

## US DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

## **VETERANS HEALTH ADMINISTRATION**

Deficiencies in Attention Deficit Hyperactivity Disorder Diagnostic Assessment, Evaluation of Stimulant Medication Risks, and Policy Guidance

22-03013-129

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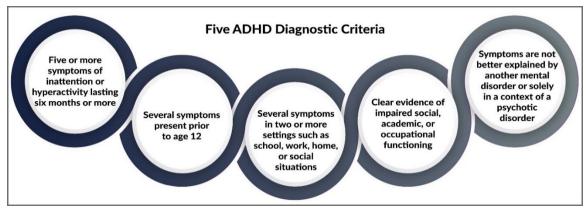
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## **Executive Summary**

The VA Office of Inspector General (OIG) conducted a national review to evaluate Veterans Health Administration's (VHA's) attention deficit hyperactivity disorder (ADHD) diagnostic assessment practices, stimulant medication (stimulant) prescribing practices, training expectations, and policies. ADHD diagnoses and stimulant prescribing to treat adult ADHD have increased in recent decades in the general population.<sup>1</sup> Within VHA, the number of unique patients with an ADHD diagnosis increased from 69,883 in 2018 to 111,313 in 2022 (59 percent). The number of patients with a diagnosis of ADHD who were prescribed a stimulant also increased from 40,874 in 2018 to 62,469 in 2022 (53 percent).

The Diagnostic and Statistical Manual of Mental Disorders (DSM) characterizes ADHD as "a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development."<sup>2</sup> Licensed independent practitioners can diagnose ADHD using the American Psychiatric Association's criteria, which is delineated in the DSM (see figure 1).<sup>3</sup>



*Figure 1. ADHD Diagnostic Criteria. Source: DSM. Note: For individuals 17 and older, only five symptoms are required for a diagnosis.* 

<sup>&</sup>lt;sup>1</sup> "Morbidity and Mortality Weekly Report," Centers for Disease Control and Prevention, accessed October 26, 2023, <u>http://dx.doi.org/10.15585/mmwr.mm7213a1</u>.

<sup>&</sup>lt;sup>2</sup> Diagnostic and Statistical Manual of Mental Disorders Fifth Edition, Text Revision (DSM-5-TR), "Attention-Deficit/Hyperactivity Disorder," accessed July 18, 2022, <u>https://dsm.psychiatryonline.org/</u>doi/full/10.1176/appi.books.9780890425787.x01 Neurodevelopmental Disorders#BCFHAEIJ.

<sup>&</sup>lt;sup>3</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This policy was in effect during the time frame of this review and was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023. These policies contain similar language related to the definition of a licensed independent practitioner, which is an individual permitted by the law and VA facility medical staff bylaws to provide patient care within the scope of practice of the individual's license and privileges without supervision or direction.

As there are no biological, medical, or genetic diagnostic tests for ADHD, a diagnostic assessment requires a qualified provider to collect sufficient information to determine whether a patient meets DSM diagnostic criteria.<sup>4</sup> An accurate and timely diagnosis allows a provider to individualize clinical decision-making based on the correct understanding of a patient's health problems and can result in a positive outcome for the patient.<sup>5</sup> In contrast, a diagnosis made in error can cause harm to a patient, including hindering or delaying necessary treatment and receiving treatment that is not warranted or is harmful.<sup>6</sup>

The Food and Drug Administration has approved non-stimulant and stimulant medications for the treatment of ADHD.<sup>7</sup> Stimulants are considered a first-line treatment for ADHD and are not recommended for patients with serious cardiac risks or a history of substance or alcohol dependence.<sup>8</sup> The Drug Enforcement Administration classifies stimulants as Schedule IIN controlled substances and regulates their use because of the risk for abuse when not used as prescribed.<sup>9</sup> Since 2016, VHA requires prescribers to query state prescription drug monitoring programs, which are state-level databases that allow prescribers to review a patient's prescription

<sup>7</sup> The Food and Drug Administration is the federal agency responsible for protecting public health "by assuring the safety, efficacy, and security of human and veterinary drugs." "Dealing with ADHD: What You Need to Know," Food and Drug Administration <u>https://www.fda.gov/consumer-updates/treating-and-dealing-</u>

adhd?utm\_source=twitterfeed&utm\_medium=twitter; Stimulant medications "speed up the body's systems," and include "prescription drugs such as amphetamines [Adderall and Dexedrine] methylphenidate [Concerta and Ritalin]."; "Drug Fact Sheet," Department of Justice/Drug Enforcement Administration, accessed September 27, 2022, <a href="https://www.dea.gov/sites/default/files/2020-06/Stimulants-2020.pdf">https://www.dea.gov/sites/default/files/2020-06/Stimulants-2020.pdf</a>.

<sup>&</sup>lt;sup>4</sup> "Diagnosis of ADHD in Adults," National Resource Center on ADHD: A Program of Children and Adults with Attention Deficit Hyperactivity Disorder, accessed June 14, 2022, <u>https://chadd.org/wp-content/uploads/2018/05/Diagnosis.pdf</u>; DSM, "Attention Deficit Hyperactivity Disorder."

<sup>&</sup>lt;sup>5</sup> National Academies of Sciences, Engineering, and Medicine, Institute of Medicine, Board on Health Care Services, Committee on Diagnostic Error in Health Care, "The Diagnostic Process," chap. 2 in *Improving Diagnosis In Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.

<sup>&</sup>lt;sup>6</sup> National Academies of Sciences, Engineering, and Medicine, Institute of Medicine, Board on Health Care Services, Committee on Diagnostic Error in Health Care, "Summary" in *Improving Diagnosis In Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.

<sup>&</sup>lt;sup>8</sup> "Stimulant and Related Medications: Use in Adults," Department of Health and Human Services, accessed September 29, 2022, <u>https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/stim-adult-factsheet11-14.pdf</u>; "Medication Management," Children and Adults with Attention Deficit Hyperactivity Disorder, accessed April 3, 2023, <u>https://chadd.org/for-adults/medication-management</u>; A first-line treatment is "the preferred, standard, or first choice" treatment;*Merriam-Webster.com Dictionary*, "first-line," accessed August 10, 2023, <u>https://www.merriam-webster.com/thesaurus/first-line</u>.

<sup>&</sup>lt;sup>9</sup> "Controlled Substance Schedules," Department of Justice Drug Enforcement Administration, accessed September 29, 2022, <u>https://www.deadiversion.usdoj.gov/schedules/schedules.html</u>. Schedule IIN drugs "have a high potential for abuse which may lead to severe psychological or physical dependence." "Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®)."

history, to inform clinical practice and protect patients at risk for misuse of controlled substances.<sup>10</sup>

#### Methodology

The OIG identified 17,463 unique patients with an ADHD diagnosis who received a new stimulant prescription from a VHA provider from October 1, 2020, through September 30, 2022.<sup>11</sup> The OIG reviewed the electronic health records (EHRs) of randomly-selected patients prescribed a new stimulant in a mental health (40 patients) or primary care (40 patients) setting, and evaluated the fidelity of the providers' ADHD diagnostic assessment, as well as documentation of contraindications to stimulant prescribing. Additionally, the OIG sent a questionnaire to 3,048 unique VHA providers who prescribed new stimulants in mental health or primary care settings to assess perceptions of ADHD diagnostic and prescribing training and knowledge. The OIG received 1,676 completed questionnaires (55 percent).

