of consultant pharmacist.
- e. Verify a current list of trained authorized personnel, in accordance with NM Department of Health requirements, is maintained at the licensed location and available for inspection by the NM Board of Pharmacy.
- f. Approve a policy and procedures manual outlining procedures for the receipt, storage, record keeping, administration and accountability of all dangerous drugs. This includes policies and procedures for the removal and destruction of unwanted, unused, outdated or recalled dangerous drugs. Must verify compliance with all training and protocols required by the NM Department of Health.
- K. Labeling and Relabeling: No labeling or relabeling will occur.
- L. Samples: Only samples of albuterol MDIs and/or epinephrine auto-injector may be stocked in a Class D clinic.
- M. Drug Destruction and Returns: Removal options for unusable, unwanted albuterol MDI and/or epinephrine are: transfer to another licensed clinic, return to the legitimate source of supply, or to a reverse distributor. Remaining portions of used dangerous drugs may be destroyed by the consultant pharmacist. Destruction record must be maintained on-site and available for inspection by the NM Board of Pharmacy
- N. Drug and device procurement: All drugs shall be obtained from a NM Board of pharmacy licensed distributor, resident pharmacy, drug manufacturer representative, or transferred from another class D clinic (only appropriately stored, unused and in date stock). Procurement records shall be maintained on-site and available for inspection by the NM Board of Pharmacy.
- O. Records: All records required by the NM Board of Pharmacy shall be maintained on site and available for inspection for 3 years.

Policy and Procedure Manual periodic review dates:

PHARMACIST	DATE of review and approval

Medication access is limited to trained and authorized personnel.

All trained and authorized individuals must read the manual, and sign below. I have read and understand this drug policy and procedure manual:

Printed Name		Signature	 Date
			 Date
			 Date
			 Date
			 Date
	<u> </u>		 Date
	-		 Date
			 Date
			Date

School Based Class D Clinic

Emergency Medication Perpetual Inventory for *Epinephrine auto-injector*

Clinic Name:		

Date	Student Name & id number/ Source of medication / Disposition other than administration	Lot	Exp.	Quantity Received	Quantity removed from Stock	Reason for Removal (See below)*	Person documenting Removed/added to/from inventory ^t	Ending Inventory	Pharmacist reviewed administration records within 72 hours Yes or No
example 8/1/2015	example Cardinal	example zy109	example 9/1/2016	2			lmk	2	
example 8/14/2015	example John Doe #1000001	example zy109	example 9/1/2016		1	A	lmk	1	
example 9/20/2016	example Cardinal	example AB123	example 7/1/2017	1			lmk	2	
Daggar for l					1.10		ing drug shall be th		

^{*}Reason for Removal:

t Person adding or removing drug shall be the one to complete the entry

A= Administration, E= Expired, T=Transferred, R=Recalled, D=Destroyed

School Based Class D Clinic

Emergency Medication Perpetual Inventory for <u>Albuterol MDI</u>
Clinic Name:

Date	Student Name & id number/ Source of medication / Disposition other than administration	Lot	Ехр.	Quantity Received	Quantity removed from Stock	Reason for Removal (See below)*	Person documenting Removed from /added to inventory ^t	Ending Inventory	reviewed administration records within 72 hours Yes or No

A= Administration, E= Expired, T=Transferred, R=Recalled, D=Destroyed

^{*}Reason for Removal

t Person adding or removing drug shall be the one to complete the entry

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Min Temp																															
Max Temp																															
Room																				•											
Temp °F																															
≥86																															
85																															
84																															
83																															
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																											5	X			
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62																															
61																															
60																															
<59																															

School Based Emergency Medicine Class D Clinic Drug Storage Area Temperature Log

Clinic Name:_____

Month/Year:_____

Person checking the temperature will initial the box corresponding to the temperature on the appropriate date. * If the temperature is out of range, take corrective action. Document result. If temp is above 86°F or below 59°F contact consultant pharmacist for instructions and complete the Quarterly Medication Inspection/Drug Storage Out of Temp Range Report.

School Based Emergency Medicine Class D Clinic Quarterly (During School Session)/ Medication Inspection/ Drug Storage out of Temp Range (≤59°F or ≥86°F) Report

Inspection type: quarterly or out of range temperatures* Completed by (initials) Is drug in date? Are unwanted/ unusable drugs quarantined Are drug storage conditions proper (clean, sanitary, orderly, etc.)? Are the contents of the epinephrine auto-injector clear and no particulates? Medication is in original manufacturer's packaging until time of use? Secondary container contents, including expiration dates, are listed and attached to container? Has drug been exposed to temperatures ≤59°F or ≥86°F? Tange? For out of range temperature, when pharmacist contacted what instructions were given? What occurred as a	What occurred as a result of the pharmacists instructions?
Inspection out of rang out of rang out of rang out of rang conditions and are drugs at proper (conditions with the secondary conditions and are the conditions are th	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
Y or N	
*Inspection type Initials Printed name & Title Initials Printed Name & Title Q= quarterly, Out of Temp Range: TR ———————————————————————————————————	

