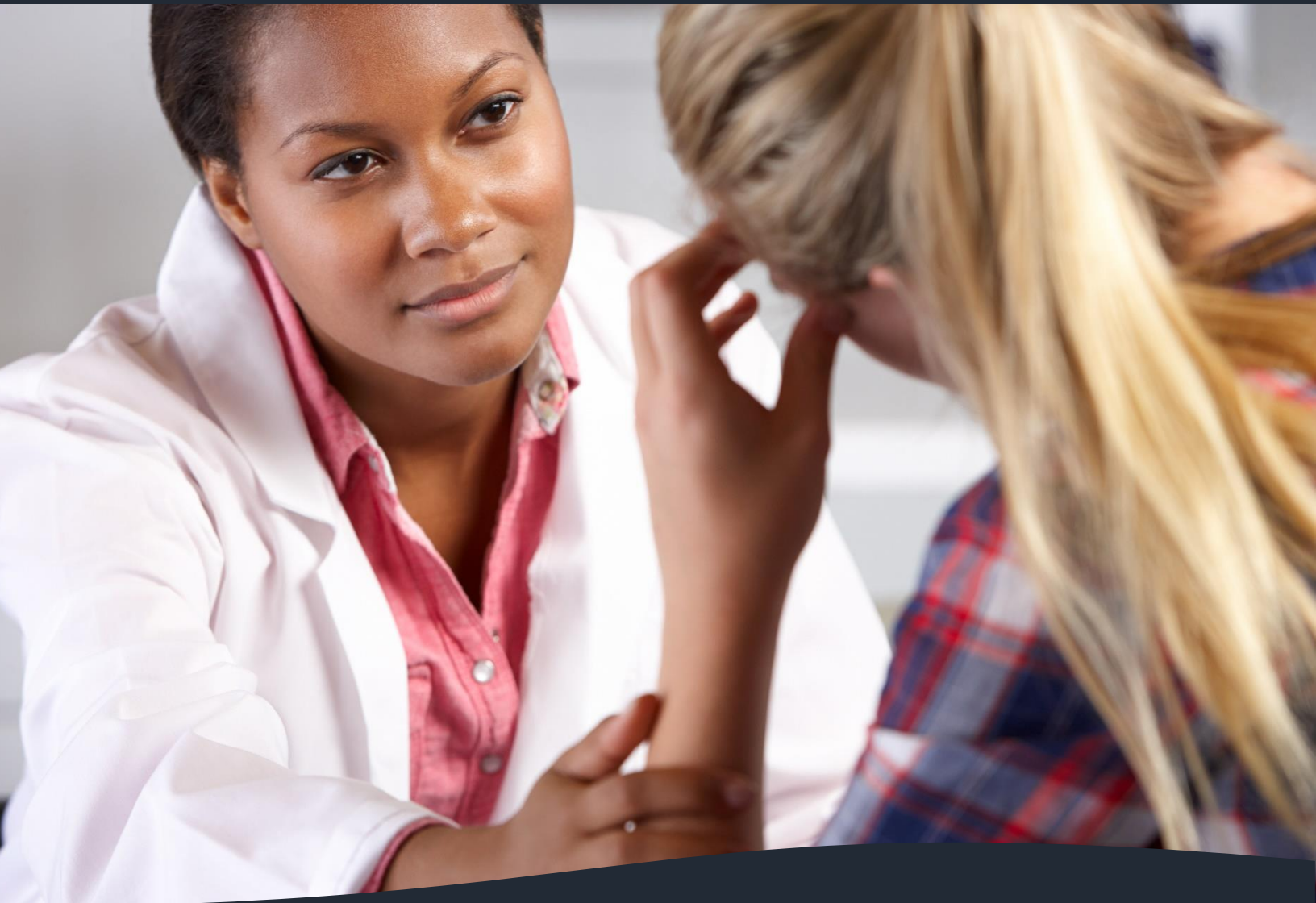


January 2023



Prescribing Guidelines for Pennsylvania



CENTRAL NERVOUS SYSTEM (CNS) STIMULANTS IN PEDIATRIC PATIENTS

For the purposes of this document, the term “pediatric patient” includes children and adolescents younger than 18 years old. It is important to note that existing literature on stimulant prescribing for pediatric patients does not include well-defined, consistent age ranges.