#### **Review Results**

*The OIG found that prescribers documented insufficient information to support ADHD diagnoses corresponding to new stimulant prescriptions and used inconsistent assessment methods.* Among EHRs that did not include documentation of any ADHD DSM diagnostic criteria, 43 percent of mental health and 60 percent of primary care EHRs indicated that the stimulant was prescribed to facilitate continuity of care and documented the patient's reported history of ADHD diagnosis and treatment. However, 50 percent of mental health and 46 percent of primary care prescribers relied on the patient's self-report and did not document an attempt to verify the prior diagnosis by a medical provider. Failure to establish or verify an ADHD diagnosis prior to initiating a stimulant may result in a patient receiving treatment that is not warranted or is harmful.<sup>12</sup>

While the OIG found that most EHRs included documentation of a diagnostic interview, fewer included documentation of other assessment methods that may be important to determine if a patient meets diagnostic criteria, such as information from family members or friends, symptom checklists, or standardized testing instruments. In response to an OIG questionnaire item soliciting feedback or comments related to diagnosing ADHD, 28 percent of respondents indicated a need for more support to complete psychometric testing in the diagnostic process. A prescriber's documented diagnostic impression, based on established DSM criteria, is critical to

<sup>&</sup>lt;sup>10</sup> VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP)*, October 19, 2016, amended October 21, 2019.

<sup>&</sup>lt;sup>11</sup> The OIG identified the unique patients through VA administrative data.

<sup>&</sup>lt;sup>12</sup> National Academies of Sciences, Engineering, and Medicine, Institute of Medicine, Board on Health Care Services, Committee on Diagnostic Error in Health Care, "Summary" in *Improving Diagnosis In Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.

effective treatment planning. Thus, the OIG would expect VHA prescribers to document assessment of diagnostic criteria to support an ADHD diagnosis. The absence of an accurate ADHD diagnosis may contribute to inappropriate or unnecessary treatment due to a limited understanding of a patient's symptoms.

*The OIG found that prescribers inadequately assessed the risks and contraindications of stimulants when prescribed to treat ADHD*. In EHR reviews, the OIG found documentation of cardiac risk monitoring in 64 percent of mental health and 97 percent of primary care records. Providers documented urine toxicology testing in 41 percent of mental health and 46 percent of primary care EHRs.<sup>13</sup> Given the importance of considering cardiac risk and potential substance misuse to inform treatment decisions, mitigate risk, and promote safe patient care, the OIG would expect prescribers to assess and document risks and contraindications prior to initiating a stimulant to treat ADHD.

The OIG found 92 percent of mental health and 83 percent of primary care EHRs included documentation of a prescription drug monitoring program query prior to the initiation of a new stimulant, which was consistent with VHA expectations of 75 percent for new and 95 percent for active controlled substance prescriptions. However, the OIG would expect the prescription drug monitoring program query goal for new controlled substance prescriptions to meet or exceed the goal established for active prescriptions.

According to a leader in the Office of Mental Health and Suicide Prevention, VHA does not require ongoing training related to ADHD assessment, diagnosis, or treatment and that qualification standards require that mental health and primary care providers hired by VHA have skills to diagnose mental disorders. In response to the OIG questionnaire, 70 percent of respondents indicated having "received ADHD diagnostic assessment training," including 78 percent of mental health and 33 percent of primary care prescribers. Additionally, approximately one-third of questionnaire respondents reported not having received ADHD diagnosis training and perceived being only *somewhat knowledgeable* or *not knowledgeable* about ADHD diagnosis.

# The OIG found deficiencies in prescribers' reported ADHD diagnostic and stimulant prescribing training as well as prescribers' knowledge of topics related to ADHD diagnosis

*and stimulant prescribing.* More than 90 percent of mental health prescriber respondents reported having received stimulant prescribing training, while fewer than 50 percent of primary care prescriber respondents reported having received stimulant prescribing training. Additionally, 13 percent of mental health and 65 percent of primary care respondents reported being *somewhat knowledgeable* or *not knowledgeable* about prescribing stimulant medication for the treatment of ADHD. Lack of training and knowledge related to ADHD diagnosis and stimulant prescribing may contribute to insufficient diagnostic assessment, inappropriate

<sup>&</sup>lt;sup>13</sup> A toxicology test detects the type and approximate amount of legal and illegal drugs a person has taken.

prescribing of stimulants, and compromise patient safety. The OIG determined that lack of clarity regarding the referral expectations for "complex" mental health conditions may contribute to patients not receiving referrals for mental health care to establish accurate diagnosis and treatment.

The OIG determined that VHA has no established policies or clinical practice guidance related to the assessment, diagnosis, and treatment of ADHD. In interviews with the OIG, both Office of Mental Health and Suicide Prevention and Office of Primary Care leaders acknowledged a lack of formal policy or guidance. A leader from the Office of Primary Care also stated that there is often "tension" on who "takes the lead on these issues," and indicated an expectation that mental health should take the lead "because they're the people we're going to be going to, to do this for primary care." VHA has made optional resources related to ADHD assessment, diagnosis, and treatment available. However, the OIG concluded that VHA's lack of ADHD-related policies and clinical practice guidance may contribute to limited awareness of clinical expectations and resources to determine a patient's need for comprehensive mental health evaluation.

The OIG made five recommendations to the Under Secretary for Health related to diagnostic assessment to establish a diagnosis prior to initiating stimulant medication treatment, assessment of risks and contraindications associated with stimulant medication, evaluation of prescription drug monitoring program goals, evaluation of the referral process for complex mental health conditions, and ADHD diagnostic and treatment policy and clinical practice guidance.

#### VA Comments and OIG Response

During VHA's review of an OIG draft report, it is usual practice for VHA to submit comments for consideration and discussion.<sup>14</sup> The OIG reviewed VHA comments and based on the review, some changes were made to the report for clarification, but no changes were made to the OIG findings. The Under Secretary for Health concurred with the recommendations and provided an acceptable action plan (see appendix A). The OIG will follow up on the planned actions until they are completed.

The V. Vaigh. M.

JOHN D. DAIGH, JR., M.D. Assistant Inspector General for Healthcare Inspections

<sup>&</sup>lt;sup>14</sup> VA OIG GM Directive 308, Comments to Draft Report, April 10, 2014, amended April 24, 2019.

