The 2016 - 2017 Florida Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents were updated to provide a guide for clinicians in using psychotherapeutic medications to treat children and adolescents with behavioral health conditions. The guidelines cover a range of conditions that providers may encounter in their clinical practice including: attention-deficit hyperactivity disorder (ADHD), severe or chronic impulsive aggression, anxiety disorders, bipolar disorder and major depressive disorder (MDD). The guidelines also include treatment of insomnia, obsessive compulsive disorder (OCD), post-traumatic stress disorder (PTSD), early-onset schizophrenia and tic disorders. We have updated the guidelines to include the new DSM-5 diagnosis of disruptive mood dysregulation disorder (DMDD).

Visit our website medicaidmentalhealth.org to view these guidelines.

Please contact Sabrina Singh at sabrinasingh@usf.edu if you would like to preorder hardcopies of the guidelines.

THE PHARMACIST’S CORNER

The Pharmacist’s Corner of our newsletter is devoted to providing prescribers with the most current information on psychotherapeutic drugs and mental health treatment. The Pharmacist’s Corner is written by Thea Moore, PharmD, BCPP and includes contributions from Olivia Pane, PharmD, Sarah Steinhardt, PharmD, JD, MS, Kaitlyn Straus, PharmD Candidate, and Justine Fullenwider, PharmD Candidate. Dr. Moore is an Associate Professor in the Department of Pharmacotherapeutics and Clinical Research at the University of South Florida College of Pharmacy.

Increasing Access to Naloxone in Florida

Thea Moore, PharmD, BCPP, and Justine Fullenwider, PharmD Candidate

Fatal drug overdoses have increased dramatically over the past three decades. A majority of these overdoses were attributed to heroin and prescription opioids. Greater than 28,000 deaths per year are attributable to heroin and prescription opioids. Opioid overdose is reversible through timely use of the medication naloxone and provision of other emergency care.

In order to address this opioid epidemic, the majority of states have created and/or amended laws to allow increased access to emergency care and medical treatment of opioid overdose with agents such as naloxone.

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Forty-seven states and the District of Columbia have passed legislation designed to improve layperson naloxone access. These states have made it easier for bystanders or people who might be in a position to assist in an overdose to access the medication, encouraged those individuals to summon emergency responders, or both. Naloxone is a prescription medication but is not a controlled substance. Naloxone is not thought to cause abuse or dependence. The federal government has the authority to determine whether a drug requires a prescription and states have the authority to determine which providers can issues prescriptions and who can dispense these prescriptions. This power that the states have allow them to increase access to certain medications, such as naloxone. Around the US, different states have laws that permit naloxone to either be prescribed via a standing order, prescribed by a pharmacist, or be dispensed under a collaborative practice agreement with a physician.

On March 25th 2016, Florida Governor Rick Scott signed into law a measure that allows pharmacists to dispense naloxone with a physician’s standing order. Making naloxone more available was one of the recommendations of the Orange Country Heroin Task Force.

HB 1241: Ordering of Medication
Ordering of Medication; Providing that a pharmacist may dispense an emergency opioid antagonist pursuant to a non-patient-specific standing order for an auto injection delivery system or intranasal application delivery system; revising the authority of a licensed physician assistant to order medication under the direction of a supervisory physician for a specified patient; revising the term "prescription" to exclude an order for drugs or medicinal supplies dispensed for administration; authorizing a licensed practitioner to authorize a licensed physician assistant or advanced registered nurse practitioner to order controlled substances for a specified patient under certain circumstances, etc.

The law became effective on 7/1/2016.

What we know about Florida: It appears from information received from CVS and Walgreens pharmacies, that Florida will have a protocol based availability for naloxone. This means that a patient or caregiver may go into any pharmacy that has this protocol in place and request naloxone. The pharmacist would then process the request as a “prescription” under a standing protocol. The “prescription” is then processed under the protocol doctor and given to the patient. This process is similar to the process in place for pharmacists to administer vaccinations and immunizations.

The protocol in place in CVS pharmacies in Florida indicates that the pharmacist must counsel the purchaser on how to use naloxone, how to recognize signs of overdose and importance of calling 911 after administering a dose to someone and staying with the person until help arrives. Pharmacists must be satisfied that buyers understand these conditions prior to dispensing the medication. This is consistent with the process utilized in other states like Ohio.

The price: Per CVS, the cost would be $45 per dose of naloxone auto-injector and $90 for the intranasal form of the drug. An article from September 7, 2016 indicated that a two-dose pack of the nasal spray was purchased in a CVS pharmacy for $126.45.

CVS has alerted pharmacists at their 878 stores in Florida. It does not appear that all of these stores have the drug available at this time.

For more information, visit [http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0381/Sections/0381.887.html](http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0381/Sections/0381.887.html)
Obesity in the United States is now considered to be an epidemic, with data from the Centers for Disease Control and Prevention (CDC) reporting that an alarming 34.9% of U.S. adults are obese. There are several major causes of overweight and obesity, the most common being excess calorie intake and lack of physical activity. Certain medications may also lead to weight gain as an unfavorable side effect, including many psychotropic medications. Psychotropic agents with the highest incidence of weight gain include the mood stabilizer lithium, the antidepressants paroxetine and amitriptyline, and the atypical antipsychotics clozapine, olanzapine, quetiapine and risperidone. Studies have shown an average weight gain of 10 kilograms (kg) in patients treated with clozapine after 52 weeks, 6.26 kg with olanzapine after 60 weeks, 3.19 kg with quetiapine after 52 weeks, and 8.3 kg with risperidone over a two-year period.

Regardless of the cause of weight gain, obesity can have significant consequences. Obesity is associated with increased risk for stroke, heart disease, certain cancers, and type 2 diabetes. Further, atypical antipsychotics have the potential to cause other metabolic side effects in addition to weight gain, one of which is the development or worsening of type 2 diabetes. It is therefore equally important to focus on weight loss as both a preventive measure and as part of the management of type 2 diabetes in patients receiving atypical antipsychotics.

In order to address the growing need for weight loss strategies in patients with type 2 diabetes who are overweight or obese, the American Diabetes Association (ADA) has updated its Standards of Medical Care, which is published annually in *Diabetes Care* based on an extensive literature review. The ADA guideline includes several key recommendations which providers are encouraged to take into consideration when treating patients with diabetes. The ADA begins by recommending that BMI be assessed at each visit, and by suggesting a goal of at least 5% weight loss for those who are overweight or obese by means of dietary interventions, physical activity, and behavioral therapy. With regard to diet, the ADA recommends promoting weight loss by prescribing a deficit of 500 to 750 calories per day or by suggesting that patients consume 1200-1500 calories per day (women) or 1500 – 1800 calories per day (men). The guideline also mentions that diets varying in carbohydrate, fat, and protein content are all equally effective in achieving weight loss, and that short-term, very low calorie diets (800 calories per day or fewer) can be prescribed to achieve higher amounts of weight loss under the close monitoring of a trained professional. Finally, once patients have successfully achieved their weight loss goals, the ADA recommends that those patients be placed on a long-term weight maintenance program with monthly check-ins to ensure continued success.

In addition to lifestyle interventions, the ADA guideline also discusses pharmacotherapy options for overweight and obese patients with type 2 diabetes. First, it is suggested that providers choose agents for treatment of diabetes that promote weight loss or that have a neutral effect on weight, if possible.

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THE PHARMACIST’S CORNER
American Diabetes Association 2016 Guideline Update: Spotlight on Obesity Management continued...

Table 1: Diabetes medications and their Association with Weight

<table>
<thead>
<tr>
<th>Weight Loss</th>
<th>Weight Neutral</th>
<th>Weight Gain</th>
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<tbody>
<tr>
<td>biguanides</td>
<td>dipeptidyl peptidase-4 (DPP-4) inhibitors</td>
<td>insulin sulfonylureas</td>
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<tr>
<td>- metformin</td>
<td>sitagliptin</td>
<td>- glyburide</td>
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<tr>
<td>alpha-glucosidase inhibitors</td>
<td></td>
<td>- glipizide</td>
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<tr>
<td>- acarbose</td>
<td>linagliptin</td>
<td>- glimepiride</td>
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<td></td>
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<td>glinides</td>
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<tr>
<td>glucagon-like peptide-1 (GLP-1) receptor agonists</td>
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<td>thiazolidinediones</td>
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<td>- exenatide</td>
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<td></td>
<td>albiglutide</td>
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<td>amylin mimetics</td>
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<tr>
<td>- pramlintide</td>
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<tr>
<td>sodium-glucose cotransporter-2 (SGLT-2) inhibitors</td>
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<td>- canagliflozin</td>
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<td>Dapagliflozin</td>
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Additionally, the guideline discusses the use of medications that can be used on a long-term basis as an adjunct to diet, physical activity, and behavioral therapy to assist with weight loss. The five classes of medications that are approved for long-term treatment of obesity and that are discussed in the ADA guideline are lipase inhibitors (orlistat- Xenical®), selective serotonin 5HT2c agonists (lorcaserin- Belviq®), sympathomimetic amine anorectic / antiepileptic combinations (phentermine/topiramate- Qsymia®), opioid antagonist / aminoketone antidepressant combinations (naltrexone/bupropion- Contrave®) and human glucagon-like peptide 1 receptor agonists (liraglutide- Saxenda®). These medications are approved for use in patients who have a BMI of 27 kg/m² or greater with one additional obesity-related comorbid condition, or in patients who have a BMI of 30 kg/m² or greater regardless of additional comorbidities. If a provider and patient choose to utilize one of these medications, the patient should be assessed on a monthly basis for the first three months of therapy, and any medication that fails to achieve at least a 5% weight loss over the first three months of therapy should be discontinued.

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Finally, bariatric surgery is included in the guideline as an additional strategy for weight loss in patients with type 2 diabetes who have a BMI that is greater than 35 kg/m$^2$. This is especially beneficial for patients who are unable to achieve weight loss and improve glycemic control with lifestyle interventions and pharmacotherapy.\(^7\)

Given the strong association between type 2 diabetes and obesity and the existing evidence to indicate that weight loss is a beneficial component of the management of diabetes, clinicians are encouraged to review the obesity recommendations in the 2016 ADA Standards of Medical Care in Diabetes and to utilize these recommendations when appropriate. The guideline provided by the ADA may also serve as a helpful tool for providers who have patients with psychotropic medication-induced weight gain and/or diabetes, and its recommendations should be considered for these patients as well.


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**Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program Update**

*Thea Moore, PharmD, BCPP*

It was announced in May 2016 that the full REMS program (Phase 2) launch would occur in December 2016. On December 16, 2016 it was announced that the date of this launch has been postponed. “recent technical and logistical challenges” were cited as the reasons that the launch of the full program has been postponed. Reportedly, this phased approach to full implementation is being done to “ensure that patients relying on clozapine are able to maintain access...while ensuring that the risks associated with it are appropriately managed.”

**What does this mean for prescribers and pharmacies?**

Prescribers and pharmacies are encouraged to use this additional time to certify in the program prior to the full launch which would include a fully implemented predispense authorization (PDA) for pharmacies. Prescribers should submit absolute neutrophil count (ANC) results as required (every 7, 15, or 31 days based on patients’ monitoring frequency) and ensure the ANC is current.

At this time, so as not to disrupt the patient’s ability to access clozapine, patients are able to obtain clozapine even if the PDA is not obtained, prescriber not certified, pharmacy not certified, the ANC results are not entered and/or the ANC is not current. Once the full launch has taken place, the patient’s ability to receive clozapine will be impacted by failure to meet these criteria.
Starting January 1, 2017, Physician Assistants (PA’s) and Advanced Registered Nurse Practitioners (ARNP’s) can prescribe controlled substances. ARNPs may only prescribe or dispense a controlled substance as defined by Florida Statute 893.03 if they have graduated from a program with a masters or doctoral degree in a clinical nursing specialty area, with training in specialized practitioner skills. All PAs and ARNPs must complete at least 3 hours of continuing education of the safe and effective prescribing of controlled substances. PAs and ARNPs must report themselves as controlled substance prescribers on their practitioner profile if they plan to prescribe for the treatment of chronic non-malignant pain. Qualified ARNPs and PAs can prescribe substances listed as Schedule II, Schedule III, or Schedule IV according to Florida House bill 423 and House Bill 375. In addition, ARNPs who are certified as psychiatric nurses can prescribe certain controlled substances according to Florida House Bill 977. House Bill 375 was signed into law in March 2016; House Bills 375 and 423 were signed into law in April 2016.

According to the new laws, prescribing privileges for controlled substances listed in Schedule II are limited to a 7-day supply and do not include prescribing of psychotropic medications for children under 18 years of age, unless the prescriber is an ARNP who is qualified as a Psychiatric Nurse. The new laws also stipulate that only licensed allopathic or osteopathic physicians may prescribe controlled substances or dispense medications in a registered pain management clinic.

To facilitate safe prescribing of controlled substances, the Florida Board of Nursing has established a Committee to recommend a formulary of controlled substances that an ARNP may or may not prescribe for specific uses or in limited quantities. For physician assistants, the supervising physician must delegate authority to the PA outlining which medicinal drugs the physician designates the PA to prescribe.


For information from the Florida Board of Nursing, visit [http://floridasnursing.gov/](http://floridasnursing.gov/).


References:

Florida Medicaid Drug Therapy Management Program for Behavioral Health

Working with Medicaid providers to:
- Improve behavioral health prescribing practices
- Improve patient adherence to medication
- Reduce clinical risks and medication side effects
- Improve behavioral and physical health outcomes

The following treatment guidelines are available on our website at medicaidmentalhealth.org.
- Autism Spectrum Disorder & Intellectual Disability Disorder: Psychotropic Medication Recommendations for Target Symptoms in Children and Adolescents
- Best Practice Psychotherapeutic Medication Guidelines for Adults
- Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach
- Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents

The Florida Clozapine Hotline and The Florida Pediatric Psychiatry Hotline are free services that provide consultation about medication management.

**Florida Clozapine Hotline**
1-727-562-6762

**Florida Pediatric Psychiatry Hotline**
1-866-487-9507

If you would like hard copies of any of our guidelines mailed to you, please contact Sabrina Singh at sabrinasingh@usf.edu.

For more information, visit us at medicaidmentalhealth.org