MINNESOTA
OFFICE OF OMBUDSMAN
FOR MENTAL HEALTH AND
DEVELOPMENTAL DISABILITIES

"Giving Voice to Those Seldom Heard"

121 7th Place East, Suite 420, Metro Square Building
Saint Paul, Minnesota 55101

Voice: 651-757-1800
Toll Free: 800-657-3506
Fax: 651-797-1950
TTY/Voice: Minnesota Relay Service 711
https://mn.gov/omhdd

December 2022

Dear Colleague:

Extending best wishes to you and the clients with whom you work.

I am retiring as Medical Review Coordinator in early December 2022 after more than twenty three years as the Medical Review Coordinator and a total of 30 years of employment with the State of Minnesota. It has been a privilege working with so many of you as you work every day to provide quality services to our mutual clients. Thank you for your dedication and service.

While the phone numbers for the Office of Ombudsman for Mental Health and Developmental Disabilities are not changing, the office is in the process of moving from its former location in the Metro Square building in downtown St. Paul to a new location. Please watch for a forthcoming announcement with details about the new location!

The past nearly three years during the COVID-19 pandemic have been challenging and likely will remain so. This office continues to recommend the following sources of up to date information about COVID-19:

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

MDH - Community Settings: COVID-19
(https://www.health.state.mn.us/diseases/coronavirus/communities.html)

Minnesota's COVID-19 Response - Stay Safe MN (https://mn.gov/covid19/)

CDC – Centers for Disease Control and Prevention - Coronavirus (COVID-19)
(https://www.cdc.gov/coronavirus/2019-ncov/index.html)

The Medical Review Subcommittee (MRS) continues to review reports of individual deaths and 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.

Announcing the Winter Alerts for 2023 (https://mn.gov/omhdd/documents/medical-alerts.jsp)

Winter Alert **Frostbite Alert** **Hypothermia Alert** **NWS Wind Chill Chart**

For continued updates from the OMHDD, you can Subscribe to the OMHDD Medical Alerts E-Mail List Service. When you subscribe to this service, you will be notified by e-mail when new Medical Alerts are posted to OMHDD website.

Method for Reporting Deaths and Serious Injuries

In early 2020, OMHDD made webform reporting available for the routine reporting of deaths and serious injuries. Webform reporting is the preferred method of 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 – Download Forms / Minnesota.gov (mn.gov) (https://mn.gov/omhdd/reporting-death-or-serious-injury/download-forms.jsp)

While webform reporting has been going well so far, the office has received Serious Injury reports on the Death Report webform and Death Reports on the Serious Injury webform. If, for example, you report a death on the Serious Injury webform, the data you reported must be manually transferred to a death report form, and the number assigned to the report you have made will no longer apply.

In addition, while the office recognizes that you may not have all the information requested on the forms, please provide the information to which you do have access, for example: the client's first and last names, the client's date of birth, the date of death (when applicable/known), the contact information for the reporter including the reporter's title (case manager, social worker, program director, mental health practitioner, etc.) and the Reporter's Facility/Agency Name.

Please Note: Both the Death Report and Serious Injury Report forms will timeout after 15 minutes of inactivity. Although the form can be printed after submission, it cannot be "saved" for later completion.

Both online Death Reports and online Serious Injury Reports permit the secure upload of up to ten attachments.

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

Fax: 651-797-1950 Please note the fax number. (The old back-up fax number is no longer available.)

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

FDA MedWatch Safety Alerts and Drug Safety Communications

Since the 2022 Summer Alert, the FDA has released **MedWatch Safety Alerts** and **Drug Safety Communications** for many products and medications, some of which are prescribed for and used by

clients of the OMHDD. Some of the most recent MedWatch Safety Alerts and Drug Safety Communications follow:

Do Not Use Certain Mighty Bliss Electric Heating Pads Due to Risk of Injury: FDA Safety Communication (https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-mighty-bliss-electric-heating-pads-due-risk-injury-fda-safety-communication?utm_medium=email&utm_source=govdelivery)

Date Issued: October 25, 2022

The U.S. Food and Drug Administration (FDA) is warning consumers, caregivers and health care providers not to use the recalled **Mighty Bliss electric heating pads** distributed by Whele LLC (doing business as Perch) due to the risks of injury, including electric shocks, skin burns, rashes or irritation…

Recommendations for Patients, Caregivers and Health Care Providers Who May Have the Recalled Electric Heating Pad

- Check your heating pad to determine if you have a recalled Mighty Bliss electric heating pad. If you have this product, stop using it and follow the recommendations in the recall notice.
- Do NOT use the recalled Mighty Bliss electric heating pads.
- Do NOT purchase the recalled Mighty Bliss electric heating pads.
- Consumers with questions about this recall can call 866-918-8768, Monday through Friday from 8am to 5pm EST, or email mightyblissheatingpad7692@sedgwick.com.