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### **Abbreviations**

ADHD	attention deficit hyperactivity disorder
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- DSM Diagnostic and Statistical Manual of Mental Disorders
- EHR electronic health record
- OIG Office of Inspector General
- VHA Veterans Health Administration



## Introduction

The VA Office of Inspector General (OIG) conducted a national review after an OIG-identified increase in attention deficit hyperactivity disorder (ADHD) diagnoses and stimulant medication (stimulant) prescriptions within the Veterans Health Administration (VHA) from October 1, 2018, through September 30, 2022.<sup>15</sup> The OIG evaluated VHA leaders' expectations and policies related to the diagnosis and treatment of ADHD. Specifically, the OIG assessed VHA's ADHD diagnostic assessment practices, stimulant prescribing practices, training expectations, and policies.

#### Background

The Diagnostic and Statistical Manual of Mental Disorders (DSM) characterizes ADHD as a mental disorder marked by "a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development."<sup>16</sup> It is one of the most commonly diagnosed mental disorders among children.<sup>17</sup> A "substantial proportion" of children with ADHD continue to experience impairing symptoms into adulthood.<sup>18</sup> Across development into adolescence and adulthood, hyperactive symptoms tend to become less noticeable, while inattentive and impulsive symptoms may persist.<sup>19</sup> In the general population, ADHD diagnosis and stimulant prescribing to treat adult ADHD has increased in recent decades, "with a notable upturn" in adult stimulant prescriptions in 2020 and 2021.<sup>20</sup>

Adults with ADHD may be more prone to some health conditions such as hypertension and obesity than those without ADHD and may experience more psychological stressors including

<sup>&</sup>lt;sup>15</sup> Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Implementation of Psychotropic Drug Safety Initiative (PDSI) Phase 5: Stimulant Safety Initiative (VIEWS 6089962)," October 15, 2021.

<sup>&</sup>lt;sup>16</sup> Diagnostic and Statistical Manual of Mental Disorders Fifth Edition, Text Revision (DSM-5-TR), "Attention-Deficit/Hyperactivity Disorder," accessed July 18, 2022,

https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425787.x01\_Neurodevelopmental\_Disorders# BCFHAEIJ. The DSM-5-TR, published in 2022, integrated the 2013 DSM-5 diagnostic criteria with updated descriptive text related to ADHD. For the purposes of this report, the OIG refers to DSM to indicate criteria established in the DSM-5 and maintained in the DSM-5-TR.

<sup>&</sup>lt;sup>17</sup> "Data and Statistics on Children's Mental Health" Centers for Disease Control and Prevention, accessed October 30, 2023, <u>https://www.cdc.gov/childrensmentalhealth/data.html#print</u>.

<sup>&</sup>lt;sup>18</sup> DSM, "Attention-Deficit/Hyperactivity Disorder."

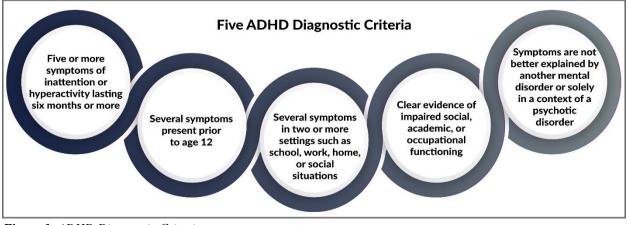
<sup>&</sup>lt;sup>19</sup> DSM, "Attention-Deficit/Hyperactivity Disorder."

<sup>&</sup>lt;sup>20</sup> "Morbidity and Mortality Weekly Report," Centers for Disease Control and Prevention, accessed October 26, 2023, <u>http://dx.doi.org/10.15585/mmwr.mm7213a1</u>.

lower self-esteem, reduced work achievements or unemployment, and increased interpersonal conflict and family discord than those without ADHD.<sup>21</sup>

#### ADHD Diagnostic Criteria and Assessment

Licensed independent practitioners can diagnose ADHD using the American Psychiatric Association's criteria delineated in the DSM.<sup>22</sup> As of 2013, the DSM included five criteria for the diagnosis of adult ADHD (see figure 1).<sup>23</sup>



*Figure 1. ADHD Diagnostic Criteria. Source: DSM. Note: For individuals 17 and older only, five symptoms are required.* 

#### **DSM ADHD Symptoms**

There is no biological, medical, or genetic test that is diagnostic for ADHD.<sup>24</sup> An ADHD diagnostic assessment requires a qualified practitioner to collect sufficient information to determine whether a patient meets DSM diagnostic criteria (see table 1).<sup>25</sup>

<sup>&</sup>lt;sup>21</sup> DSM, "Attention-Deficit/Hyperactivity Disorder."

<sup>&</sup>lt;sup>22</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This policy was in effect during the time frame of this review and was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023. These policies contain similar language related to the definition of a licensed independent practitioner. Licensed independent practitioners are individuals permitted by the law and VA facility medical staff bylaws to provide patient care within the scope of practice of the individual's license and privileges without supervision or direction; "Diagnosis of ADHD in Adults," National Resource Center on ADHD: A Program of Children and Adults with Attention Deficit Hyperactivity Disorder, accessed June 14, 2022, <u>https://chadd.org/wp-content/uploads/2018/05/Diagnosis.pdf</u>.

<sup>&</sup>lt;sup>23</sup> DSM, "Attention-Deficit/Hyperactivity Disorder."

<sup>&</sup>lt;sup>24</sup> DSM, "Attention-Deficit/Hyperactivity Disorder"; "Diagnosis of ADHD in Adults."

<sup>&</sup>lt;sup>25</sup> "Diagnosis of ADHD in Adults."

#### Table 1. DSM ADHD Symptom Criteria

Inattention Symptoms	
Often fails to give close or during other activities	attention to details or makes careless mistakes in schoolwork, at work, s.
Often has difficulty sust	aining attention in tasks or play activities.
Often does not seem to	listen when spoken to directly.
Often does not follow th the workplace.	rough on instructions and fails to finish schoolwork, chores, or duties in
Often has difficulty orga	nizing tasks and activities.
Often avoids, dislikes, c	or is reluctant to engage in tasks that require sustained mental effort.
Often loses things nece	ssary for tasks or activities.
Is often easily distracted	d by extraneous stimuli.
Is often forgetful in daily	v activities.
Hyperactivity/Impulsivity	Symptoms
Often fidgets with or tap	os hands or feet or squirms in seat.
Often leaves seat in situ	uations when remaining seated is expected.
Often runs about or clim	nbs in situations where it is inappropriate.
Often unable to play or	engage in leisure activities quietly.
Is often "on the go," act	ing as if "driven by a motor."
Often talks excessively.	
Often blurts out an answ	ver before a question has been completed.
Often has difficulty wait	ing his or her turn.
Often interrupts or intru	des on others.
Source: DSM	

Source: DSM.

Clinical practice guidelines can help ensure that the diagnostic assessment is completed appropriately and may recommend providers

- complete a history and physical examination, obtaining information from the patient about presence, onset, duration, and functional impact of symptoms;
- screen for medical conditions, psychiatric conditions, and substance use that may better explain the symptoms;<sup>26</sup>

<sup>&</sup>lt;sup>26</sup> "Attention Deficit and Hyperactivity Disorder (ADHD): Screening, Referral and Treatment – Adult - Ambulatory Clinical Practice Guidelines," University of Wisconsin Health, accessed December 6, 2023, <u>https://www.uwhealth.org/cckm/cpg/psychiatry/related/Attention-Deficit-and-Hyperactivity-Disorder-ADHD-Screening,-Referral-and-Treatment---Adult---Ambulatory-180525.pdf</u>.

