Utah Department of Health & Human Services

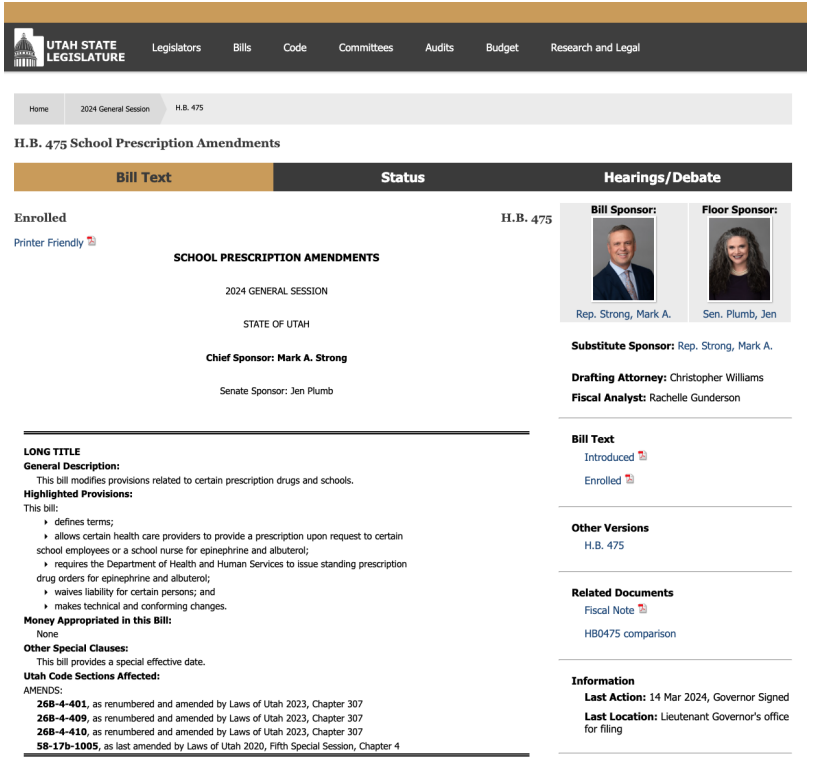
HB475 Standing Orders

Stock Albuterol and Stock Epinephrine

HB475- Prescription Amendments

This bill:

- defines terms
- allows certain health care providers to provide a prescription upon request to certain school employees or a school nurse for epinephrine and albuterol;
- requires the Department of Health and Human Services to issue standing prescription drug orders for epinephrine and albuterol
- waives liability for certain persons
- makes technical and conforming changes.



UTAH STATE LEGISLATURE | Legislators | Bills | Code | Committees | Audits | Budget | Research and Legal

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H.B. 475 School Prescription Amendments

Bill Text | Status | Hearings/Debate

Enrolled

Printer Friendly

H.B. 475

SCHOOL PRESCRIPTION AMENDMENTS

2024 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Mark A. Strong

Senate Sponsor: Jen Plumb

LONG TITLE
General Description:
This bill modifies provisions related to certain prescription drugs and schools.
Highlighted Provisions:
This bill:
- defines terms;
- allows certain health care providers to provide a prescription upon request to certain school employees or a school nurse for epinephrine and albuterol;
- requires the Department of Health and Human Services to issue standing prescription drug orders for epinephrine and albuterol;
- waives liability for certain persons; and
- makes technical and conforming changes.

Money Appropriated in this Bill:
None
Other Special Clauses:
This bill provides a special effective date.
Utah Code Sections Affected:
AMENDS:
26B-4-401, as renumbered and amended by Laws of Utah 2023, Chapter 307
26B-4-409, as renumbered and amended by Laws of Utah 2023, Chapter 307
26B-4-410, as renumbered and amended by Laws of Utah 2023, Chapter 307
58-17b-1005, as last amended by Laws of Utah 2020, Fifth Special Session, Chapter 4

Bill Sponsor: Rep. Strong, Mark A.

Floor Sponsor: Sen. Plumb, Jen

Substitute Sponsor: Rep. Strong, Mark A.

Drafting Attorney: Christopher Williams
Fiscal Analyst: Rachelle Gunderson

Bill Text
Introduced
Enrolled

Other Versions
H.B. 475

Related Documents
Fiscal Note
HB0475 comparison

Information
Last Action: 14 Mar 2024, Governor Signed
Last Location: Lieutenant Governor's office for filing

DHHS to issue a standing prescription drug order

(2) Under Section 58-17b-1004, the Department of Health and Human Services shall have a physician acting in the physician's capacity as an employee of the Department of Health and Human Services issue a standing prescription drug order authorizing the dispensing of:

(a) an epinephrine auto-injector in accordance with an epinephrine protocol; and

(b) stock albuterol in accordance with a stock albuterol protocol.

(3) Under Section 58-17b-1004, a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of:

(a) an epinephrine auto-injector in accordance with an epinephrine protocol; or

(b) stock albuterol in accordance with a stock albuterol protocol.

