



DISTRICT OF COLUMBIA

OFFICE OF THE STATE SUPERINTENDENT OF

EDUCATION

DATE: July 30, 2019

TO: District of Columbia School Epinephrine Liaisons

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SUBJECT: Epinephrine Expiration Date Extension and Recommendations for the Use of Expired Adult Auto-Injectors

The Allergy Management Team at the Office of the State Superintendent of Education (OSSE) is sharing important information from the U.S. Food and Drug Administration (FDA) and recommendations from the Food Allergy Research & Education (FARE) Chief Medical Officer and Clinical Advisory Board Executive Committee regarding the use of expired adult auto-injectors.

The FDA has announced a four month expiration date extension of the EpiPen® adult dose auto-injectors (0.3 mg) and its authorized generic version in an effort to assist with the ongoing epinephrine supply interruptions.¹ The four month expiration date extension **only** applies to EpiPen® adult dose auto-injectors (0.3 mg) and its authorized generic version with original expiration dates between February 2019 and October 2020. This extension **does not** apply to EpiPen Jr® pediatric dose auto-injectors (0.15 mg) and its authorized generic version.

The FARE Chief Medical Officer and Clinical Advisory Board Executive Committee has issued recommendations regarding the use of expired epinephrine auto-injectors impacted by the recent FDA extension.^{2 3}

NATIONAL EPINEPHRINE SHORTAGE:

Starting in 2018, the supplier of epinephrine auto-injectors for the EpiPen4Schools® Program (Mylan) and the pharmacy assisting with the orders (BioRidge Pharma) shared information about a national epinephrine shortage. The ongoing shortage has impacted the timeliness of replacing epinephrine auto-injectors in District schools and their ability to maintain two unexpired auto-injectors of each dose

¹ <https://www.fda.gov/drugs/drug-shortages/extended-use-dates-provided-pfizer>

² <https://www.foodallergy.org/about/media-press-room/fare-medical-advisors-letter-to-fda-on-epinephrine>

³ <https://www.foodallergy.org/alert-epinephrine-shortage>

(adult and pediatric). As a result, OSSE will not consider a school out of compliance with the stocked undesignated epinephrine auto-injector requirement as long as the school has placed an order for a replacement auto-injector and is awaiting receipt. Schools must continue to place their replacement orders 90-120 days prior to expiration.

In an effort to address the current shortage, and after careful review of the product stability data provided by the manufacturer, the FDA has recently announced a four month extended expiration date of all lots of EpiPen® adult dose auto-injectors (0.3 mg) and its authorized generic version with original expiration dates between February 2019 and October 2020.

RECOMMENDATIONS:

In response to the national shortage, schools should adhere to the following recommendations:

- Verify if your adult dose auto-injector (0.3 mg) has an extended expiration date. See the attached appendix with new extended expiration dates. The four month extension **only** applies to EpiPen® adult auto-injectors (0.3 mg) and authorized generic version with original expiration dates between February 2019 and October 2020. It **does not** apply to EpiPen Jr® pediatric auto-injectors (0.15 mg) and authorized generic version.
- If your adult auto-injector (0.3 mg) has an extended expiration date, continue to store and administer it as you would any unexpired auto-injector. These auto-injectors are approved safe and effective to administer by the FDA.
- Do not dispose of any expired auto-injectors until you receive a replacement. The FDA may continue to issue extension notices for other expiring or expired epinephrine auto-injectors. Continue to store all expired epinephrine auto-injectors as normal and place a note on them to indicate they are expired.
- FARE and the District's prescribing physician have stated that it is safe to administer an expired epinephrine auto-injector if an unexpired auto-injector is not available. While an expired epinephrine auto-injector is safe, its efficacy will eventually decrease. FARE recommends that properly stored epinephrine (out of direct light and at room temperature) is effective to use up to nine months after the manufacturer's original expiration date. Because an expired epinephrine is safe, administering an expired epinephrine auto-injector may have some benefit while its efficacy continues to decline, thus it may be better than not administering one at all.
- Do not use epinephrine auto-injectors if the solution looks pinkish, more than slightly yellow, cloudy, or if it contains particles. Epinephrine Liaisons must continue to regularly inspect epinephrine auto-injectors for discoloration, cloudiness, or other concerns. Notify OSSE immediately if there are concerns with your supply.
- In case of an anaphylactic emergency, immediately administer the epinephrine auto-injector, then call 9-1-1. If an expired epinephrine auto-injector was administered, notify the responding emergency medical technician that the epinephrine was expired. Notify OSSE within 24 hours of the incident and file a report.

SUMMARY:

The FDA announced a four month expiration date extension of all lots of EpiPen® adult auto-injectors (0.3 mg) and authorized generic version with original expiration dates between February 2019 and

October 2020. This extension **does not** apply to EpiPen Jr® pediatric auto-injectors (0.15 mg) and authorized generic version.

Schools should not discard any expired auto-injectors until a replacement is received. Expired epinephrine is safe and should be kept on hand for emergencies, especially during the ongoing shortage. FARE has recommended that properly stored EpiPens are effective up to nine months after the original expiration date. The only exception to this is if the solution shows particles, discoloration, or cloudiness, so Epinephrine Liaisons should continue to regularly inspect the supply on a monthly basis. During an anaphylactic emergency, if an unexpired auto-injector is unavailable, an expired auto-injector should be used, followed by immediate medical attention.

Schools are required to continue working with OSSE to make replacement orders for used and expiring epinephrine auto-injectors. Orders must be placed 90-120 days prior to the original expiration date. OSSE maintains close communication with Mylan and BioRidge Pharma regarding the timely shipment for all placed orders.

Please do not hesitate to contact OSSE Allergy Management Team at osse.epi@dc.gov if you have any questions or concerns.

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[See next page for appendix]

APPENDIX: New Extended Adult Epinephrine Auto-Injector Expiration Dates

IMPACTED PRODUCT⁴

| Manufacturer's Original Expiration Date | New Expiration Date <i>Please note: Expiration dates are valid through the last day of the month listed</i> |
|--|--|
| Feb 2019 | Jun 2019 |
| Mar 2019 | Jul 2019 |
| Apr 2019 | Aug 2019 |
| Jun 2019 | Oct 2019 |
| Jul 2019 | Nov 2019 |
| Aug 2019 | Dec 2019 |
| Sep 2019 | Jan 2020 |
| Oct 2019 | Feb 2020 |
| Nov 2019 | Mar 2020 |
| Dec 2019 <i>(only available in Epinephrine Injection 0.3 mg)*</i> | Apr 2020 |
| Jan 2020 | May 2020 |
| Feb 2020 <i>(only available in Epinephrine Injection 0.3 mg)*</i> | Jun 2020 |
| Mar 2020 <i>(only available in Epinephrine Injection 0.3 mg)*</i> | Jul 2020 |
| Apr 2020 | Aug 2020 |
| May 2020 <i>(only available in Epinephrine Injection 0.3 mg)*</i> | Sep 2020 |
| Jun 2020 | Oct 2020 |
| Aug 2020 <i>(only available in Epinephrine Injection 0.3 mg)*</i> | Dec 2020 |
| Sept 2020 | Jan 2021 |
| Oct 2020 <i>(only available in Epinephrine Injection 0.3 mg)*</i> | Feb 2021 |

***Epinephrine Injection, USP Auto-Injectors 0.3 mg**

- NDC 49502-102-02 appears on the box
- NDC 49502-102-01 appears on the individual device within the box

EpiPen® (epinephrine injection, USP) 0.3 mg Auto-Injectors

- NDC 49502-500-02 appears on the box
- NDC 49502-500-01 appears on the individual device within the box

Do not use epinephrine auto-injectors if the solution looks pinkish, more than slightly yellow, cloudy, or if it contains particles. Continue to regularly inspect epinephrine auto-injectors for discoloration, cloudiness, or other concerns. Notify OSSE immediately if there are concerns with your supply.

⁴ <https://www.fda.gov/drugs/drug-shortages/extended-use-dates-provided-pfizer>