Recommendations for Patients, Caregivers and Health Care Providers When Using Any Electric Heating Pad

- Always follow the safety instructions included with your electric heating pad.
- Use the electric heating pad for only 15-20 mins at a time to avoid the risk of burns.
- Stop using the heating pad if you notice any frayed wires, holes, or tears.
- Stop using the device if sparking occurs.
- Make sure there is no water nearby the heating pad when it is being used.
- Always start with the lowest setting and turn up the heat only if it is needed.
- Place towels between the heating pad and skin to help reduce the risk of burns.
- Never sleep with the heating pad on.
- Do not use the heating pad nearby an oxygen tank.
- Do not use pins, nails, thumbtacks or other metal items to puncture the heating pad.
- If the heating pad has a fabric cover, keep the fabric cover on the heating pad.
- Do not let children use the heating pad unsupervised.
- If you experience any adverse events with use of any electric heating pad, please report the event to the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products.

Pulse Oximeter Accuracy and Limitations: FDA Safety Communication
(https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication)

UPDATE: November 7, 2022

On November 1, 2022, the FDA convened a virtual public meeting of the CDRH Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee to share information and perspectives from interested parties about ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentations.

The FDA is reviewing the committee's recommendations and will consider additional actions as needed. The FDA will share with the public any additional updates to the information and recommendations below.

Date Issued: February 19, 2021

The Coronavirus Disease 2019 (COVID-19) pandemic has caused an increase in the use of pulse oximeters, and a recent report (Sjoding et al.) suggests that the devices may be less accurate in people with dark skin pigmentation. The U.S. Food and Drug Administration (FDA) is informing patients and health care providers that although pulse oximetry is useful for estimating blood oxygen levels, pulse oximeters have limitations and a risk of inaccuracy under certain circumstances that should be considered. Patients with conditions such as COVID-19 who monitor their condition at home should pay attention to all signs and symptoms of their condition and communicate any concerns to their health care provider.

FDA investigating risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia (denosumab) - *May necessitate increased blood calcium monitoring*
(https://www.fda.gov/drugs/drug-safety-and-availability/fda-investigating-risk-severe-hypocalcemia-patients-dialysis-receiving-osteoporosis-medicine-prolia)

11-22-2022 FDA Drug Safety Communication

The U.S. Food and Drug Administration (FDA) is investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with the osteoporosis medicine Prolia (denosumab). Our review of interim results from an ongoing safety study of Prolia suggests an increased risk of hypocalcemia, or low calcium levels in the blood, in patients with advanced kidney disease. Preliminary results from a separate internal FDA study further investigating hypocalcemia in dialysis patients treated with Prolia show a substantial risk with serious outcomes, including hospitalization and death.

Because of the frequency and seriousness of these risks, we are alerting health care professionals and patients about them and that we are continuing to evaluate this potential safety issue with Prolia use in patients with advanced kidney disease, particularly those on dialysis. We will communicate our final conclusions and recommendations when we have completed our review or have more information to share.

Patients should not stop Prolia treatment without first consulting your health care professional, as stopping may worsen your bone condition. Talk to your health care professional about any concerns you may have, including possible alternative treatments. Tell your health care professional if you experience any symptoms of low blood calcium levels such as unusual tingling or numbness in the hands, arms, legs, or feet; painful muscle spasms or cramps; voice box or lung spasms causing difficulty breathing; vomiting; seizures; or irregular heart rhythm…

Additional FDA MedWatch Safety Alerts and Drug Safety Communications are available at https://www.fda.gov/medical-devices/safety-communications/2022-safety-communications and FDA Drug Safety Communications (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications).

Medication Administration

When administering prescription and over-the-counter medications to your clients, please 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.

During the COVID-19 pandemic, this office continues to see cases where a client is found to have a positive test for COVID-19 but remains at the residence in "quarantine." Unfortunately, COVID-19 in some clients can rapidly cause serious problems with breathing/respiration leading to the death of the client before medical aid can be sought. Please be certain that when clients remain home after a positive COVID-19 test, their attending residential staff are aware of how to care for the client, know whom to call for assistance (the facility's nurse, if there is one, OR the client's primary physician/clinic), and when to call 911.

Thank you for your interest in the Medical Alerts.

Please call the main office of at 651-757-1800 or Toll Free: 1-800-657-3506 with any questions or concerns about the Winter Alerts.

Sincerely,

Jo Zillhardt, PMH-BC, RN, PHN
Medical Review Coordinator