Epinephrine and Stock Albuterol
Protocol Overview

The Protocol Includes:

Physicians must specify authorized dispensers by license number (DHHS)

Annual reviews of dispensing practices by the physician are required (DHHS)

Record-keeping for each dispensing must include: (Done by pharmacist in redcap)

- The recipient's name (qualified adult/entity).
- Details of the epinephrine auto-injector dispensed or the stock albuterol dispensed.
- Other relevant information.

A rule must be created and approved by the division in collaboration with the Physicians Licensing Board and the Pharmacy Board, following Utah's rulemaking process.

(iv) is approved by the division (DOPL) through rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians Licensing Board created in Section 58-67-201 and the board.

Pharmacy Practice Act
58-17b-1005
Standing prescription drug orders for epinephrine auto-injectors and stock albuterol.

Immunity from Liability

Immunity from Liability Overview
Under Utah Code 26B-4-410:

Pharmacists and other authorized prescribers are protected from civil and criminal liability when acting in good faith regarding standing orders for albuterol and epinephrine in schools. This immunity extends to actions taken or not taken during anaphylactic reactions or asthma emergencies.

Key Points for Pharmacists:

- Good faith actions are covered under the law.
- Protection applies to prescribing, dispensing, and participating in training programs.
- The law preserves any other existing legal immunities or defenses.

Utah Code

Effective 8/1/2024
26B-4-410 Immunity from liability.
(1) The following, if acting in good faith, are not liable in any civil or criminal action for any act taken or not taken under the authority of Sections 26B-4-406 through 26B-4-411 with respect to an anaphylactic reaction, or asthma emergency:
(a) a qualified adult;
(b) a physician, physician assistant, pharmacist, or any other person or entity authorized to prescribe or dispense prescription drugs;
(c) a person who conducts training described in Section 26B-4-407 or 26B-4-408;
(d) a qualified epinephrine auto-injector entity;
(e) a qualified stock albuterol entity;
(f) the department;
(g) a local health department;
(h) a local education agency; and
(i) a local emergency medical services entity.
(2) Section 53G-9-502 does not apply to the administration of an epinephrine auto-injector or stock albuterol in accordance with this part.
(3) This section does not eliminate, limit, or reduce any other immunity from liability or defense against liability that may be available under state law.

Amended by Chapter 311, 2024 General Session

Burden on Pharmacists

Limited time demand - expected to have limited number of individuals requesting medications under these standing orders, specifically representatives from schools.

Costs of medications will be covered by school funds.

Pharmacists will be required to report to Utah DHHS once a year using the online RedCAP similar to naloxone and contraceptive

Training will be required, however this needs to be formalized and should be limited as these are routine medications.

Standing Order for Stock Albuterol

Utah Department of Health & Human Services

Utah Statewide Standing Order
Dispensing of Stock Albuterol for Public or Private Schools

Purpose:
The purpose of this standing order is to facilitate access to stock albuterol for public and private schools in Utah, ensuring they are equipped to respond effectively to asthma emergencies among students.

Authority:
This standing order serves as a prescription for FDA-approved stock albuterol for qualified entities in Utah. This standing order authorizes pharmacists to dispense FDA-approved stock albuterol to entities that include public and private schools employing or contracting with qualified adults who are likely to encounter students experiencing an asthma emergency. This standing order also authorizes qualified adults to obtain stock albuterol for use in emergencies involving asthma at these public or private schools.

Pursuant to UCA §26B-4-409, this standing order authorizes pharmacists licensed under UCA §58-17b Pharmacy Practice Act to dispense stock albuterol to public or private schools according to the provisions of UCA §26B-4-409 and section R911-5-2700, as well as the requirements outlined in this standing order.

Immunity:
In accordance with UCA §26B-4-410, pharmacists who dispense stock albuterol to public or private schools under this standing order are protected from civil liability, provided they comply with the provisions of this standing order. This immunity covers actions performed in good faith and in accordance with the standing order requirements.

Dispensing Guidelines:
FDA-approved albuterol may be dispensed under this standing order to:

- Public or private school employees or contracted staff members who are likely to encounter individuals experiencing an asthma emergency.

Authorized Products:

Stock albuterol formulations may be dispensed under this standing order as long as they have been approved by the FDA. Stock albuterol may be delivered as an inhaler or a nebulizer with a mouthpiece or mask. Administration of albuterol should be as directed.

