MINNESOTA
OFFICE OF OMBUDSMAN
FOR MENTAL HEALTH AND
DEVELOPMENTAL DISABILITIES

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Dear Colleagues,

While the COVID health emergency officially ended on May 11, we continue to see many cases in community and congregate care settings. We will therefore continue to recommend the following source for up-to-date information about COVID-19:

Minnesota Department of Health Coronavirus Disease 2019 (COVID-19) Homepage
(https://www.health.state.mn.us/diseases/coronavirus/index.html)

The Medical Review Subcommittee (MRS) reviews reports of individual deaths and analyzes accumulated data on all deaths and serious injuries reported to the Office of Ombudsman for Mental Health and Developmental Disabilities (OMHDD). Periodically, the MRS develops Medical Alerts based upon those reviews. No Medical Alerts were issued this year.

We have updated the **Summer Alerts for 2023** (https://mn.gov/omhdd/documents/medical-alerts.jsp):

Summer Alert Heat Stroke Alert Insect Sting Alert Water Safety Alert

For continued updates from the (OMHDD), you can Subscribe to the OMHDD Medical Alerts E-Mail List Service (https://public.govdelivery.com/accounts/MNOMHDD/subscriber/new?qsp=CODE_RED). When you subscribe to this service, you will be notified by e-mail when new Medical Alerts and/or Seasonal Alerts are posted to the OMHDD website.

Please Use the Webforms for Reporting Deaths and Serious Injuries

In 2020 the OMHDD made webform reporting available for routine reporting of deaths and serious injuries. Webform reporting is the preferred method for reporting deaths and serious injuries, but the paper forms remain available on the OMHDD website for use when preferred by reporters.

Death Review webform (https://omhddcms.i-sight.com/portal/death-review)

Serious Injury webform (https://omhddcms.i-sight.com/portal/serious-injury)

Reporting Death or Serious Injury – Downloadable Forms
(https://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp)

While the office recognizes that you may not have all the information requested on the forms, please provide all information you do have access to, for example: the client's first and last name, the client's date of birth, the date of death, if known, and the contact information for the reporter

including the reporter title (case manager, social worker, program director, mental health practitioner, etc.), as well as the reporter facility/agency name (when applicable).

Reports of deaths and serious injuries may be faxed to the OMHDD at the following number:

Fax: 651-797-1950

Thank you for continuing to report Serious Injuries and Deaths to the OMHDD and for your ongoing support with the review process. Please call Voice: 651-757-1800 or Toll Free: 1-800-657-3506 with any questions.

Mpox

The first two Minnesota cases of mpox of 2023 have been identified, which makes now a great time to review what providers and clients need to know about prevention, monitoring, and treatment. Symptoms may include a rash that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus, as well as fever and/or chills, swollen lymph nodes, headache, fatigue, and body aches.
Vaccination makes getting and spreading mpox less likely, but infections after any vaccination are possible. No vaccine is 100% effective. Getting vaccinated against mpox may help make the symptoms less severe and easier to manage, and it may help protect against severe infection, hospitalization, and death. There is plenty of supply in Minnesota for people to get vaccinated.
For more information, check out the following resources:
Mpox: Get the Facts (state.mn.us)
(https://www.health.state.mn.us/diseases/monkeypox/monkeypox.pdf)
Your Health | Mpox | Poxvirus | CDC (https://www.cdc.gov/poxvirus/mpox/your-health/index.html)

FDA Drug Alerts and Statements

Since the 2022 Winter Alert, the Food and Drug Administration (FDA) has released Drug Alerts and Statements (https://www.fda.gov/drugs/drug-safety-and-availability/drug-alerts-and-statements) for several medications, products, and substances, some of which are prescribed for or used by clients of the OMHDD. These alerts include the following:

FDA alerts health care professionals of risks to patients exposed to xylazine in illicit drugs
(https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-risks-patients-exposed-xylazine-illicit-drugs)

[11/08/2022] Health care professionals should be cautious of possible xylazine inclusion in fentanyl, heroin, and other illicit drug overdoses, as naloxone may not be able to reverse its effects. FDA is aware of increasing reports of serious side effects from individuals exposed to fentanyl, heroin, and other illicit drugs contaminated with xylazine.

Xylazine is FDA-approved for use in animals as a sedative and pain reliever. Xylazine is not safe for use in humans and may result in serious and life-threatening side effects that appear to be similar to those commonly associated with opioid use, making it difficult to distinguish opioid overdoses from xylazine exposure. … Routine toxicology screens do not detect xylazine, and additional analytical techniques are required to detect xylazine when it might be involved in illicit drug overdoses, particularly when there are other signs or symptoms of xylazine exposure.

Health care professionals should continue to administer naloxone for opioid overdoses and consider xylazine exposure if patients are not responding to naloxone or when there are signs or symptoms of xylazine exposure (e.g., severe, necrotic skin ulcerations). Health care professionals should provide appropriate supportive measures to patients who do not respond to naloxone.

Please refer to the complete FDA alert for more details.

For additional information, visit Fentanyl (https://www.health.state.mn.us/communities/opioids/basics/fentanyl.html) on the Minnesota Department of Health website.

FDA warns consumers not to purchase or use EzriCare Artificial Tears due to potential contamination
(https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination)

[2/2/2023] FDA is warning consumers and health care practitioners not to purchase and to immediately stop using EzriCare Artificial Tears or Delsam Pharma's Artificial Tears due to potential bacterial contamination. Using contaminated artificial tears increases risk of eye infections that could result in blindness or death. Patients who have signs or symptoms of an eye infection should talk to their health care provider or seek medical care immediately.

[2/21/2023] In addition to Artificial Tears products, FDA is also now warning consumers and health care professionals not to purchase or use Delsam Pharma's Artificial Eye Ointment due to potential bacterial contamination. This is an over-the-counter product, manufactured by Global Pharma Healthcare Private Limited, intended to be sterile.

Please refer to the complete FDA alert for more details.

FDA warns consumers to not purchase or use Nose Slap and Soul Slap products marketed for alertness and energy boosting
(https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-nose-slap-and-soul-slap-products-marketed-alertness-and)

[5/1/2023] FDA is warning consumers to not purchase or use Nose Slap and Soul Slap products, which are unapproved drugs marketed to promote alertness and boost energy.

These products are inhalants and primarily contain ammonia. Inhaling ammonia can quickly lead to eye, nose, and throat irritation; coughing; and airway constriction.

FDA has received reports of adverse events such as shortness of breath, seizures, migraines, vomiting, diarrhea, and fainting from consumers after using the Nose Slap or Soul Slap products. These products may have been purchased online through the Nose Slap website.

Please refer to the complete FDA alert for more details.

Certain Philips Respironics Ventilators, BiPAP Machines, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication
(https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due)

[11/12/2021] The FDA issued a safety communication to provide additional information to patients, caregivers, and health care providers about two recent issues in certain reworked Philips Trilogy 100 and Trilogy 200 ventilators. These Philips Trilogy 100 and Trilogy 2000 ventilators were a part of this recall in June 2021 for issues with the polyester-based polyurethane (PE-PUR) sound abatement foam breakdown. The silicone foam material used to replace the PE-PUR foam in the reworked ventilators may potentially move and block the airpath, which may reduce air flow in the ventilator and could also cause the device to alarm. Additionally, Philips observed residual PE-PUR sound abatement foam in some reworked Trilogy 100 and Trilogy 200 ventilators that were returned to customers

[4/7/2023] The FDA classified Certain Reworked DreamStation CPAP, BiPAP Machines for the risk they may deliver inaccurate or insufficient therapy as a Class I recall, the most serious type of recall.

Please refer to the complete FDA alert for more details.

Medication Administration

When administering prescription and over-the-counter medications to your clients, always be aware of the potential side effects of the medications. Document any changes in the client's condition that the medications are intended to treat, as well as any side effects observed and/or reported by your clients, so the health care provider/prescriber can be informed. Make sure staff who administer medications understand what they need to look out for.

Certain medications are more likely to cause problems than others. Pay attention to possible Adverse Drug Events from Specific Medicines (https://www.cdc.gov/medicationsafety/adverse-drug-events-specific-medicines.html).

Please be aware of the Medical Review Subcommittee's Medical Alerts that may apply to your clients. The OMHDD continues to receive reports of the deaths of clients who had been given pain reducing medications for fevers of unknown origin and clients whose pulse oximeter readings were under 90%. In these cases, neither the client's physician, nor other health care provider was notified, nor was 911 called until after the client stopped breathing.

Use of over-the-counter medications and possible delay of treatment [PDF] (https://mn.gov/omhdd/assets/OTC-and-Delay-of-Tx-2013_tcm23-27625.pdf)

Breathing Alert – think pink, not blue! [PDF] (https://mn.gov/omhdd/assets/breathing-alert-2013_tcm23-27664.pdf)

Medical Alert - Pulse Oximetry [PDF] (https://mn.gov/omhdd/assets/PulseOximetry2016_tcm23-264999.pdf)

Thank you for your interest in the Medical and Seasonal alerts.

Please call me at 651-757-1802 or 1-800-657-3506 with any questions or concerns.

Sincerely,

Annelies Stevens de Jong, BSN, RN, PHN, CDDN
Medical Review Coordinator