Central Nervous System (CNS) stimulants (referred to as “stimulants” throughout this guideline) are a common pharmacological treatment for pediatric patients with attention-deficit hyperactivity disorder (ADHD).

Stimulants are known to cause increased wakefulness, reduced appetite, and feelings of euphoria brought on by the rapid release of neurotransmitters, including dopamine, serotonin, and norepinephrine.¹ Common prescription stimulants, typically prescribed for the treatment of ADHD, include amphetamines (e.g., Adderall® and Dexedrine®) and methylphenidate (e.g., Ritalin® and Concerta®).

Many stimulant medications are a Schedule II controlled substance, designated by the U.S. Drug Enforcement Administration (DEA). As defined by the DEA, Schedule II controlled substances have a higher potential for misuse and abuse which underscores the need for safe prescribing and patient education when initiating and providing chronic stimulant therapy. This guideline provides information on effective prescribing practices of stimulants for pediatric patients and discusses trends among stimulant prescribing in Pennsylvania and misuse, care during chronic stimulant therapy,

discontinuation of stimulant therapy, and non-stimulant treatment options.

Trends²

Analysis of dispensation data from the Pennsylvania Prescription Drug Monitoring (PDMP) System shows that, in Pennsylvania, there has been a 10.8% decrease in the number of prescription stimulant dispensations from quarter 3 (July-September) of 2016 to quarter 3 of 2021 for children ages 0-14 years. For children and young adults ages 15-24 years, there has been a 5.1% increase in the number of prescription stimulant dispensations during the same period.

From quarter 3 of 2016 to quarter 3 of 2021, non-fatal overdoses involving prescription or illicit stimulants increased by 39.3% for children ages 0-14 years (0.57 per 10,000 stimulant overdose-related emergency department visits to 0.79 per 10,000). During the same period, non-fatal overdoses involving prescription or illicit stimulants also increased by 62.1% for children and young adults ages 15-24 years (1.8 per 10,000 stimulant overdose-related emergency department visits to 2.9 per 10,000).

In Pennsylvania, most stimulant-related fatal overdoses (among all age groups) also involve an opioid, and stimulant-related overdose deaths are mostly driven by the illicit stimulant cocaine. Stimulant-related fatal overdoses are rare among the 0-14 years age group

(<5 from years 2017-2021) and among teens and young adults ages 15-24 years, fatal overdoses decreased by 39.1% between years 2017 to 2021.

The Substance Abuse and Mental Health Services Administration (SAMHSA) has found that the misuse of prescription stimulants among youth is a public health concern. In 2019, 1.7% of children ages 12-17 years reported the misuse of prescription stimulants in the past year.² Additionally, 67% of high school seniors who reported the misuse of prescription stimulants in 2019 (in the past year), did so simultaneously with other substances (e.g., alcohol or marijuana).² Further, college students who misuse prescription stimulants are more likely to report heavy drinking when compared to those who do not misuse prescription stimulants.² Adolescent patients, in particular, can benefit from ongoing education on the importance of taking prescription stimulants as prescribed and the risks associated with polysubstance use and misuse.

Practice Recommendations

Between 70-80% of pediatric patients with ADHD have fewer ADHD symptoms when taking stimulant medication.³ While stimulant medication may be efficacious treatment for ADHD and other conditions, providers should incorporate the following considerations and practices into their care of pediatric patients who may be initiated and prescribed stimulant therapy.

Evaluation and Initiation of Therapy^{3-8, 32-34}

1. Before initiating stimulant therapy, providers should conduct and document a history that includes a detailed mental and physical examination that uses evidence-based screening and diagnostic tools and establishes screening and diagnosis for comorbidities.
 - a. Pediatric patients with ADHD may have comorbid illnesses or conditions. In fact, an estimated 50% of children with ADHD have at least one mental health comorbid condition.⁴ The American Academy of Pediatrics recommends that providers assess and screen for other conditions, such as developmental disorders and physical conditions, that may cause similar symptoms to and/or co-exist with ADHD.
 - b. The American Academy of Pediatrics guidelines for diagnosis and evaluation of ADHD recommend that providers evaluate pediatric patients for ADHD if they are having academic or behavioral problems and show signs of inattention, hyperactivity, or impulsivity.⁵ Reports on the patient's symptoms may be obtained from parents, legal guardians, school staff, other family members, and/or mental health providers or specialists involved with the patient's

care.⁵ Information should also be obtained from the pediatric patient.

- c. A diagnosis for ADHD should be established prior to starting a pediatric patient on stimulant therapy. The criteria for the diagnosis of ADHD are defined in the “Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).” The criteria for the diagnosis of ADHD may be found from the [Centers for Disease Control and Prevention](#). Diagnostic accuracy for ADHD is improved by using psychometrically validated measures of symptoms and impairment.
 - d. Stimulants may be considered for pediatric patients with diagnosed narcolepsy. A preliminary diagnosis of narcolepsy may be made based on excessive daytime sleepiness, sudden loss of muscle tone (cataplexy), hypnagogic hallucinations, or sleep paralysis.³²⁻³³ Pediatric patients rarely demonstrate all four symptoms.³⁴ Formal diagnosis requires an overnight stay at a sleep center for sleep analysis by a sleep specialist.³²
2. When considering stimulant therapy, the active use of other medication, including other controlled substances, should be considered. Concurrent use of controlled substances and/or

other prescribed medications may reduce the desired effect. Pennsylvania state law requires providers to obtain and review a report from the Prescription Drug Monitoring Program (PDMP) System before prescribing a controlled substance. Care should be taken to obtain PDMP data from all relevant states, which can usually be accomplished through the Pennsylvania PDMP System.

3. Stimulants may be avoided in patients with psychotic symptoms or unmanaged bipolar disorder. Concurrent stimulant use with monoamine oxidase inhibitors (MAOI) or use in 14 days preceding MAOI treatment may not be advised. Similarly, if there is a history of mania or psychosis, severe anorexia, narrow-angle glaucoma, uncontrolled hyperthyroidism or hypertension, or symptomatic cardiovascular disease stimulant use may not be advised.
4. Medical records from past healthcare providers should be obtained, and reviewed, as they often are a valuable source of regarding past care, including response to medications.
5. The initial patient evaluation should include documentation of a diagnosis, treatment plan, and goals of therapy. Goals of therapy should be specific and measurable and should be integrated into ongoing patient monitoring throughout treatment. Providers are also encouraged to provide and document education to pediatric patients and guardians

on the risks associated with prescription stimulants, including the risk for misuse.

6. When initiating stimulant therapy, providers may consider only providing enough medicine to last until the next appointment.
 - a. Immediate release amphetamine is the most diverted and misused prescription stimulant.⁹
 - b. Stimulants are available in various dosage forms such as oral suspensions, sprinkle capsules, liquids, chewable tablets, and patches. The patient's preference and needs should be considered when prescribing a particular form. Stimulants allow for appreciable flexibility in dosing and the predominant differences between stimulant formulations are the onset and duration of therapeutic effects, allowing providers to tailor use in settings/times where impairment exists. The duration of the selected medication and efficacy make it important to identify the times of day when ADHD produces the most impairment. Similarly, the duration of stimulant medication can also impact tolerability, especially sleep onset and dinner appetite.
7. Short-acting stimulant medications may be easily titrated to dosages that produce

symptom relief with manageable adverse reactions. They are often used as the initial treatment for children weighing less than 16 kg. However, longer acting medications can be more beneficial as they do not have to be administered at school and reduce the burden of multiple doses a day. Various dosage formulations exist for prescription stimulants that may be more accommodating to children, such as chewable tablets, oral solutions and suspensions, and transdermal patches.

8. Older pediatric patients may require more than 12 hours of coverage to ensure adequate focus and concentration during evening study time and driving. If there is a recurring need to extend beyond 12 hours, healthcare providers may consider alternating use of longer acting stimulant formulations or approved nonstimulants. Sleep onset and duration should be closely monitored.
9. For the treatment of narcolepsy in pediatric patients, providers may reference [the American Academy of Sleep Medicine \(AASM\) Treatment Practice Guidelines](#). Modafinil and sodium oxybate are conditionally recommended by AASM for the treatment of narcolepsy in pediatric patients.³⁵

Care During Chronic Stimulant Therapy¹⁰⁻²⁶

1. Parents/guardians of pediatric patients should receive ongoing education on proper storage and disposal of medications. Medications should always be stored and locked out of children's reach and sight. Even though many medications have safety caps, children may be able to open them. Parents/guardians should be advised to teach children what medicine is and why a trusted adult must be the one to give it to them. The Centers for Disease Control and Prevention has compiled [tips on medication safety for parents/guardians](#) and [Pennsylvania's Prescription Drug Take-Back Program](#) allows people to discard old, unwanted, or unused medication for free.
2. At least half of the pediatric patients whose symptoms fail to respond to one stimulant medication may have a positive response to an alternative medication.
 - a. Subtypes of ADHD does not predict response to certain drugs.
3. Healthcare providers may consider administering urine drug screening throughout the duration of stimulant therapy to confirm that prescribed medication is being taken as prescribed. Medication counts may also be considered, particularly if there is concern about diversion or storage.
4. Good treatment plans will include close monitoring to determine how much the

treatment is helping the patient's behavior and making changes, as necessary, along the way. Medications can affect pediatric patients differently and may cause side effects such as sleep problems. Guardians and parents should be encouraged to monitor closely for adverse side effects.

- a. Studies have shown that 46% of pediatric patients are adherent to treatment with stimulants.¹³ Young children tend to adhere to the medication regimen somewhat more than older children, perhaps indicating effects of parental surveillance. Ideally, a treatment plan is crafted in conjunction with the family or guardians to identify the goals for treatment and then used to create the medication plan. Regular contact between the family/guardian and provider has been found to improve adherence as has periodic reassessment using structured ratings of efficacy and tolerability.

Discontinuation of Stimulants²⁷⁻²⁸

The following are best practices and considerations for healthcare providers when patients discontinue treatment with prescription stimulants and/or when patients present symptoms of possible stimulant or substance use disorder.

1. In patients who have engaged in aberrant drug-related behaviors, such as taking more medication than prescribed or sharing medication with other people, providers should carefully determine if the risks associated with chronic stimulant therapy outweigh documented benefit. Providers may also consider assessing whether aberrant drug-related behaviors such as taking more medication than prescribed may be due to undertreatment of the condition.
2. It is advised that pediatric patients who stop stimulants do not restart use at the full therapeutic dose after an extended absence due to the risk of increased side effects.
3. Patients presenting symptoms of possible stimulant and/or substance use disorder should receive a facilitated referral for addiction specialty evaluation and treatment. Patients at risk for a substance use disorder should not be abruptly dismissed from the practice without a referral to treatment.
 - a. Examples of possible symptoms related to stimulant and/or substance use disorder include but are not limited to continued use of stimulants despite harmful physical, social, or mental health problems caused or exacerbated by a stimulant, or recurrent stimulant use resulting in a person's inability to complete work, school, or home obligations.²⁷
 - b. Healthcare providers may utilize [evidence-based screening and assessment tools](#) (categorized by use per age of patient) to identify patients who may be at risk for a stimulant and/or substance use disorder. Universal screening approaches, such as Screening, Brief Intervention, and Referral to Treatment (SBIRT), may help providers deliver early intervention and treatment services for people who are at risk for developing or who have a substance use disorder. Learn more about [SBIRT](#).
 - c. A healthcare provider may refer a patient and/or their parent/guardian to their insurance carrier who can help the patient identify local treatment providers who are covered under their insurance plan.
 - d. Patients and/or their parent/guardians who are uninsured or underinsured may be referred to their local county drug and alcohol program, which is known as a Single County Authority in Pennsylvania. Information on Single County Authorities in Pennsylvania may be found [here](#).

- e. A patient who is diagnosed with a stimulant use disorder may be treated with motivational interviewing, cognitive behavioral therapy, contingency management, or community reinforcement approach; all of which have been shown to decrease stimulant frequency of use and quantity. Unlike opioids, there is no FDA-approved medication currently available for stimulant use disorder. A detailed review of treatment for stimulant use disorder goes beyond the scope of this document. However, more information on stimulant use disorder treatment may be found [here](#).

Prescription Stimulant Treatment in Patients with Substance Use Disorder

While stimulants do have the potential for misuse, evidence suggests stimulants may be effective in patients with an existing substance use disorder and co-occurring ADHD.³¹ The decision regarding use of stimulant medication for patients who have a substance use disorder should be made on individual risk-benefit analysis. Patients with a co-occurring substance use disorder should be monitored closely to ensure prescribed stimulants are being used properly and substance use is not worsened.

1. In a [study](#) that analyzed stimulant prescriptions and drug-related poisoning risk among persons

receiving buprenorphine treatment for opioid use disorder, stimulant use was associated with improved retention to buprenorphine treatment.²⁸ A slight increase in risk of drug-related poisoning was also observed however this risk may be offset by the associated prolonged exposure to buprenorphine, which is a protective factor against overdose.²⁸

Non-Stimulant Treatment Options

Please note, a detailed review of non-stimulant treatment options goes beyond the scope of this document. Non-stimulant treatment considerations have been summarized for the following disorders and conditions: ADHD and narcolepsy.

ADHD^{3, 35-37}

For the treatment of ADHD, stimulants remain a primary treatment option. However, research and data support the use of various non-pharmacological treatments that may also be considered. The American Academy of Pediatrics recommends the following:³

1. *Patients aged 4-5 years:* The recommended treatment is behavior therapy first, [parent training in behavior management](#), and/or [behavioral classroom interventions](#). Methylphenidate may be considered if behavioral interventions do not provide significant improvement and the child continues to have serious problems.

2. *Patients 6 years and older:* The recommended treatment is FDA-approved medication along with parent training in behavior management and/or behavioral classroom interventions. The school setting is a necessary part of any [treatment plan](#) for school-aged pediatric patients. These plans can include educational interventions and individual school supports. School treatment plans also often include an Individualized Education Program (IEP) or a 504 plan that describes accommodations.

Healthcare providers may also encourage patients/guardians of pediatric patients with diagnosed ADHD to identify and request accommodation needs in school or workplace settings. The Americans with Disabilities Act of 1990 recognizes ADHD as a recognized disability and qualified individuals may consider requesting reasonable accommodations in work or school settings if it does not create undue hardship. Primary care providers may consider providing a referral for a behavioral health specialist for direct psychosocial treatment for ADHD and support in developing workplace or school accommodations.

Healthcare providers may also consider non-stimulant pharmacological treatment for ADHD. The FDA has approved non-stimulants to treat symptoms of ADHD: Strattera (atomoxetine), Intuniv (guanfacine), and Kapvay (clonidine). Non-stimulants do not work as quickly as stimulants, but their effect may last up to 24

hours. They may be a useful alternative to pediatric patients who do not tolerate stimulants well.

Narcolepsy²⁹⁻³⁰

There are several non-pharmacological approaches that may be used on their own or in combination with stimulant therapy for the treatment of narcolepsy in pediatric patients. A wide range of psychosocial treatments have proven to be effective with fewer adverse concerns, compared to stimulants. Behavioral changes such as avoidance of excessive caffeine, avoidance of medications that contribute to daytime sleepiness, maintaining a sleep schedule, and practicing sleep hygiene have also been proven effective for the treatment of narcolepsy. Pediatric patients with diagnosed narcolepsy may also be encouraged to participate in active play/exercise daily, avoid large meals right before bed, and relax before bed. Like ADHD, narcolepsy is also recognized under the Americans with Disabilities Act. Pediatric patients with narcolepsy may consider disclosing their diagnosis and working with employers/school to develop a modified schedule that allows them to complete tasks when they are the most alert. Sleep specialists, for example, may help patients learn about best practices when communicating with work or school officials about accommodations.

Conclusion

The trends discussed in these guidelines emphasize the important role that healthcare providers play in safely and effectively prescribing stimulants and educating pediatric patients and their guardians on the importance of taking prescription stimulants as prescribed, safely storing, and disposing unused medication, and the potential risks of prescription stimulants including misuse and use disorder. **These guidelines are intended to help healthcare providers improve patient outcomes and to supplement, but not replace, an individual provider’s clinical judgement. Clinical decision making should be based on a relationship between the provider and patient, and an understanding of the patient’s clinical situation, functioning, and life context.**

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