Albuterol via inhaler	Albuterol via nebulizer
Rx: albuterol HFA inhaler(s) generic. (90) mcg per actuation	Rx: Albuterol sulfate 2.5 mg/0.05 ml solution for nebulization for patients 12 years of age and older Rx: Albuterol sulfate 0.63 mg to 1.25 mg/3 ml solution for nebulization for patients 2 to 12 years of age
Sig: Use per student's asthma action plan To be administered, as needed to an individual exhibiting symptoms of respiratory distress in accordance with guidelines pursuant to UCA 26B-4-409. The albuterol HFA must be administered by a trained school employee or a licensed healthcare provider Quantity (state number) inhaler(s) Quantity (state number) disposable valved holding chambers generic	Sig: Use per student's asthma action plan To be administered, as needed to an individual exhibiting symptoms of respiratory distress in accordance with guidelines pursuant to UCA 26B-4-409. The albuterol nebulizer solution must be administered by a trained school employee or licensed healthcare provider. Quantity (state number) ampules Quantity (state number) universal disposable nebulizer sets

Reporting:
As required in [insert new rule], the pharmacist-in-charge (or a responsible corporate officer) for each pharmacy licensee dispensing stock albuterol to a public or private school under this standing order must affirm compliance with the protocol in **UCA §58-17b-1005** and report the following information:

- The qualified adult recipient's name.
- The entity requesting the medication.
- Details of the albuterol dispensed.
- Other relevant information.

Reports must be submitted no later than 10 days after December 31 of each calendar year. The Utah Department of Health and Human Services will provide a link to enrolled pharmacies for report submission.

Registration:
Pharmacies that plan to dispense stock albuterol to a public or private school under this standing order are requested to voluntarily enroll with the Utah Department of Health and Human Services at [Insert new red cap link]. In addition to any other requirements under Utah or federal law, pharmacy licensees must retain the data specified in [insert new rule].

Education:Pharmacists who dispense stock albuterol to a public or private school under this order should, at a minimum, provide patient counseling to the qualified adult or stock albuterol entity regarding:

- The appropriate administration and storage of the stock albuterol.
- Potential side effects and risks associated with the stock albuterol.
- When to seek emergency medical attention.

Educational materials for pharmacists to provide to the qualified adults receiving stock albuterol can be found at [link for pharmacist training on albuterol].

As per UCA §26B-4-408, each primary and secondary school in the state, both public and private, that has stock albuterol must provide initial and annual refresher training on the storage and emergency use of stock albuterol to any teacher or school employee who volunteers to become a qualified adult. This training ensures that all qualified adults are equipped to handle asthma emergencies effectively. Educational training is available at https://usbe.instructure.com/enroll/H8KRLR, with additional resources at https://heal.utah.gov/SN-documents/.

Effective Period for this Order:
The Utah Department of Health and Human Services will review this standing order and consult with the Utah Board of Pharmacy as new information becomes available. Recommendations and support for revisions will be considered prior to re-issuance, or at least every two years.

Standing Order for Epinephrine

Utah Department of Health & Human Services

Utah Statewide Standing Order
Dispensing of Epinephrine Auto-Injectors for
Qualified Epinephrine Auto-Injector Entities

Purpose:
The purpose of this standing order is to facilitate access to stock epinephrine auto-injectors for qualified epinephrine auto-injector entities in Utah, ensuring they are prepared to respond effectively to students experiencing life-threatening allergic reactions or anaphylaxis.

Authority:
This standing order serves as a prescription for FDA-approved epinephrine auto-injectors for qualified epinephrine auto-injector entities. This standing order authorizes pharmacists to dispense FDA-approved epinephrine auto-injectors to entities that have a relationship with a qualified adult likely to encounter individuals who may experience anaphylaxis. This standing order authorizes a qualified adult to obtain stock epinephrine auto-injectors for use in emergencies involving individuals who may experience life-threatening allergies or anaphylaxis.

Qualified epinephrine auto-injector entities include:

- Recreation camps
- Educational facilities, schools, or universities
- Daycare facilities
- Youth sports leagues
- Amusement parks
- Food establishments
- Places of employment
- Recreation areas

Pursuant to UCA §26B-4-409, this standing order authorizes pharmacists licensed under the UCA §58-17b Pharmacy Practice Act to dispense stock epinephrine auto-injectors to qualified epinephrine auto-injector entities in accordance with the provisions of UCA §26B-4-409 and section R911-5-2700. This standing order also incorporates the requirements outlined in the referenced statutes and rules.

Immunity: In accordance with UCA §26B-4-410, pharmacists who dispense stock epinephrine auto-injectors to qualified entities under this standing order are protected from civil liability, provided they comply with the provisions of this standing order. This immunity covers actions performed in good faith and in accordance with the standing order requirements.

Dispensing Guidelines:
The following individuals may receive FDA-approved epinephrine auto-injectors under this standing order:

- Public or private school employees or contracted staff members likely to have contact with individuals who may experience life-threatening or anaphylactic emergencies.

Authorized Products:
Stock epinephrine auto-injector formulations approved by the FDA may be dispensed under this standing order. The epinephrine auto-injector must be administered as an injection. Administration should follow the manufacturer's directions.

Medication Name	Population authorized for use
Epinephrine auto-injector, USP 0.3 mg EpiPen 2-pak auto-injector, USP 0.3 mg Auvi-Q auto-injector, USP 0.3 mg	Individuals weighing 66 pounds or greater
Epinephrine auto-injector, USP 0.15 mg EpiPen Jr. 2-pak auto-injector, USP 0.15 mg Auvi-Q auto-injector, USP 0.15 mg	Individuals weighing between 33 and 66 pounds
Auvi-Q auto-injector, USP 0.1 mg	Individuals weighing between 16.5 and 33 pounds

Reporting:
As required in [insert new rule], the pharmacist-in-charge (or a responsible corporate officer) for each pharmacy licensee dispensing stock epinephrine auto-injectors to a qualified epinephrine auto-injector entity under this standing order must affirm compliance with the protocol in **UCA §58-17b-1005** and report the following information:

- The qualified adult recipient's name.
- The entity requesting the medication.
- Details of the epinephrine auto-injector dispensed.
- Other relevant information.

Reports must be submitted no later than 10 days after December 31 of each calendar year. The Utah Department of Health and Human Services will provide a link to enrolled pharmacies for report submission.

Registration:
Pharmacies intending to dispense stock epinephrine auto-injectors under this standing order are encouraged to voluntarily enroll with the Utah Department of Health and Human Services at {Insert new red cap link}. In addition to any other requirements under Utah or federal law, pharmacy licensees must retain the data specified in [insert new rule].

Education:
Pharmacists dispensing stock epinephrine auto-injectors must, at a minimum, provide patient counseling to the qualified adult or qualified epinephrine auto-injector entity receiving the epinephrine auto-injector regarding:

- The appropriate administration and storage of the epinephrine auto-injector.
- Potential side effects and risks associated with the epinephrine auto-injector.
- To seek emergency medical attention following administration.

Educational materials for individuals receiving epinephrine auto-injectors and for dispensers can be found at **{Insert new link}**. Additional information and resources are available at https://www.foodallergy.org/resources. Training for school stock epinephrine auto-injectors is available at https://heal.utah.gov/SN-training/.

Effective Period for this Order:
The Utah Department of Health and Human Services will review this standing order and consult with the Utah Board of Pharmacy as new information becomes available. Recommendations and support for revisions will be considered prior to re-issuance, or at least every two years.

What we are hoping from DOPL

What still needs to happen?

A rule needs to be written by the Division. Has this process started?

- What is the current status of drafting this rule?
- Who is leading the effort, and what is the timeline for completion?

Provide Comment:

Utah Standing Order Albuterol

Utah Standing Order Epinephrine

Answer Questions

-Who can assist with identifying the requirements for RedCap reporting?

-Are there additional educational requirements that should be added.

-Can we send out enrollment reminders on the listserv

RedCap Reporting Questions

1) Will we require re-enrollment every so many years, or is there only one required enrollment?

2) Will the authority for the standing order stay with individual pharmacists, or the pharmacies?

3) If the pharmacy is the enrolling/reporting body, can anyone report for that pharmacy?

4) If a pharmacist holds the prescription authority, will only one pharmacist be required to enroll per pharmacy?

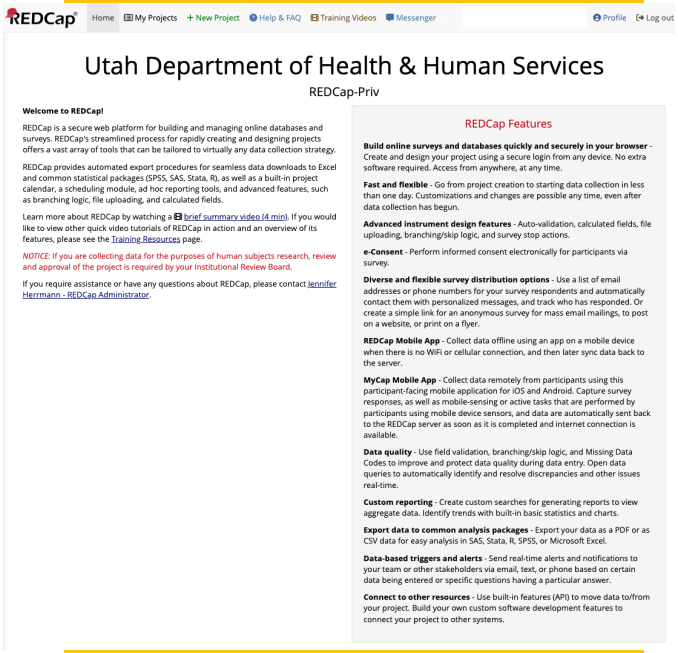
5) Are the pharmacists required to re-enroll if they move pharmacies?

6) Will a pharmacist need to report for every pharmacy they work at (if there are multiple), or only the ones they dispensed at that year?

7) Will the dispensing pharmacist need to complete any additional training as part of enrollment? If so, will it need to be repeated? How are we going to keep track of this?

8) Utah code requires the name of the adult/certified handler or injector to be included with the report. Do we need any extra protections on REDCap for this?

9) Will we need any form of reporting/follow-up with school representatives getting the medications? I remember seeing on one of the code pages that they are required to take a course. If they are, how are we going to keep track of this?



