



State of Minnesota
The Office of Ombudsman for
Mental Health and Developmental Disabilities
121 7th Place E. Suite 420 Metro Square Building, St. Paul, Minnesota 55101-2117

November 2015

Dear Colleague:

Greetings from the Office of Ombudsman for Mental Health and Disabilities. This cover letter is to announce the [Winter Alerts for 2015/2016](#) from the Medical Review Subcommittee:

2015/2016 Winter Alert Hypothermia Alert Frostbite Alert
NWS Wind Chill Chart

If you haven't already, please visit our website to sign up for our List Service for e-mail notification of our Medical Alerts at <https://webmail.mnet.state.mn.us/mailman/listinfo/Medical-alert>

Death and Serious Injury Reporting Update:

Reports of deaths and serious injuries can be faxed or telephoned to the Office of Ombudsman for Mental Health and Developmental Disabilities at the following numbers:

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

It has come to our attention that our new fax number only can receive faxes from digital (not analog) fax machines. If you are using an older (analog) fax machine and have difficulty faxing reports to our office, please use our old fax number: 651-296-1021.

This Office had hoped to be able to offer on-line reporting of deaths and serious injuries through our website. There has been a delay in that availability. We suggest you ensure that you and your colleagues are members of the List Service (as noted above) for immediate notification when on-line reporting becomes available. We continue to accept reports via fax machine, and we encourage you to use the updated report forms available on our website at <http://mn.gov/omhdd/report-death-or-serious-injury/download/>

Please review the following two Medical Alerts –

In addition this year, we are asking you to review two of our previously issued Medical Alerts, because we continue to see deaths of clients related to the issues identified in the Alerts. They are

1. **Client Residence Information for Health Care Providers:** “The Medical Review Subcommittee (MRS) continues to review a large number of cases in which the client had appeared ill to residential staff shortly before his or her unexpected death. Residential staff brought the client to the clinic, to Urgent Care, or to the Emergency Department for assessment, and the client was returned home to the residential facility only to die unexpectedly at the residence....”

<http://mn.gov/omhdd/images/client-residence.pdf>

and

2. **Use of over-the-counter medications and possible delay of treatment – Bottom Line:** Unless otherwise directed by the client’s primary health care provider, the Medical Review Subcommittee recommends that providers DO NOT ADMINISTER “as needed” or “prn” medications to reduce a fever for longer than 24 hours without obtaining a professional assessment by the client’s primary health care provider.

<http://mn.gov/omhdd/images/OTC-and-Delay-of-Tx-2013.pdf>

MedWatch Updates:

This office continues to recommend that providers, families and clients be aware of the FDA’s MedWatch website, which provides updated and on-going information about warnings and alerts for medications and medical devices. The FDA has released MedWatch Safety Alerts for many medications, many of which are prescribed for clients of this Office. These medications include:

1. **Clozapine:** Drug Safety Communication - FDA Modifies Monitoring for Neutropenia; Approves New Shared REMS Program; [Posted 09/15/2015]; ISSUE: FDA is making changes to the requirements for monitoring, prescribing, dispensing, and receiving the schizophrenia medicine clozapine, to address continuing safety concerns and current knowledge about a serious blood condition called severe neutropenia. Severe neutropenia is a dangerously low number of neutrophils, white blood cells that help fight infections. Severe neutropenia can be life-threatening. For the complete safety alert, please see the following:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm462229.htm>

2. **Codeine Cough-and-Cold Medicines** in Children: Drug Safety Communication - FDA Evaluating Potential Risk of Serious Side Effects; [Posted 07/01/2015]; ISSUE: FDA is investigating the safety of using codeine-containing medicines to treat coughs and colds in children under 18 years because of the potential for serious side effects, including slowed or difficult breathing. Children, especially those who already have breathing problems, may be more susceptible to these serious side effects. In 2013, FDA warned against using codeine in children who recently had surgery to remove their tonsils and/or adenoids. In April 2015, the European Medicines Agency (EMA) announced that codeine must not be used to treat cough and cold in children under 12 years, and that codeine is not recommended in children and adolescents between 12 and 18 years who have breathing problems, including those with asthma and other chronic breathing problems. FDA will continue to evaluate this safety issue and will consider the EMA recommendations. Final conclusions and recommendations will be communicated when the FDA review is complete. For the complete safety alert, please see the following:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm>