School Based Emergency Medicine Class D Clinic Drug Transfer Form (Copy must be kept at both sites)

Date	Drug Name	Lot	Exp	Quantity Transferred	Transferring clinic name (From)	Initials of Person Releasing Medication*	Receiving Clinic Name (To)	Initials of person accepting medication*
							_	
nitials	Printed name & Titl	le			Initials	Printed Name	& Title	

* Initials	Printed name & Title	Initials	Printed Name & Title



BOARD OF PHARMACY

New Mexico Regulation and Licensing Department

BOARDS AND COMMISSIONS DIVISION

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www.RLD.state.nm.us/pharmacy.aspx

SCHOOL BASED EMERGENCY MEDICINE CLASS D CLINIC ANNUAL SELF-ASSESSMENT FORM

Clinic Name:		Date:		
	Ci			
Clinic Phone:	Cinic Fax:			
Clinic Contact	person & Phone number:			
MBOP Licen	se Number:	Expiration Date:		
Consultant Pha	rmacist Name and Phone Number:			
1. POLICY AN	D PROCEDURE MANUAL			
	t, approved, NM Board of Pharmacy Policy and Procedure Manu	nal Maintained on site:	Yes	No
	viewed and approved by consultant pharmacist (annually):		Yes	No
	viewed and signed by personnel trained and authorized to admini			
	dheres to NM Board of Pharmacy approved Policy and Procedur		Yes	No
	tions stocked are limited to epinephrine auto-injector and/ or all	buterol MDI:	Yes	No
2. RECEIPT RE			**	
	e receipt records are maintained (perpetual inventory form):		Yes	No
	ource is registered with the NM Board of Pharmacy:	1'	Yes	No
_	records are signed and dated by person accepting receipt of med		Yes	No
-	records are maintained on-site and available for inspection or 3	years:	Yes	No
3. DRUG STOF			V	NI.
	ications are stored under clean, sanitary and orderly conditions:	£	Yes	No
_	nd are kept in the manufacturer's original packaging until time or		Yes	No No
	tions are kept in a secondary, secure but unlocked tamper-eviden		Yes	No
	ondary container has a list of contents attached to outside of the re stored in a restricted, secure but unlocked area and readily ass		Yes Yes	No No
	ature logs for the drug storage area are maintained within approp		Yes	No
	ed and/ or unusable drug is placed in a secure quarantine area:	mate range.	Yes	No
-	ly medication inspection reports are completed and available for	inspection:	Yes	No
	G AND REPACKAGING	inspection.	103	110
	ing or repackaging, occurs at this clinic:		Yes	
1 0	G AND DISTRIBUTING		103	
	sing or distribution occurs at this clinic:		Yes	
-	ATION AND REMOVAL RECORDS		100	
	are kept of medications removed from stock (Perpetual Invent	ory form):	Yes	No
	s of transfer, return to wholesaler, reverse distributor and/or dest		100	110
	ection by the NM Board of Pharmacy:		Yes	No
	Γ AND LICENSING			
-	nt and appropriate drug information reference, in print or online,	is available:	Yes	No
	of the NM State Board of Pharmacy drug laws and regulations,		Yes	No
	control center's telephone number is available:	in print of online, is available.	Yes	No
	school based emergency medicine class D clinic license is poste	ь ч .	Yes	No
	ant pharmacist's current license is posted:	a.	Yes	No
	school based emergency medicine class D clinic self-assessmen	at form is posted:	Yes	No
	ND AUTHORIZED PERSONNEL	ti form is posed.	103	110
	record of training of authorized personnel maintained:		Yes	No
	to medications is limited to trained and authorized personnel		Yes	No
	NT PHARMACIST (TO BE COMLETED BY CONSULTANT	TPHARMACIST)	103	110
	s a current and appropriate drug information reference is available		Yes	No
	s and approves clinic's NM Board of Pharmacy required records		Yes	No
	es the removal of dangerous drugs, and ensures proper documen	· ·	Yes	No
		Policy and Procedure Manual (and annual approval is documented):		No
	s compliance with all training and protocols for School Based En		103	110
Health			Yes	No
f. Verifie	s compliance with proper drug storage conditions:		Yes	No
	entation of consultant pharmacist's activities and communication	ns are maintained at the clinic and available for inspection:	Yes	No
	I CERTIFY THE INFORMATION PRO	OVIDED ON THIS FORM IS TRUE AND ACCURATE		
	Printed name and title of clinic representative I HAVE REVIEWED AND APPROVE	Signature Dat E THIS COMPLETED SELF-ASSESSMENT FORM	8	
	Printed name of Consultant R.Ph.	Consultant R.Ph. signature Dat	e	