References

Utah Legislature. (2024). *HB0475 – Standing orders for epinephrine auto-injectors and stock albuterol*. https://le.utah.gov/~2024/bills/static/HB0475.html

Utah Legislature. (2023). *58-17b-1004: Dispensing of prescription drugs—Pharmacist responsibilities*. Utah Code. https://le.utah.gov/xcode/Title58/Chapter17B/C58-17b-S1004_2023050320230503.pdf

Utah Legislature. (2024). *58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol*. Utah Code. https://le.utah.gov/xcode/Title58/Chapter17B/C58-17b-S1005_2024080120240501.pdf

Utah Legislature. (2024). *26B-4-409. Standing orders for epinephrine auto-injectors and stock albuterol*. Utah Code. https://le.utah.gov/xcode/Title26B/Chapter4/26B-4-S409.html?v=C26B-4-S409_2023050320230503

Utah Legislature. (2024). *26B-4-410. Immunity from liability*. Utah Code. https://le.utah.gov/xcode/Title26B/Chapter4/C26B-4-S410_2024080120240501.pdf

Utah Administrative Code. (2024). *R911-5-2700: Emergency use of epinephrine auto-injectors and stock albuterol inhalers*. https://adminrules.utah.gov/public/rule/R911-5/Current%20Rules

Draft Albuterol Standing Order https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:99d6b45f-0f32-3635-8326-7795667bd7c6

Draft Epinephrine Standing Order https://acrobat.adobe.com/link/review?uri=urn:aaid:scds:US:663cac71-b70b-3a39-8bbe-8e787e5bfb58

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DRAFT

Utah Statewide Standing Order
Dispensing of Albuterol for Public or Private Schools

Purpose:
The purpose of this standing order is to facilitate access to stock albuterol for public and private schools in Utah, ensuring they are equipped to respond effectively to asthma emergencies among students.

Authority:
This standing order serves as a prescription for FDA-approved stock albuterol for qualified entities in Utah. This standing order authorizes pharmacists to dispense FDA-approved stock albuterol to entities that include public and private schools employing or contracting with qualified adults who are likely to encounter students experiencing an asthma emergency. This standing order also authorizes qualified adults to obtain stock albuterol for use in emergencies involving asthma at these public or private schools.

Pursuant to UCA §26B-4-409, this standing order authorizes pharmacists licensed under UCA §58-17b Pharmacy Practice Act to dispense stock albuterol to public or private schools according to the provisions of UCA §26B-4-409 and section R911-5-2700, as well as the requirements outlined in this standing order.

Immunity:
In accordance with UCA §26B-4-410, pharmacists who dispense stock albuterol to public or private schools under this standing order are protected from civil liability, provided they comply with the provisions of this standing order. This immunity covers actions performed in good faith and in accordance with the standing order's requirements.

Dispensing Guidelines:
FDA-approved albuterol may be dispensed under this standing order to:

- Public or private schools employees or contracted staff members who are likely to encounter individuals experiencing an asthma emergency.

Authorized Products:
Stock albuterol formulations may be dispensed under this standing order as long as they have been approved by the FDA. Stock albuterol may be delivered as an inhaler or a nebulizer with a mouthpiece or mask. Administration of albuterol should be as directed.

Albuterol via inhaler	Albuterol via nebulizer
Rx: albuterol HFA inhaler(s) generic. (90) mcg per actuation	Rx: Albuterol sulfate 2.5 mg/0.05 ml solution for nebulization for patients 12 years of age and older
	Rx: Albuterol sulfate 0.63 mg to 1.25 mg/3 ml solution for nebulization for patients 2 to 12 years of age
Sig: Use per student's asthma action plan To be administered, as needed to an individual exhibiting symptoms of respiratory distress in accordance with guidelines pursuant to UCA 26B-4-409. The albuterol HFA must be administered by a trained school employee or a licensed healthcare provider Quantity (state number) inhaler(s) Quantity (state number) disposable valved holding chambers generic	Sig: Use per student's asthma action plan To be administered, as needed to an individual exhibiting symptoms of respiratory distress in accordance with guidelines pursuant to UCA 26B-4-409. The albuterol nebulizer solution must be administered by a trained school employee or licensed healthcare provider. Quantity (state number) ampules Quantity (state number) universal disposable nebulizer sets

Reporting:
As required in [insert new rule], the pharmacist-in-charge (or a responsible corporate officer) for each pharmacy licensee dispensing stock albuterol to a public or private school under this standing order must affirm compliance with the protocol in UCA §58-17b-1005 and report the following information:

- The qualified adult recipient's name.
- The entity requesting the medication.
- Details of the albuterol dispensed.
- Other relevant information.

Reports must be submitted no later than 10 days after December 31 of each calendar year. The Utah Department of Health and Human Services will provide a link to enrolled pharmacies for report submission.