3. **Invokana and Invokamet (canagliflozin):** Drug Safety Communication - New Information on Bone Fracture Risk and Decreased Bone Mineral Density; [Posted 09/10/2015]; ISSUE: FDA has strengthened the warning for the type 2 diabetes medicine canagliflozin (Invokana, Invokamet) related to the increased risk of bone fractures, and added new information about decreased bone mineral density. To address these safety concerns, FDA added a new

Warning and Precaution and revised the Adverse Reactions section of the Invokana and Invokamet drug labels. For the complete safety alert, please see the following:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm461876.htm>

4. **Kayexalate (sodium polystyrene sulfonate):** Drug Safety Communication - FDA Requires Drug Interaction Studies; [Posted 10/22/2015]; **ISSUE:** FDA is requiring the Kayexalate manufacturer to conduct studies to investigate Kayexalate's potential to bind to other medications administered by mouth – drug interactions that could affect how well the other medications work. The approved labeling for Kayexalate describes its potential to decrease absorption of lithium and thyroxine; however, extensive drug-drug interaction studies with Kayexalate have not been performed. During FDA's review of another potassium-lowering drug, Veltassa (patiromer), we found that Veltassa bound to about half of the medications tested, some of which are commonly used in patients who require potassium-lowering drugs. Such binding could decrease the effects of these medications. The label for Veltassa contains a warning not to take other orally administered medications within 6 hours of taking Veltassa.... For the complete safety alert, please see the following:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm468720.htm>

5. **Non-aspirin Nonsteroidal Anti-inflammatory Drugs (NSAIDs):** Drug Safety Communication - FDA Strengthens Warning of Increased Chance of Heart Attack or Stroke; [Posted 07/09/2015]; **ISSUE:** FDA is strengthening an existing label warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) increase the chance of a heart attack or stroke. Based on FDA's comprehensive review of new safety information, FDA is requiring updates to the drug labels of all prescription NSAIDs. As is the case with current prescription NSAID labels, the Drug Facts labels of over-the-counter (OTC) non-aspirin NSAIDs already contain information on heart attack and stroke risk. FDA will also request updates to the OTC non-aspirin NSAID Drug Facts labels. See the [FDA Drug Safety Communication](#) (Table 1) for a list of non-aspirin nonsteroidal anti-inflammatory drug products. Prescription NSAID labels will be revised to reflect the following information:

- The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.
- The risk appears greater at higher doses. - It was previously thought that all NSAIDs may have a similar risk. Newer information makes it less clear that the risk for heart attack or stroke is similar for all NSAIDs; however, this newer information is not sufficient for us to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID.
- NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.
- In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.
- Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.
- There is an increased risk of heart failure with NSAID use.

For the complete safety alert, please see the following:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm454141.htm>

- 6. Hepatitis C Treatments Viekira Pak and Technivie:** Drug Safety Communication - Risk of Serious Liver Injury; [Posted 10/22/2015]; ISSUE: FDA is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, FDA is requiring the manufacturer to include information about serious liver injury adverse events to the Contraindications, Warnings and Precautions, Postmarketing Experience, and Hepatic Impairment sections of the Viekira Pak and Technivie drug labels. For the complete safety alert, please see the following:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm468757.htm>

Additional information about MedWatch Safety Alerts can be obtained at the FDA's website: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm>

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 call me, at either the toll free or voice numbers, with any questions or concerns. Thank you for your interest in our Medical Alerts and for your continued cooperation with the Office of Ombudsman for Mental Health and Developmental Disabilities.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Jo Zillhardt', with a horizontal line extending to the right.

Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator