State of Minnesota

The Office of Ombudsman for Mental Health and Developmental Disabilities

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"Giving Voice to Those Seldom Heard"

November 2017

Dear Colleague:

Greetings from the Office of Ombudsman for Mental Health and Developmental Disabilities. This cover letter is to announce the Winter Alerts for 2017/2018 from the Medical Review Subcommittee:

Winter Alert 2017-2018 - Hypothermia Alert - Frostbite Alert - NWS Wind Chill Chart

Please review the following new Medical Alert – **"Pseudoseizures" and "Nosebleed" leading to a**

Delay of Treatment and Death of a Client

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 OMHDD Medical Alerts Email List Service Link

Death and Serious Injury Reporting Update:

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

Fax: 651-797-1950

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.

If you have questions about reporting or need to contact our office, please call either of the following numbers:

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

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 – and vitamins – include:

The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication - Date Issued: November 28, 2017 - Summary of Problem and Scope:

Biotin in blood or other samples taken from patients who are ingesting high levels of biotin in dietary supplements can cause clinically significant incorrect lab test results. The FDA has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests.

Biotin in patient samples can cause falsely high or falsely low results, depending on the test. Incorrect test results may lead to inappropriate patient management or misdiagnosis. For example, a falsely low result for troponin, a clinically important biomarker to aid in the diagnosis of heart attacks, may lead to a missed diagnosis and potentially serious clinical implications. The FDA has received a report that one patient taking high levels of biotin died following falsely low troponin test results when a troponin test known to have biotin interference was used.

The FDA is aware of people taking high levels of biotin that would interfere with lab tests. Many dietary supplements promoted for hair, skin, and nail benefits contain biotin levels up to 650 times the recommended daily intake of biotin. Physicians may also be recommending high levels of biotin for patients with certain conditions such as multiple sclerosis (MS). Biotin levels higher than the recommended daily allowance may cause interference with lab tests.

Patients and physicians may be unaware of biotin interference in laboratory assays. Even physicians who are aware of this interference are likely unaware as to whether, and how much biotin, patients are taking. Since patients are unaware of biotin interference, patients may not report taking biotin supplements to their physicians, and may even be unware they are taking biotin (e.g., when taking products generally labeled for their benefits to hair and nails)…. Additional information can be found at
FDA.Gov/The FDA Warns FDA Warns that Biotin May Interfere with Lab Tests Link

Kayexalate (sodium polystyrene sulfonate): Drug Safety Communication - FDA Recommends Separating Dosing - Posted 09/06/2017 - ISSUE: FDA is recommending that patients avoid taking the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) at the same time as other medicines taken by mouth. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines. To reduce this likelihood, we recommend separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least 3 hours. We are updating the sodium polystyrene sulfonate drug labels to include information about this dosing separation. Additional information can be found at FDA.Gov/Kayexalate (sodium polystyrene sulfonate) Link

Opioid Addiction Medications in Patients Taking Benzodiazepines or CNS Depressants: Drug Safety Communication - Careful Medication Management Can Reduce Risks - Posted 09/20/2017 - ISSUE: Based on additional review, FDA is advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care professionals can reduce these risks. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment (MAT) drugs and benzodiazepines together…. BACKGROUND: Many patients with opioid dependence may also use benzodiazepines or other CNS depressants, either under a health care professional's direction or illicitly. Although there are serious risks with combining these medicines, excluding patients from MAT or discharging patients from treatment because of use of benzodiazepines or CNS depressants is not likely to stop them from using these drugs together. Instead, the combined use may continue outside the treatment setting, which could result in more severe outcomes.

RECOMMENDATIONS: Health care professionals should take several actions and precautions and develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. These include:
•Educating patients about the serious risks of combined use, including overdose and death that can occur with CNS depressants even when used as prescribed, as well as when used illicitly.
•Developing strategies to manage the use of prescribed or illicit benzodiazepines or other CNS depressants when starting MAT.
•Tapering the benzodiazepine or CNS depressant to discontinuation if possible.
•Verifying the diagnosis if a patient is receiving prescribed benzodiazepines or other CNS depressants for anxiety or insomnia, and considering other treatment options for these conditions.
•Recognizing that patients may require MAT medications indefinitely and their use should continue for as long as patients are benefiting and their use contributes to the intended treatment goals.
•Coordinating care to ensure other prescribers are aware of the patient's buprenorphine or methadone treatment.
•Monitoring for illicit drug use, including urine or blood screening.

Patients taking MAT drugs should continue to take these medicines as prescribed. Do not stop taking other prescribed medicines without first talking to your health care professional. Before starting any new medicines, tell your health care professional that you are taking MAT. Do not take non-prescribed benzodiazepines or other sedatives (See Table 2 in the Drug Safety Communication, List of Benzodiazepines and Other CNS Depressants) or use alcohol when taking MAT because the combined use increases the possibility of harm, including overdose and death.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program. The safety alert can be found at FDA.Gov/MedWatch Safety Information and Adverse Event Reporting Program Link

Additional information about MedWatch Safety Alerts can be obtained at the FDA's website: FDA.Gov/Medical Product Safety Information

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.

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. Please call me, at either the toll free or voice numbers above, with any questions or concerns.

Sincerely,
Jo Zillhardt, BSN, RN-BC, PHN
Medical Review Coordinator