MINNESOTA
OFFICE OF OMBUDSMAN
FOR MENTAL HEALTH AND
DEVELOPMENTAL DISABILITIES

"Giving Voice to Those Seldom Heard"

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Dear Colleague:

Extending best wishes to you and the clients with whom you work. The past few months have been challenging and likely will remain so. This office recommends the following sources of up to date information about COVID-19:

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

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

The OMDHH wishes to remind providers that even when Minnesotans are recommended to **Stay Safe MN** and limit interactions with others, it is still important for all of us to go outside, take walks, and go for drives while practicing social (actually physical) distancing.

The Medical Review Subcommittee (MRS) continues to review reports of individual deaths and reviews 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 Summer Alerts for 2020 (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. When you subscribe to this service, you will be notified by e-mail when new Medical Alerts are posted to the OMHDD website.

New Method for Reporting Deaths and Serious Injuries

Earlier in 2020 the 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 – Downloadable Forms (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, if known, and the contact information for the reporter including the reporter title (case manager, social worker, program director, mental health practitioner, etc.) and the Reporter Facility/Agency Name (if applicable).

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.

MedWatch Safety Alerts are now called Drug Safety Communications by the FDA

Since the 2019-2020 Winter Alert, the FDA has released **Drug Safety Communications** for many medications, some of which are prescribed for clients of the OMHDD. These medications include the following:

FDA strengthens warning that untreated constipation caused by schizophrenia medicine clozapine (Clozaril) can lead to serious bowel problems - *Risk increased at higher doses or when taken with other constipating medicines* (https://www.fda.gov/drugs/drug-safety-and-availability/fda-strengthens-warning-untreated-constipation-caused-schizophrenia-medicine-clozapine-clozaril-can)

01-28-2020 FDA Drug Safety Communication - The Food and Drug Administration (FDA) is strengthening an existing warning that constipation caused by the schizophrenia medicine clozapine (Clozaril, Fazaclo ODT, Versacloz, generics) can, uncommonly, progress to serious bowel complications. This can lead to hospitalization or even death if constipation is not diagnosed and treated quickly. Constipation is a frequent and known side effect of clozapine, but serious and fatal events continue to be reported.

Clozapine affects how the intestines (bowels) function in the majority of patients. It produces effects ranging from constipation (trouble having a bowel movement), which is a common occurrence, to serious but uncommon bowel problems, including complete blockage of the bowels. We found that because of the way clozapine works this risk is greater with clozapine than with the other schizophrenia medicines in its drug class. The risk is further increased at higher doses of clozapine and when it is co-prescribed with a type of medicine called

anticholinergics, which can slow the movement in the intestines, and other medicines that cause constipation, including opioids. Many different kinds of medicines have these anticholinergic effects….

FDA requests the withdrawal of the weight-loss drug Belviq, Belviq XR (lorcaserin) from the market - Potential risk of cancer outweighs the benefits (https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market)

2-13-2020 FDA Drug Safety Communication - The U.S. Food and Drug Administration (FDA) has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the U.S. market because a safety clinical trial shows an increased occurrence of cancer. The drug manufacturer, Eisai Inc. has submitted a request to voluntarily withdraw the drug….

FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis - Risks may include suicidal thoughts or actions (https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug)

3-4-2020 FDA Drug Safety Communication - The U.S. Food and Drug Administration (FDA) is strengthening existing warnings about serious behavior and mood-related changes with montelukast (Singulair and generics), which is a prescription medicine for asthma and allergy.

We are taking this action after a review of available information led us to reevaluate the benefits and risks of montelukast use. Montelukast prescribing information already includes warnings about mental health side effects, including suicidal thoughts or actions; however, many health care professionals and patients/caregivers are not aware of the risk. We decided a stronger warning is needed after conducting an extensive review of available information and convening a panel of outside experts, and therefore determined that a Boxed Warning was appropriate.

Because of the risk of mental health side effects, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medicines. For allergic rhinitis, also known as hay fever, we have determined that montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy medicines. For patients with asthma, we recommend that health care professionals consider the benefits and risks of mental health side effects before prescribing montelukast….

Additional information can be obtained at 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.

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 reading 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 Alerts.

Please call me at 651-431-5202 or 1-800-657-3506 with any questions or concerns.

Sincerely,

Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator