State of Minnesota

The Office of Ombudsman for Mental Health and Developmental Disabilities

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"Giving Voice to Those Seldom Heard"

November 2016

Dear Colleague:

Greetings from The Office of Ombudsman for Mental Health and Disabilities. This cover letter is to announce the Winter Alerts for 2016/2017 from the Medical Review Subcommittee:

2016/2017 Winter Alert **Hypothermia Alert** **Frostbite Alert** **NWS Wind Chill Chart**

Please review the following new Medical Alert – Pulse Oximetry

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 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.

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. Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR): Drug Safety Communication - Strengthened Kidney Warnings. ISSUE: FDA has strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR). Based on recent reports, we have revised the warnings in the drug labels to include information about acute kidney injury and added recommendations to minimize this risk. The complete warning can be found at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm506554.htm

2. Direct-Acting Antivirals for Hepatitis C: Drug Safety Communication - Risk of Hepatitis B Reactivating. ISSUE: The FDA is warning about the risk of hepatitis B virus (HBV) becoming an active infection again in any patient who has a current or previous infection with HBV and is treated with certain direct-acting antiviral (DAA) medicines for hepatitis C virus. In a few cases, HBV reactivation in patients treated with DAA medicines resulted in serious liver problems or death. HBV reactivation usually occurred within 4-8 weeks. As a result, FDA is requiring a Boxed Warning, our most prominent

warning, about the risk of HBV reactivation to be added to the drug labels of these DAAs directing health care professionals to screen and monitor for HBV in all patients receiving DAA treatment. This warning will also be included in the patient information leaflet or Medication Guides for these medicines. The complete warning can be found at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm523690.htm

3. Opioid Pain or Cough Medicines Combined With Benzodiazepines: Drug Safety Communication - FDA Requiring Boxed Warning About Serious Risks and Death. ISSUE: FDA review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, FDA is adding Boxed Warnings, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines. See the Drug Safety Communication for a listing of all approved prescription opioid pain and cough medicines, and benzodiazepines and other CNS depressants. The complete warning can be found at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm518710.htm

4. Testosterone and Other Anabolic Androgenic Steroids (AAS): FDA Statement - Risks Associated With Abuse and Dependence. ISSUE: FDA approved class-wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS. The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act. Testosterone and other AAS are abused by adults and adolescents, including athletes and body builders. Abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The complete warning can be found at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm526151.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,

Jo Zillhardt, RN-BC, PHN
Medical Review Coordinator