Registration:
Pharmacies that plan to dispense stock albuterol to a public or private school under this standing order are requested to voluntarily enroll with the Utah Department of Health and Human Services at [Insert new red cap link]. In addition to any other requirements under Utah or federal law, pharmacy licensees must retain the data specified in [insert new rule].

Education:
Pharmacists who dispense stock albuterol to a public or private school under this order should, at a minimum, provide patient counseling to the qualified adult or stock albuterol entity regarding:

- The appropriate administration and storage of the stock albuterol.
- Potential side effects and risks associated with the stock albuterol.
- When to seek emergency medical attention.

Educational materials for pharmacists to provide to the qualified adults receiving stock albuterol can be found at [link for pharmacist training on albuterol].

As per UCA §26B-4-408, each primary and secondary school in the state, both public and private, that has stock albuterol must provide initial and annual refresher training on the storage and emergency use of stock albuterol to any teacher or school employee who volunteers to become a qualified adult. This training ensures that all qualified adults are equipped to handle asthma emergencies effectively. Educational training is available at https://usbe.instructure.com/enroll/H8KRLR, with additional resources at https://heal.utah.gov/SN-documents/.

Effective Period for this Order:
The Utah Department of Health and Human Services will review this standing order and consult with the Utah Board of Pharmacy as new information becomes available. Recommendations and support for revisions will be considered prior to re-issuance, or at least every two years.

Leisha Nolen, MD, PhD
Utah State Epidemiologist
Utah Department of Health and Human Services
DEA Number: xxxxxxxxx
NPI Number: xxxxxxxxxx

DRAFT

Utah Statewide Standing Order
Pharmacist Dispensing of Epinephrine Auto-Injectors for Qualified Epinephrine Auto-Injector Entities

Purpose:
The purpose of this standing order is to facilitate access to stock epinephrine auto-injectors for qualified epinephrine auto-injector entities in Utah, ensuring they are prepared to respond to students experiencing an anaphylactic emergency.

Authority:
This standing order serves as a prescription for FDA-approved epinephrine auto-injectors for qualified epinephrine auto-injector entities. This standing order authorizes pharmacists to dispense FDA-approved epinephrine auto-injectors to entities that have a relationship with a qualified adult likely to encounter individuals who may experience anaphylaxis. This standing order authorizes a qualified adult to obtain stock epinephrine auto-injectors for use in emergencies involving individuals who may experience life-threatening allergies or anaphylaxis.

Qualified epinephrine auto-injector entities include:

- Recreation camps
- Educational facilities, schools, or universities
- Daycare facilities
- Youth sports leagues
- Amusement parks
- Food establishments
- Places of employment
- Recreation areas

Dispensing Guidelines:
The following individuals may receive FDA-approved epinephrine auto-injectors under this standing order:

- Public or private school employees or contracted staff members likely to have contact with individuals who may experience life-threatening or anaphylactic emergencies.

Authorized Products:
Stock epinephrine auto-injector formulations approved by the FDA may be dispensed under this standing order. The epinephrine auto-injector must be administered as an injection. Administration should follow the manufacturer's directions.

Medication Name	Population authorized for use
Epinephrine auto-injector, USP 0.3 mg EpiPen 2-pak auto-injector, USP 0.3 mg Auvi-Q auto-injector, USP 0.3 mg	Individuals weighing 66 pounds or greater
Epinephrine auto-injector, USP 0.15 mg EpiPen Jr. 2-pak auto-injector, USP 0.15 mg Auvi-Q auto-injector, USP 0.15 mg	Individuals weighing between 33 and 66 pounds
Auvi-Q auto-injector, USP 0.1 mg	Individuals weighing between 16.5 and 33 pounds

Reporting:
As required in **(insert new rule)**, the pharmacist-in-charge (or a responsible corporate officer) for each pharmacy licensee dispensing stock epinephrine auto-injectors to a qualified epinephrine auto-injector entity under this standing order must affirm compliance with the protocol in **UCA §58-17b-1005** and report the following information:

- The qualified adult recipient's name.
- The entity requesting the medication.
- Details of the epinephrine auto-injector dispensed.
- Other relevant information.

Reports must be submitted no later than 10 days after December 31 of each calendar year. The Utah Department of Health and Human Services will provide a link to enrolled pharmacies for report submission.

Registration:
Pharmacies intending to dispense stock epinephrine auto-injectors under this standing order are encouraged to voluntarily enroll with the Utah Department of Health and Human Services at **{Insert new red cap link}**.
In addition to any other requirements under Utah or federal law, pharmacy licensees must retain the data specified in **(insert new rule)**.

Education:
Pharmacists dispensing stock epinephrine auto-injectors must, at a minimum, provide patient counseling to the qualified adult or qualified epinephrine auto-injector entity receiving the epinephrine auto-injector regarding:

- The appropriate administration and storage of the epinephrine auto-injector.
- Potential side effects and risks associated with the epinephrine auto-injector.
- To seek emergency medical attention following administration.

Educational materials for individuals receiving epinephrine auto-injectors and for dispensers can be found at **{Insert new link}.** Additional information and resources are available at https://www.foodallergy.org/resources.
Training for school stock epinephrine auto-injectors is available at https://heal.utah.gov/SN-training/.

Effective Period for this Order:
The Utah Department of Health and Human Services will review this standing order and consult with the Utah Board of Pharmacy as new information becomes available. Recommendations and support for revisions will be considered prior to re-issuance, or at least every two years.

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Leisha Nolen, MD, PhD
Utah State Epidemiologist
Utah Department of Health and Human Services
DEA Number: xxxxxxxxx
NPI Number: xxxxxxxxxx

Date Issued: June 12, 2024

Subject: Drug Supply Chain Security Act Exemptions from Certain Requirements Under Section 582 of the FD&C Act for Small Dispensers Until November 27, 2026

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) to exempt certain dispensers - and, where noted, those dispensers' trading partners[1] - from certain requirements in section 582 of the FD&C Act[2] as outlined below until November 27, 2026.

In August 2023, FDA announced two compliance policy guidances (collectively the "2023 Compliance Policy Guidances")[3] that explained, among other things, FDA's enforcement policy with respect to: (a) the enhanced drug distribution security requirements[4] in section 582(g)(1) of the FD&C Act; and (b) verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act. Together, the 2023 Compliance Policy Guidances establish a 1-year stabilization period, from November 27, 2023, to November 27, 2024, to accommodate additional time that trading partners in the pharmaceutical distribution supply chain may need to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) enhanced drug distribution security requirements.

Since publishing the 2023 Compliance Policy Guidances, FDA has continued to receive comments and feedback from stakeholders and trading partners, particularly small dispensers, expressing concern with readiness to implement requirements under section 582(g)(1) of the FD&C Act at the conclusion of the stabilization period on November 27, 2024. Specifically, small dispensers have described challenges related to the time, costs, and resources needed to further develop the robust technologies and processes to enable data exchange, establish business relationships with their trading partners, and operationalize business practices. FDA recognizes that small dispensers may still need additional time beyond November 27, 2024, when the enforcement policy set forth in the 2023 Compliance Policy Guidances concludes, to focus resources and efforts on refining systems and technological infrastructures. Accordingly, FDA is issuing the exemptions outlined below to accommodate the additional time beyond November 27, 2024, that may be needed by small dispensers to fully transition to interoperable, electronic product tracing at the package level under the DSCSA. The FDA has determined the exemptions outlined below are

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[1] *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the product tracing requirements of section 582 of the FD&C Act.

[2] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued guidance on waivers, exceptions, and exemptions from section 582 of the FD&C Act requirements. *Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry* (August 2023). This guidance includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or posting on the Agency's website if an exception or exemption applies to a broad segment of industry). An exception or exemption that FDA establishes may be limited in duration or valid until further notice from the Agency." Consistent with that guidance, we are posting these exemptions on our website.

[3] For more information, see the compliance policy guidances for industry, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies* (August 2023) and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies, Revision 1* (August 2023).

[4] *Enhanced drug distribution security requirements* refer to the requirements for interoperable, electronic, package-level product tracing, including systems and processes, in section 582(g)(1) of the FD&C Act.

appropriate to maintain public health and help ensure continued patient access to certain prescription drugs in the United States.

For the purpose of the exemptions outlined below, a dispenser[5] is considered a "small dispenser" if the corporate entity that owns the dispenser has a total[6] of 25 or fewer full-time employees[7] licensed as pharmacists or qualified as pharmacy technicians.[8] We believe this definition best incorporates small pharmacy operations and those who are most in need of additional time to comply with the requirements of sections 582(g)(1) and 582(d)(4) of the FD&C Act outlined below.

If a small dispenser relies on the exemptions outlined below, we recommend communicating such reliance to its trading partners as needed to further facilitate distribution of product without difficulty or delay. The exemptions described below do not apply to other requirements in section 582 of the FD&C Act.

FDA has determined that the following FD&C Act exemptions for small dispensers - and, where noted, their trading partners - are appropriate from November 27, 2024, until November 27, 2026:

- The requirements under section 582(d)(4)(A)(ii)(II) of the FD&C Act for dispensers to verify the product identifier of the statutorily designated proportion of suspect or illegitimate product in the dispenser's possession or control. Small dispensers are still obligated to meet all other verification requirements of section 582(d)(4) of the FD&C Act.
- The requirement under section 582(g)(1)(A) of the FD&C Act that the transaction information and the transaction statements be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of section 582(h) of the FD&C Act. Small dispensers and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements[9] for transactions of product with each other during the exemption period.
- The requirement under section 582(g)(1)(B) of the FD&C Act that the transaction information required to be exchanged include the product identifier at the package level for each package included in the transaction. For transactions to which small dispensers are a party, small dispensers and their trading partners may continue to exchange transaction information with each other that does not include the product identifier at the package level for each package included in the transaction.
- The requirement under section 582(g)(1)(C) of the FD&C Act that systems and processes for verification of product at the package level, including the standardized numerical identifier, be in accordance with the standards established under the guidance issued pursuant to section 582(a)(2) of the FD&C Act and the guidances issued pursuant to paragraphs (2), (3), and (4) of section 582(h) of the FD&C Act. Small dispensers and their trading partners may continue to rely on current methods for verification activities with each other

[5] See Section 581(3) of the FD&C Act for the definition of *dispenser*.
[6] The total number of employees as of November 27, 2024.
[7] For the purpose of these exemptions, we are adopting the Internal Revenue Service's (IRS) definition of "full-time employee." The IRS defines a *full-time employee* as "for a calendar month, an employee employed on average at least 30 hours of service per week, or 130 hours of service per month." For additional information on identifying full-time employees, see https://www.irs.gov/affordable-care-act/employers/identifying-full-time-employees.
[8] We recognize that section 582(g) refers to "dispensers with 25 or fewer full-time employees" without limiting such employees to those who are licensed pharmacists or authorized pharmacy technicians. However, the exemptions being granted here, pursuant to section 582(a)(3), apply to a broader category of dispensers.

[9] Beginning on November 27, 2023, section 582(k)(1) of the FD&C Act effectively ended the requirement for trading partners to provide and receive transaction history.

during the exemption period.

- The requirement under section 582(g)(1)(D) of the FD&C Act for systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary, or other appropriate Federal or State official, in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product. Small dispensers may continue to rely on current methods to respond to such requests for such information.
- The requirement under section 582(g)(1)(E) of the FD&C Act for systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable (i) in the event of a request by the Secretary, or other appropriate Federal or State official, on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary, or other appropriate Federal or State official, with a request described in clause (i). Small dispensers may use current methods to respond to such requests with their relevant transaction information if they directly transacted the product(s) subject to the request.

The exemptions described in this notification are not intended to provide, and should not be viewed as providing, a justification for delaying efforts by small dispensers to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges small dispensers to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Sincerely,

Michael M. Levy -S

Digitally signed by Michael M. Levy -S
Date: 2024.06.10 08:33:34 -04'00'

Michael Levy, J.D.
Deputy Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

July 16, 2024

Lemrey “Al” Carter, MS, PharmD, RPh
Executive Director/Secretary
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056
acarter@NABP.pharmacy

Dear Dr. Carter:

The purpose of this letter is to bring to the attention of the National Association of Boards of Pharmacy (NABP) information related to injectable compounded drug products containing semaglutide or tirzepatide. We encourage you to share the information in this letter with your members for their awareness and consideration.

FDA is aware of increased interest in compounded semaglutide and tirzepatide products. Compounded drug products can serve an important medical need for certain patients. However, compounded drug products, including compounded semaglutide and tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality.

FDA has received reports describing patients who experienced adverse events following the administration of compounded semaglutide or tirzepatide products in doses exceeding the recommended dosing or titration schedule for FDA-approved semaglutide and tirzepatide products. The adverse events described in the reports included nausea, vomiting, fatigue, stomach pain, shortness of breath, headache, heartburn, weakness, intestinal blockage, hypoglycemia, impacted bowels, electrolyte imbalances, bowel infection, ketoacidosis, pancreatitis, and rhabdomyolysis. Some of these are serious adverse events and some of the patients reported seeking medical attention for their symptoms.

FDA’s ability to derive conclusions about safety concerns from these reports is limited because, for example, compounding pharmacies that are not registered with the FDA as outsourcing facilities generally do not submit adverse event reports to the FDA, and among the reports submitted, reported information varies. However, certain factors noted in the reports that may have contributed to the adverse events include the following:

- Prescribers started patients on doses that were approximately two to four times higher than the recommended starting doses of FDA-approved semaglutide and

tirzepatide products.
- Compounded semaglutide products were prescribed to be administered twice a week instead of once weekly, which is the recommended frequency of administration for FDA-approved semaglutide and tirzepatide products.
- Prescribers titrated the patients' doses every one to two weeks instead of every four weeks, which is the recommended titration schedule of FDA-approved semaglutide and tirzepatide products.

Health care providers and your members may consider information about the potential for adverse events when doses, dose frequencies, or titration schedules vary from those of the FDA-approved products, and when weighing the risks versus benefits and determining appropriate doses and titration and dosing schedules for patients.

FDA encourages health care professionals and compounders to report adverse events or quality problems experienced with the use of compounded drugs to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at MedWatch: The FDA Safety Information and Adverse Event Reporting Program or

- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

We are also sending this letter to the Alliance for Pharmacy Compounding, the Federation of State Medical Boards, the National Council of State Boards of Nursing, and the Outsourcing Facility Association, for your awareness.

We look forward to continuing to work with you on matters related to drug compounding. If you have questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

Shannon Glueck, Pharm.D.
Branch Chief, Compounding Branch 4
Division of Compounding II
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food & Drug Administration