- gather collateral information, reviewing medical records, academic records, and information on employment performance to aid in understanding the presence, onset, duration, and functional effect of symptoms; and
- administer validated behavioral rating scales and psychometric tests, using established tools to collect information on symptoms and functioning from the patient and others in their home, school, social, or work environments.

An ADHD diagnosis requires the presence of several symptoms prior to the age of 12.<sup>27</sup> As such, establishing the diagnosis in adults can be difficult due to unreliable patient recall of childhood symptoms. Additionally, differentiating ADHD symptoms from substance use or misuse can be challenging, and evidence that the ADHD symptoms began prior to a patient's history of substance use or misuse may be helpful when making an ADHD diagnosis.

An accurate and timely diagnosis allows a provider to individualize clinical decision-making based on the correct understanding of a patient's health problems and can result in a positive outcome for the patient.<sup>28</sup> In contrast, a diagnosis made in error can cause harm to a patient, including hindering or delaying necessary treatment and receiving treatment that is not warranted or is harmful.<sup>29</sup>

#### **ADHD Treatment**

Treatment for ADHD includes both non-medication and medication interventions.<sup>30</sup> While there is no cure for ADHD, medication may alleviate symptoms and improve functioning.<sup>31</sup> The Food

<sup>&</sup>lt;sup>27</sup> DSM, "Attention-Deficit/Hyperactivity Disorder."

<sup>&</sup>lt;sup>28</sup> National Academies of Sciences, Engineering, and Medicine, Institute of Medicine, Board on Health Care Services, Committee on Diagnostic Error in Health Care, "The Diagnostic Process," chap. 2 in *Improving Diagnosis In Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.

<sup>&</sup>lt;sup>29</sup> National Academies of Sciences, Engineering, and Medicine, Institute of Medicine, Board on Health Care Services, Committee on Diagnostic Error in Health Care, "Summary" in *Improving Diagnosis In Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.

<sup>&</sup>lt;sup>30</sup> Josh Geffen and Kieran Forster, "Treatment of adult ADHD: a clinical perspective," *Therapeutic Advances in Psychopharmacology* 8, (January 2018): 25–32.

<sup>&</sup>lt;sup>31</sup> "Adult attention-deficit/hyperactivity disorder," Mayo Clinic, accessed April 3, 2023, <u>https://www.mayoclinic.org/diseases-conditions/adult-adhd/diagnosis-treatment/drc-20350883?p=1;</u> "Dealing with ADHD: What you need to know," US Food and Drug Administration, accessed September 29, 2022, <u>https://www.fda.gov/consumers/consumer-updates/dealing-adhd-what-you-need-know</u>.

and Drug Administration has approved stimulant and non-stimulant medications for the treatment of ADHD.<sup>32</sup> Stimulant medications are considered a first-line treatment for ADHD.<sup>33</sup>

## Scope and Methodology

The OIG initiated this national review on December 12, 2022, to evaluate VHA providers' (prescribers) ADHD diagnostic assessment and prescribing practices, training requirements and expectations, and policies.<sup>34</sup> The OIG evaluated the electronic health records (EHRs) of patients prescribed a new stimulant to treat ADHD by a VHA prescriber from October 1, 2020, through September 30, 2022, fiscal years (FYs) 2021 through 2022.<sup>35</sup> The OIG specifically reviewed the fidelity of providers' diagnostic assessment for ADHD to the corresponding DSM diagnostic criteria, assessment of risks and contraindications to stimulant prescribing, and prescribers' perceived ADHD-related training and knowledge.

The OIG reviewed VHA documents and policies in effect from October 1, 2020, through December 12, 2022, related to ADHD diagnostic assessment, treatment, and training. The OIG interviewed VHA leaders from the Office of Mental Health and Suicide Prevention, Office of Primary Care, Pharmacy Benefits Management Service, and the Office of Quality and Patient Safety.

The study population included patients who received a new stimulant prescription with a documented ADHD diagnosis. The OIG identified 17,463 unique patients with a diagnosis of ADHD for whom a VHA prescriber prescribed a new stimulant in FY 2021 and FY 2022.<sup>36</sup>

<sup>&</sup>lt;sup>32</sup> The Food and Drug Administration is the federal agency responsible for protecting public health "by assuring the safety, efficacy, and security of human and veterinary drugs." "Dealing with ADHD: What You Need to Know," Food and Drug Administration <u>https://www.fda.gov/consumers/consumer-updates/treating-and-dealing-adhd?utm\_source=twitterfeed&utm\_medium=twitter;</u> Stimulant medications "speed up the body's systems," and include "prescription drugs such as amphetamines [Adderall and Dexedrine] methylphenidate [Concerta and Ritalin]." "Drug Fact Sheet," Department of Justice/Drug Enforcement Administration, accessed September 27, 2022, <u>https://www.dea.gov/sites/default/files/2020-06/Stimulants-2020.pdf;</u> Non-stimulant medications work by increasing norepinephrine in the brain and typically fall into two categories, norepinephrine reuptake inhibitors or alpha-2 adrenergic agonists. "ADHD Medication," Cleveland Clinic, accessed May 15, 2023, https://my.clevelandclinic.org/health/treatments/11766-adhd-medication.

<sup>&</sup>lt;sup>33</sup> "ADHD Medication," Cleveland Clinic; A first line treatment is "the preferred, standard, or first choice" treatment. *Merriam-Webster.com Dictionary*, "first-line," accessed August 10, 2023, <u>https://www.merriam-webster.com/thesaurus/first-line</u>.

<sup>&</sup>lt;sup>34</sup> For purposes of this report, the term *prescriber* is used throughout the report to describe individuals who prescribe medication to patients; not all providers diagnosing ADHD prescribe medication.

<sup>&</sup>lt;sup>35</sup> A fiscal year is a 12-month cycle that spans October 1 through September 30. "VA Finance Terms and Definitions," VA, July 2011, accessed August 28, 2023, <u>https://www.publichealth.va.gov/docs/employeehealth/14-Finance-Terms.pdf</u>. The OIG defined a stimulant as new if the patient did not receive a stimulant from VHA during the 10 years prior to the prescription date included in the study period of October 1, 2020, through September 30, 2022.

<sup>&</sup>lt;sup>36</sup> The OIG identified the unique patients through VA administrative data.

Mental Health providers prescribed stimulants for 15,913 of 17,463 (91 percent) patients and primary care providers prescribed stimulants for 1,550 of 17,463 (9 percent) patients.

