E-News Update (July 2022)

CDC Requires Use of Digital Data Logger to Monitor Temperatures in Units that Hold COVID-19 Vaccine

On May 10, 2022, the Centers for Disease Control and Prevention (CDC) sent a communication indicating that provider locations enrolled in the COVID-19 Vaccination Program *must* use a digital data logger (DDL) to monitor temperatures in all storage units that hold COVID-19 vaccine; this includes units used for transport of COVID-19 vaccine.

All COVID-19 vaccination providers should obtain a DDL if they have not already done so. Due to supply chain delays and shortages, allowances were made in 2021 for COVID-19 Vaccination Program providers having difficulty obtaining DDLs. However, at this time, DDL supply chain issues should be resolved, and all COVID-19 Vaccination providers are required by the CDC to obtain a DDL per storage unit.

Digital data loggers are the gold standard for temperature monitoring and help to ensure that all vaccines are stored according to the manufacturer recommendations. This adds confidence that all COVID-19 doses being administered in Ohio are viable and effective in providing vaccine recipients with protection against COVID-19 disease.

Digital Data Loggers should have the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5°C (+/-1°F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- A current and valid Certificate of Calibration Testing

More information about DDLs for COVID-19 Vaccine can be found in the CDC Vaccine Storage and Handling Toolkit (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)

COVID-19 Vaccines Recommended for Infants and Young Children

The Ohio Department of Health recently announced that COVID-19 vaccines are now recommended for children 6 months through 4 years following action by the U.S. Food & Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). This is a crucial step toward strengthening protection against COVID-19 in Ohio.

Children are at risk for serious illness, including hospitalization and death, from COVID-19. The CDC recommends that people age 6 months and older get vaccinated as the best protection against these serious outcomes. The FDA authorized emergency use of new lower-dose formulations of the Pfizer and Moderna COVID-19 vaccines specially made for young children, and the CDC recommended use of the products outlined below:

- **Moderna:** A new lower dose pediatric formulation is available for children age 6 months through 5 years (two-dose primary series, with a third primary series dose for immunocompromised children).
- The FDA amended the emergency use authorization (EUA) for Moderna COVID-19 vaccine to include use of the vaccine in individuals 6 months through 17 years of age. The vaccine had previously been authorized for use in adults 18 years of age and

older and has received full FDA approval for adults.
- The CDC recommended use of the lower-dose vaccine in children age 6 months to 5 years and provided clinical recommendations.
- ***The CDC's Advisory Committee for Immunization Practices (ACIP) is scheduled to meet June 22-23, 2022, to consider Moderna vaccine for children age 6-17 years.***
- **Pfizer:** A new lower dose pediatric formulation is available for children age 6 months through 4 years (three-dose primary series).
- The FDA amended the EUA for the Pfizer COVID-19 vaccine to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had previously been authorized for use in individuals 5 years of age and older.
- The CDC recommended use of the vaccine in children age 6 months through 4 years and provided clinical recommendations.

Moderna and Pfizer COVID-19 vaccine products are age-specific with specific doses for different ages. Vaccines for older children should not be used to vaccinate these younger age groups as COVID-19 vaccines are **not** interchangeable.

Ohio vaccine providers who pre-ordered the new vaccines for children younger than age 5 should expect deliveries of the new vaccines beginning **Monday, June 20.**

Providers who would like to place orders for these two new products or any COVID-19 vaccine product can do so through the **ImpactSIIS Vaccine Ordering Management System (VOMS)**. VOMS is open for orders 24 hours a day, 7 days a week.

Providers are encouraged to order only one of the two vaccine options initially to avoid administration and/or storage errors, as each vaccine has different and unique criteria for storage and handling.

Due to national demand, placing an order through VOMS does not guarantee delivery of these new vaccine products for young children. Orders will be processed in the order received.

Vaccine ordering reminders:

- **The minimum order quantity will be 100 doses. Providers may choose either the Pfizer or the Moderna vaccines for young children.**
- Orders can be placed using the existing **COVID-19 – Pfizer and COVID-19 Moderna order sets**. The new formulation of each vaccine will be one of the product options available within the order set. Providers must enter the total quantity requested in the "Doses Requested" field in multiples of 100.
- A "soft-cap" maximum of 1,000 doses will be placed on each order at this time to help with the equitable distribution of the vaccine. Please order only what you plan to use in the near future. If you have a special request for a local vaccination effort that would require more than 1,000 doses, please call the ODH Provider Call Center at 1-844-9ODHVAX (1-844-963-4829) and we will work with you.

Guidance Document Information for DEA Registrants

The Drug Enforcement Administration (DEA) released to provide information and clarification regarding DEA's use of guidance documents, specifically why DEA is utilizing guidance documents, where to find DEA's guidance documents, and the status of certain policy directives or regulatory interpretations issued by DEA prior to the establishment of its Guidance Document Portal.

DEA's Guidance Document Portal was established pursuant to Executive Order 13891 (E.O. 13891), *Promoting the Rule of Law Through Improved Agency Guidance Documents*, signed by President Trump on October 9, 2019. The term "guidance document" was defined in E.O. 13891, in part, to mean "an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on statutory, regulatory, or technical issue, or an interpretation of a statute or regulation." E.O. 13891 required that agencies treat guidance documents as non-binding (with some exceptions), both in law and practice, take public comment into account when appropriate when formulating guidance documents, and make guidance documents readily available to the public.

In its memorandum M-20-02, dated October 31, 2019, the Office of Management and Budget directed the Department of Justice (DOJ) to publish a notice in the Federal Register announcing the existence of a new guidance portal and explaining that all guidance documents remaining in effect will be contained on the guidance portal. The DOJ guidance portal may be found at https://www.justice.gov/guidance. DEA subsequently established its

own guidance document portal, which can be found at https://apps2.deadiversion.usdoj.gov/guidance/#no-back-button. This portal contains a single, searchable, indexed database that contains links to all DEA guidance documents. Thus, both the DOJ and DEA guidance portals allow members of the public to access DEA guidance documents.

To comply with E.O. 13891, DEA undertook a review of all guidance documents that were available to the public on DEA's Diversion Control Division website at that time. Memoranda, "Dear Registrant" letters, Q&As, and any other guidance documents that were not in compliance with E.O. 13891 were removed from the website.

On January 20, 2020, President Biden signed E.O. 13992 which, among other things, revoked E.O. 13891. DEA has complied with E.O. 13992, however, DEA will continue to utilize its Guidance Document Portal to provide DEA registrants a user-friendly, searchable platform for them to expeditiously locate current DEA guidance on a wide range of pertinent topics.

- Some guidance documents issued prior to November 2019, were removed from DEA's Diversion Control Division website and are not in the guidance portal, pursuant to E.O. 13891. These guidance documents will not be restored and should be considered rescinded or not valid.
- With respect to the guidance documents that are currently listed on the Guidance Document Portal, these documents do not have the force and effect of law, and are not binding on the public in any way.
- DEA will continue to post new guidance on its Guidance Document Portal when the need arises, so DEA registrants should periodically check the portal for any new guidance that may be of interest.

For more information regarding DEA's Diversion Control Division, please visit https://www.deadiversion.usdoj.gov. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this issue or any other matter.

2022 Law and Responsible Person Review Virtual Presentations

The Board announced dates for the 2022 Law and Responsible Person Review Virtual Presentations, which will highlight the latest developments in pharmacy laws and rules.

These presentations will count for one credit hour towards Pharmacy Jurisprudence Continuing Education. To register, please go to this link with your name, license type and number, presentation date, NABP/CPE Monitor number, phone number and employer.

2022 Law Review topics will include:

- Updated state laws and regulations for terminal distributors of dangerous drugs
- Pharmacy technician updates
- State of Ohio Board of Pharmacy COVID-19 response efforts
- Pharmacy compounding rules

Responsible Person Roundtable topics will include:

- Duties of a responsible person
- General provisions of a terminal distributor of dangerous drugs
- Duty to report
- Know your resources

Who Should Attend?

- Pharmacists, pharmacy interns, registered or certified pharmacy technicians, and pharmacy compliance staff employed in outpatient/community-based pharmacies.

REMINDER: Non-Resident Nuclear Pharmacies Required to have Ohio Licensed Responsible Person

A pharmacy licensed as a non-resident pharmacy that is engaged in the preparation and distribution of radiopharmaceuticals is required to have an Ohio licensed pharmacist as the responsible person on its license. This requirement does not apply to non-resident pharmacies that engage in the preparation of radiopharmaceuticals, but do not ship radiopharmaceuticals into Ohio. For more information, please

visit pharmacy.ohio.gov/nuclear.

Please note that if you choose to unsubscribe from receiving emails, this unsubscribes you from all emails that are sent by the State of Ohio Board of Pharmacy, including renewal reminders. If you believe you have unsubscribed in error, please email contact@pharmacy.ohio.gov for assistance. If you would like to change the email address, please log into your eLicense Ohio account to update the email address on file.