MINNESOTA
OFFICE OF OMBUDSMAN
FOR MENTAL HEALTH AND
DEVELOPMENTAL DISABILITIES

"Giving Voice to Those Seldom Heard"

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Dear Colleague:

The Medical Review Subcommittee (MRS) reviews 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.

This cover letter is to announce the Summer Alerts for 2019 (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.

Reports of deaths and serious injuries can be faxed or telephoned to the OMHDD at the following numbers:

Fax: 651-797-1950 Voice: 651-757-1800 Toll Free: 1-800-657-3506

Please note the fax number. The old back-up fax number is no longer available.

Thank you for continuing to fax your Serious Injury and Death reports to the OMHDD and for your cooperation with the review process.

MedWatch Safety Alerts are now called **Drug Safety Communications** - Since the 2018-2019 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:

> **FDA adds Boxed Warning for risk of serious injuries caused by sleepwalking with certain prescription insomnia medicines [04-30-2019]** (https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia)
>
> The Food and Drug Administration (FDA) is advising that rare but serious injuries have happened with certain common prescription insomnia medicines because of sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. These complex sleep behaviors have also resulted in deaths. These behaviors appear to be more common with eszopiclone (Lunesta), zaleplon (Sonata), and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist) than other prescription medicines used for sleep.

As a result, we are requiring a Boxed Warning, our most prominent warning, to be added to the prescribing information and the patient Medication Guides for these medicines. We are also requiring a Contraindication, our strongest warning, to avoid use in patients who have previously experienced an episode of complex sleep behavior with eszopiclone, zaleplon, and zolpidem.

FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering [4-9-2019] (https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes)

The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

While we continue to track this safety concern as part of our ongoing monitoring of risks associated with opioid pain medicines, we are requiring changes to the prescribing information for these medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to health care professionals on how to safely decrease the dose in patients who are physically dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued.

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

Opioids are a class of powerful prescription medicines that are used to manage pain when other treatments and medicines cannot be taken or are not able to provide enough pain relief. They have serious risks, including abuse, addiction, overdose, and death. Examples of common opioids include codeine, fentanyl, hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone.

FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients [12-20-2018] (https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-increased-risk-ruptures-or-tears-aorta-blood-vessel-fluoroquinolone-antibiotics)

A U.S. Food and Drug Administration (FDA) review found that fluoroquinolone antibiotics can increase the occurrence of rare but serious events of ruptures or tears in the main artery of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection.

Fluoroquinolones should not be used in patients at increased risk unless there are no other treatment options available. People at increased risk include those with a history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly. We are requiring that a new warning about this risk be added to the prescribing information and patient Medication Guide for all fluoroquinolones.

Fluoroquinolone antibiotics are approved to treat certain bacterial infections and have been used for more than 30 years. They work by killing or stopping the growth of bacteria that can cause illness.

Without treatment, some infections can spread and lead to serious health problems (see List of Currently Available FDA-Approved Systemic Fluoroquinolones).

Additional information can be obtained at FDA Drug Safety Communications (https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications).

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 our 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