Among the 17,463 identified patients, the OIG randomly selected 40 patients prescribed a stimulant in a mental health setting and 40 patients prescribed a stimulant in a primary care setting for EHR review.<sup>37</sup> The OIG evaluated EHR documentation for the presence of an ADHD diagnostic assessment, including documentation of the presence of DSM ADHD criteria; an ADHD diagnosis; the method of diagnostic assessment; and an evaluation of associated risks and contraindications.<sup>38</sup>

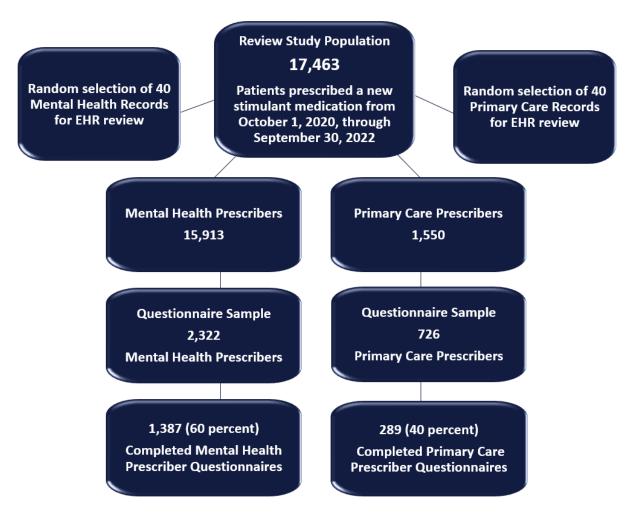
The OIG sent a questionnaire to 3,048 unique VHA prescribers (2,322 mental health and 726 primary care prescribers) who prescribed a new stimulant in mental health or primary care settings. The OIG received 1,676 (55 percent) completed questionnaires (see figure 2).<sup>39</sup> The questionnaire assessed prescribers' perceptions of ADHD diagnostic and stimulant prescribing training and knowledge, determined familiarity with the Psychotropic Drug Safety Initiative Phase 5: Stimulant Safety Initiative (Stimulant Safety Initiative), and gave prescribers the opportunity to provide qualitative comments related to ADHD diagnosis and stimulant prescribing.<sup>40</sup>

<sup>&</sup>lt;sup>37</sup> The OIG excluded five primary care EHRs because prescribers identified as primary care did not prescribe in the primary care setting and one mental health EHR because the stimulant was prescribed for a condition other than ADHD.

<sup>&</sup>lt;sup>38</sup> The OIG also determined whether the prescriber documented prescribing a stimulant to facilitate continuity of care. Continuity of care is "concerned with quality of care over time." The process of a cooperation between a patient and their prescriber for continuous healthcare management. *The American Academy of Family Physicians*, "Continuity of Care, Definition of," accessed July 19, 2023, <u>https://www.aafp.org/about/policies/all/continuity-of-care-definition.html#:~:text=Continuity%20of%20care%20is%20concerned,%2C%20cost%2Deffective%20medical %20care.</u>

<sup>&</sup>lt;sup>39</sup> Duplicate providers with more than one unique patient record, were sent only one questionnaire and providers who were not designated as mental health or primary care were not sent questionnaires. Prescribers included physicians, nurse practitioners, and clinical pharmacy specialists.

<sup>&</sup>lt;sup>40</sup> The Stimulant Safety Initiative is a VHA quality improvement effort related to psychotropic prescribing practices. The fifth phase, introduced in October 2021 and implemented in January 2022, consists of two steps to (1) "build capacity to deliver guideline concordant care to Veterans with stimulant use disorder" and (2) "increase the delivery of services for stimulant use disorder and ensure the safe and appropriate prescribing of stimulant medications." VHA Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer Memorandum, "Implementation of the Psychotropic Drug Safety Initiative (PSDI) Phase 5: Stimulant Safety Initiative," October 15, 2021.



*Figure 2.* Study population and sample population for the EHR review. Source: OIG analysis of VHA data. Note: The OIG did not assess VHA's data for accuracy or completeness.

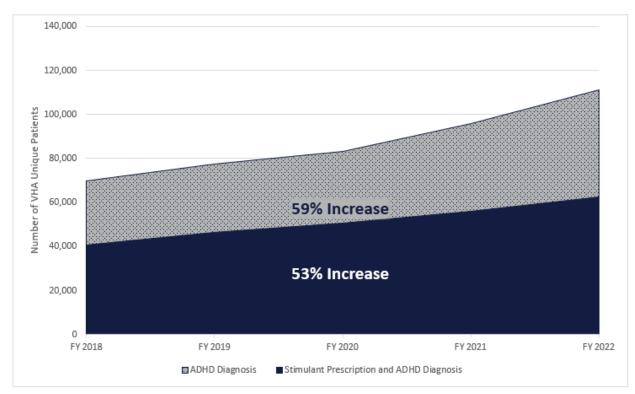
In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the review in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

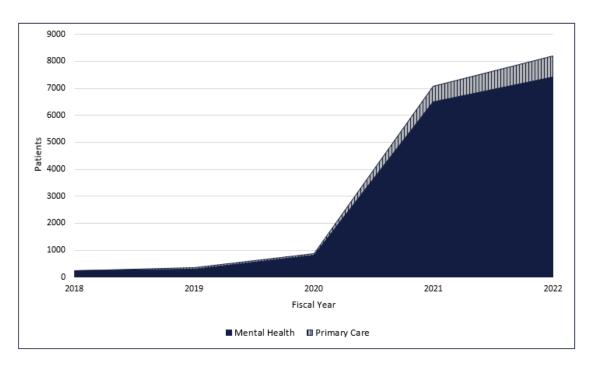
## **Review Results**

The OIG identified trends in VHA ADHD diagnosis and stimulant prescribing. The number of unique patients with an ADHD diagnosis increased from 69,883 in 2018 to 111,313 in 2022 (59 percent) and with a diagnosis of ADHD who were prescribed a stimulant increased from 40,874 in 2018 to 62,469 in 2022 (53 percent) (see figure 3).



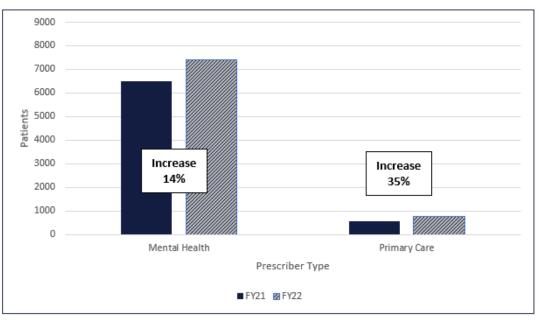
*Figure 3.* VHA increase in ADHD diagnosis and stimulant prescriptions from FY 2018 through FY 2022. Source: OIG analysis of VHA data.

Further, the number of patients with an ADHD diagnosis treated with a *new* stimulant prescription similarly increased. From FY 2018 through 2022, the number of patients diagnosed with ADHD by VHA mental health and primary care prescribers increased from 242 in 2018 to 8,204 in 2022 (3,290 percent) (see figure 4).



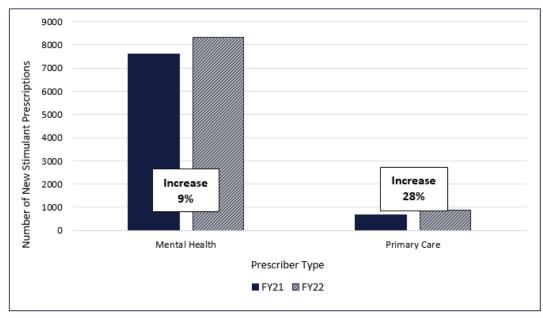
*Figure 4.* VHA patients with an ADHD diagnosis who were prescribed a new stimulant medication from FY 2018 through FY 2022. Source: OIG analysis of VHA data.

Among the OIG study population, the rate of ADHD diagnosis for patients treated with a stimulant also increased in mental health (14 percent) and primary care (35 percent) settings from FY 2021 through FY 2022 (see figure 5).



*Figure 5.* ADHD diagnosis for VHA patients with newly prescribed stimulants in FY 2021 through FY 2022. Source: OIG analysis of VHA data.

The rate of new stimulant prescriptions for the treatment of ADHD similarly increased in mental health (9 percent) and primary care (28 percent) settings from October 1, 2020, through September 30, 2022 (see figure 6).



*Figure 6.* New stimulant prescriptions for patients with an ADHD diagnosis in FY 2021 through FY 2022.

Source: OIG analysis of VHA data.

Although stimulant medications are prescribed to treat ADHD less frequently in VHA primary care than mental health settings, the increase in new stimulant prescriptions among primary care was three times greater.

To review ADHD diagnostic and stimulant practices, the OIG reviewed (1) documentation to support ADHD diagnosis and assessment methods, (2) documentation of assessment of risks and contraindications when prescribing stimulants, (3) prescribers' perceived ADHD diagnostic and stimulant prescribing training and knowledge, and (4) VHA policy and clinical practice guidance.

#### 1. Insufficient Documentation to Support ADHD Diagnosis

The OIG found that prescribers documented insufficient information to support ADHD diagnoses corresponding to new stimulant prescriptions and used inconsistent assessment methods.

A prescriber's documented diagnostic impression, based on established DSM criteria, is critical to effective treatment planning. The OIG found that 36 percent of mental health and 20 percent of primary care EHRs included documentation that the patient met all ADHD DSM diagnostic criteria. Among EHRs that did not contain documentation that the patient met all diagnostic

criteria, the OIG found that 72 percent of mental health and 64 percent of primary care EHRs included documentation that the patient met at least one DSM diagnostic criterion (see table 2).

ADHD DSM Diagnostic Criteria		Mental Health EHR		Primary Care EHR	
		Percent	Number (N=35)	Percent	
Five or more inattentive or hyperactive/impulsive symptoms	23	59	9	26	
Several symptoms present prior to age 12	28	72	14	40	
Several symptoms present in two or more settings	19	49	10	29	
Impaired functioning	26	67	19	54	
Symptoms not better explained by another disorder	24	62	23	66	

Table 2. Documentation of ADHD Diagnostic Criteria

Source: OIG EHR review

The OIG found that 18 percent of mental health and 29 percent of primary care EHRs did not contain documentation of any DSM diagnostic criteria to support an ADHD diagnosis. Among EHRs that did not include documentation of any ADHD DSM diagnostic criteria, 43 percent of mental health and 60 percent of primary care EHRs included documentation indicating that a stimulant was prescribed to facilitate continuity of care. All prescribers who documented that a stimulant was prescribed for continuity of care also documented the patient's reported history of ADHD diagnosis and treatment. However, 50 percent of mental health and 46 percent of primary care prescribers relied on patients' self-report and did not document an attempt to verify the prior diagnosis by a medical provider. Failure to establish or verify an ADHD diagnosis prior to initiating a stimulant may result in a patient receiving treatment that is not warranted or is harmful.<sup>41</sup>

#### Lack of Comprehensive Assessment

A comprehensive ADHD diagnostic assessment requires a qualified practitioner to collect sufficient information, often from multiple sources, to determine if a patient meets DSM diagnostic criteria and inform clinical decision-making. Although providers' diagnostic procedures vary, certain elements "are considered essential for a comprehensive evaluation," including

<sup>&</sup>lt;sup>41</sup> National Academies of Sciences, Engineering, and Medicine, Institute of Medicine, Board on Health Care Services, Committee on Diagnostic Error in Health Care, "Summary" in *Improving Diagnosis In Health Care* (Washington, DC: The National Academies Press, 2015), <u>https://doi.org/10.17226/21794</u>.

- diagnostic interview(s) between the clinician and patient to explore the patient's presenting problem, current situation, and background with the goal of formulating a diagnosis, prognosis, and plan for treatment;
- collateral information gathered from family members, friends, and other individuals in the patient's support network to provide additional details and corroborate information provided in the diagnostic interview;
- symptom checklists; and
- psychometric testing, or standardized instruments "to measure behavior or mental attributes, such as attitudes, emotional functioning, intelligence, and cognitive abilities."<sup>42</sup>

The OIG reviewed patient EHRs to evaluate providers' methods of diagnostic assessment including diagnostic interview, clinical record review, psychometric testing, collateral information, and use of self-assessment instruments. The OIG found that most EHRs included documentation of a diagnostic interview; however, fewer EHRs included documentation of other assessment methods (see table 3).<sup>43</sup>

		Mental Health EHR		Primary Care EHR	
ADHD Diagnostic Assessment Method	Number (N=39)	Percent	Number (N=35)	Percent	
Diagnostic Interview	37	95	35	100	
Clinical Record Review	28	72	20	57	
Collateral Information	3	8	2	6	
Symptom Checklist	16	41	5	14	
Psychometric Testing	14	36	7	20	

#### Table 3. Assessment Methods Used to Assess ADHD Diagnosis

Source: OIG EHR review.

Note: Prescribers may have documented more than one assessment method.

Further, in the absence of definitive testing to diagnose ADHD, assessment information is gathered from multiple sources, such as symptom checklists, detailed history of past and current functioning, and collateral information. In EHR reviews, the OIG evaluated the number of

<sup>&</sup>lt;sup>42</sup> "Diagnosis of ADHD in Adults," Children and Adults with Attention Deficit/Hyperactivity Disorder. "Diagnostic Interview," American Psychological Association, accessed September 19, 2023,

https://dictionary.apa.org/diagnostic-interview; American Psychiatric Association, *Practice Guidelines for the Psychiatric Evaluation of Adults, Third Edition,* "Guidelines and Implementation," accessed September 19, 2023, https://doi.org/10.1176/appi.books.9780890426760.pe02; "Psychological Test," American Psychological Association, accessed September 19, 2023, https://dictionary.apa.org/psychological-test.

<sup>&</sup>lt;sup>43</sup> For the purposes of this review, one or more assessment methods may have been attributed based on documentation from the prescriber. The review of clinical records included VHA and non-VHA health records.

assessment methods used to diagnose ADHD and found that most diagnoses were determined using two assessment methods, most frequently the combination of diagnostic interview and clinical record review (see figure 7). In response to an OIG questionnaire item soliciting feedback or comments related to diagnosing ADHD, 28 percent of respondents indicated a need for more support to complete psychometric testing in the diagnostic process.

	Number	Number o Mental Health (n=39)	f Records Primary Care (n=35)	
Δ	None	Not Applicable	2	0
DH	One	Diagnostic Interview	6	12
e A		Diagnostic Interview & Clinical Record Review	9	13
sou	Two	Diagnostic Interview & Self-Assessment	2	1
iagı		Diagnostic Interview & Psychometric Testing	0	1
) to Di		Diagnostic Interview, Clinical Record Review & Self-Assessment	5	1
hod(s		Diagnostic Interview, Clinical Record Review & Psychometric Testing	5	2
nt Met	Three	Diagnostic Interview, Self-Assessment & Collateral Information	1	0
Number of Assessment Method(s) to Diagnose ADHD		Diagnostic Interview, Self-Assessment & Psychometric Testing	0	1
f Asse		Diagnostic Interview, Clinical Record Review & Collateral Information	0	1
nber o	Faur	Diagnostic Interview, Clinical Record Review, Psychometric Testing & Collateral Information	1	1
Nun	Four	Diagnostic Interview, Clinical Record Review, Psychometric Testing & Self-Assessment	7	2
	Five	Diagnostic Interview, Clinical Record Review, Self-Assessment, Psychometric Testing & Collateral Information	1	0

*Figure 7. Number of assessment methods used to diagnose ADHD. Source: OIG analysis of EHR review.* 

Among OIG EHR reviews of patients prescribed a new stimulant for ADHD, nearly one-fourth contained no documentation of any DSM diagnostic criteria for ADHD. The OIG would expect VHA prescribers to document assessment of diagnostic criteria to support an ADHD diagnosis. The absence of an accurate ADHD diagnosis may contribute to inappropriate or unnecessary treatment due to a limited understanding of patients' symptoms.

#### 2. Inadequate Assessment of Stimulant Risks and Contraindications

The OIG found that prescribers inadequately assessed the risks and contraindications of stimulants when prescribed to treat ADHD. The Drug Enforcement Administration classifies stimulants as Schedule IIN controlled substances and regulates their use because of risk for abuse when not used as prescribed.<sup>44</sup> Methylphenidate and amphetamine are the most commonly prescribed stimulants for the treatment of ADHD and work by increasing levels of neurotransmitters thought to play a role in attention and motivation.

Stimulants are not recommended for patients with serious cardiac risks or a history of substance or alcohol dependence.<sup>45</sup> Evaluation for those conditions and all associated risks should be considered prior to the start of a new stimulant or when a stimulant is started by a new prescriber to continue prior treatment.<sup>46</sup> Prior to starting stimulants, patients should have assessment of baseline vital signs, such as blood pressure and pulse; and a history and physical exam, inclusive of risk factors for cardiac disease, psychological conditions, and substance abuse.<sup>47</sup> Prescribers should exercise caution treating ADHD with stimulants when a patient has a history of stimulant misuse, illicit use, or current substance use, and should avoid prescribing stimulants for patients with preexisting cardiac conditions.<sup>48</sup> An accurate diagnosis, including assessment of the

<u>https://www.deadiversion.usdoj.gov/schedules/schedules.html</u>. Schedule IIN drugs "have a high potential for abuse which may lead to severe psychological or physical dependence." "Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®)"; "Organization, Mission, Functions Manual," US Department of Justice, accessed December 14, 2023,

https://www.justice.gov/doj/organization-mission-and-functions-manual-drug-enforcement-

administration#:~:text=The%20mission%20of%20the%20Drug%20Enforcement%20Administration%20%28DEA %29,destined%20for%20illicit%20traffic%20in%20the%20United%20States; The Drug Enforcement Administration enforces United States controlled substance laws and regulations.

<sup>&</sup>lt;sup>44</sup> "Medication Management," Children and Adults with Attention Deficit Hyperactivity Disorder, accessed April 3, 2023, <u>https://chadd.org/for-adults/medication-management</u>; "Controlled Substance Schedules," US Department of Justice Drug Enforcement Administration, accessed September 29, 2022,

<sup>&</sup>lt;sup>45</sup> "Stimulant and Related Medications: Use in Adults," Department of Health and Human Services, accessed September 29, 2022, <u>https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/stim-adult-factsheet11-14.pdf</u>.

<sup>&</sup>lt;sup>46</sup> "Stimulant and Related Medications: Use in Adults," Department of Health and Human Services; "FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions," US Food and Drug Administration, accessed December 12, 2023, <u>https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions</u>.

<sup>&</sup>lt;sup>47</sup> "Screening, Referral and Treatment for Attention Deficit and Hyperactivity Disorder (ADHD)-Adult -Ambulatory Clinical Practice Guidelines," University of Wisconsin Health.

<sup>&</sup>lt;sup>48</sup> "Stimulant and Related Medications: Use in Adults," Department of Health and Human Services; Laurence L Greenhill, Steven Pliszka, and Mina K. Dulcan, "Practice Parameter for the Use of Stimulant Medications in the Treatment of Children, Adolescents, and Adults," *Journal of the American Academy of Child & Adolescent Psychiatry* 41, no. 2, Supplement (February 2002): 26S–49S.

patient's symptoms, as well as consideration for the patient's medication history, negative side effects, and risk for abuse are important factors in determining whether to prescribe a stimulant.<sup>49</sup>

Leaders from the Office of Mental Health and Suicide Prevention told the OIG that prescribers are not required to conduct cardiac screening, urine toxicology testing, or assess contraindications when prescribing a stimulant to treat ADHD.<sup>50</sup> In January 2022, VHA launched the Stimulant Safety Initiative, which includes an optional objective to ensure safe stimulant prescribing by monitoring "cardiovascular vital signs" including blood pressure and pulse at least every six months and completing urine toxicology testing at least annually.<sup>51</sup> However, the Psychotropic Drug Safety Initiative Director acknowledged "widely divergent practices [in terms of] stimulant prescribing and monitoring," and indicated that the Stimulant Safety Initiative supports, but does not require, "low bar" monitoring practices.

In EHR reviews, the OIG found documentation of cardiac risk monitoring in 64 percent of mental health EHRs and 97 percent of primary care EHRs. Providers documented urine toxicology testing in 41 percent of mental health EHRs and 46 percent of primary care EHRs.

Given the importance of considering cardiac risk and potential substance misuse to inform treatment decisions, mitigate risk, and promote safe patient care, the OIG would expect prescribers to assess and document risks and contraindications prior to initiating a stimulant to treat ADHD.

#### **Prescription Drug Monitoring Program**

Since 2016, VHA requires prescribers to query state prescription drug monitoring programs, which are state-level databases that allow prescribers to review a patient's prescription history to inform clinical practice and protect patients at risk for misuse of controlled substances.<sup>52</sup> The information obtained by querying prescription drug monitoring programs enables VHA providers

www.health.pa.gov/topics/Documents/Opioids/Prescribing%20Guidelines%20for%20CNS%20Stimulants%20in%2 OAdults.pdf; "Medication Management," Children and Adults with Attention Deficit/Hyperactivity Disorder; "FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions," US Food and Drug Administration; Laurence L Greenhill, Steven Pliszka, and Mina K. Dulcan, "Practice Parameter for the Use of Stimulant Medications in the Treatment of Children, Adolescents, and Adults"; "Stimulant and Related Medications: Use in Adults," Centers for Medicare and Medicaid Services, October 2015, accessed December 19, 2023, https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/stim-adult-factsheet11-

<sup>&</sup>lt;sup>49</sup> "Central Nervous System (CNS) Stimulants in Adults," The Commonwealth of Pennsylvania, accessed December 14, 2023,

<sup>14.</sup>pdf#:~:text=Stimulant%20and%20related%20medications%20are%20FDA%20approved%20for,adults%20for%20the%20treatment%20of%20ADHD%20or%20narcolepsy.

<sup>&</sup>lt;sup>50</sup> A toxicology test detects the type and approximate amount of legal and illegal drugs a person has taken.

<sup>&</sup>lt;sup>51</sup> Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Implementation of the Psychotropic Drug Safety Initiative (PDSI) Phase 5: Stimulant Safety Initiative (VIEWS 6089962)."

<sup>&</sup>lt;sup>52</sup> VHA Directive 1306(1), *Querying State Prescription Drug Monitoring Programs (PDMP)*, October 19, 2016, amended October 21, 2019.

to identify patients who are receiving controlled substances from multiple sources, and can be helpful in preventing diversion of controlled substances and substance use disorders.<sup>53</sup> VHA requires providers to document the results of the prescription drug monitoring program query in a patient's EHR prior to initiating treatment with a controlled substance, to include stimulants.<sup>54</sup> VHA established a prescription drug monitoring program query adherence goal of 75 percent for new and 95 percent for active controlled substance prescriptions.

The OIG found that 92 percent of mental health and 83 percent of primary care EHRs included documentation of a prescription drug monitoring program query prior to the initiation of stimulant treatment. Although prescribers queried the prescription drug monitoring program at a rate consistent with VHA expectations to support safe patient care and stimulant prescribing practices, the OIG would expect the prescription drug monitoring program query goal for new controlled substance prescriptions to meet or exceed the goal established for active prescriptions. Review of the prescription drug monitoring program prior to initiating treatment with stimulants can reduce the risk of patient harm and provide opportunities to identify stimulant misuse, substance use disorder, and drug diversion.

#### 3. Deficits in ADHD-Related Training and Knowledge

The OIG found deficiencies in prescribers' reported ADHD diagnostic and stimulant prescribing training as well as prescribers' knowledge of topics related to ADHD diagnosis and stimulant prescribing.

VHA requires all medical facilities to provide assessment, diagnosis, and treatment for mental health conditions. Mental health care must include a broad range of services delivered by providers with the clinical expertise to meet patient needs.<sup>55</sup> VHA prescribers are "authorized by State licensure" and "a VA medical facility in the form of clinical privileges, scope of practice, or as a postgraduate clinical trainee" to prescribe controlled substances.<sup>56</sup> Primary care providers deliver comprehensive primary care, including routine mental health care, consistent with their clinical privileges and skill and typically provide brief treatment for "uncomplicated" mental health conditions and refer patients with "complex mental illnesses to providers of specialty

<sup>&</sup>lt;sup>53</sup> VHA Directive 1306(1).

<sup>&</sup>lt;sup>54</sup> VHA Directive 1306(1); "Controlled Substance Schedules," US Department of Justice Drug Enforcement Administration.

<sup>&</sup>lt;sup>55</sup> VHA Handbook 1160.01(1), Uniform Mental Health Services in VA Medical Centers and Clinics, September 11, 2008, amended November 16, 2015. This policy was in effect during the time frame of this review and was rescinded and replaced by VHA Directive 1160.01, Uniform Mental Health Services in VHA Medical Points of Service, April 27, 2023. Both policies contain similar language.

<sup>&</sup>lt;sup>56</sup> VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019.

mental health care."<sup>57</sup> However, VHA policy does not define "uncomplicated" or "complex" mental health conditions.

According to a leader in the Office of Mental Health and Suicide Prevention, VHA does not require ongoing training related to ADHD assessment and diagnosis. Office of Primary Care and Office of Mental Health and Suicide Prevention leaders informed the OIG that facility-level privileges require prescribers to have the skills to diagnose and treat mental health disorders and there were no specific VHA training requirements related to prescribing stimulants to treat ADHD. Additionally, they told the OIG that the qualification standards require that mental health and primary care providers hired by VHA have skills to diagnose mental disorders.<sup>58</sup>

A VHA primary care leader told the OIG that ADHD is "a complex diagnosis and it has implications long term." Further, Office of Mental Health and Suicide Prevention leaders acknowledged that ADHD is "common, but it is also complex. It is a complex evaluation." Office of Mental Health and Suicide Prevention leaders emphasized the importance of facility-level co-management of patients across mental health and primary care through service agreements and with the support of VA Central Office, noting that they are in the beginning stages and "working to make sure that we have good guidance and good tools in place to help both primary care and mental health providers in this space." VHA deployed an ADHD screening template in January 2023 to identify which patients should be referred for further ADHD evaluation. Training related to the template stated that "clinical decision making in support of ADHD diagnosis or stimulant prescribing often lacks standardization and appropriate documentation," and that "it is clear that VA providers (primarily mental health and primary care teams) need support for determining which patients" need "comprehensive diagnostic evaluation by mental health" providers.

The OIG found that 70 percent of questionnaire respondents indicated having "received ADHD diagnostic assessment training," including 78 percent of mental health and 33 percent of primary care prescribers. The majority of respondents reported receiving ADHD diagnostic training as

<sup>&</sup>lt;sup>57</sup> Clinical privileges are the services a licensed independent practitioner is authorized to provide, independently and unsupervised, and must be "facility-specific." Clinical privileges are based on the licensed independent practitioner's "clinical competence as determined by peer references, professional experience, health status, education, training, and licensure." VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This policy was in effect during the time frame of this review and was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023; VHA Handbook 1101.10(1), *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014, amended May 26, 2017; VHA Handbook 1160.01(1).

<sup>&</sup>lt;sup>58</sup> "Federal Hiring," US Office of Personnel Management, accessed August 10, 2023, https://www.opm.gov/frequently-asked-questions/employment-faq/federal-hiring/what-are-qualificationstandards/#:~:text=Qualification%20Standards%20are%20a%20description,security%2C%20and%2For%20licensur e. Qualification Standards are "a description of the minimum requirements necessary to perform work of a particular occupation successfully and safely. These minimum requirements may include specific job-related work experience, education, medical or physical standards, training, security, and/or licensure."

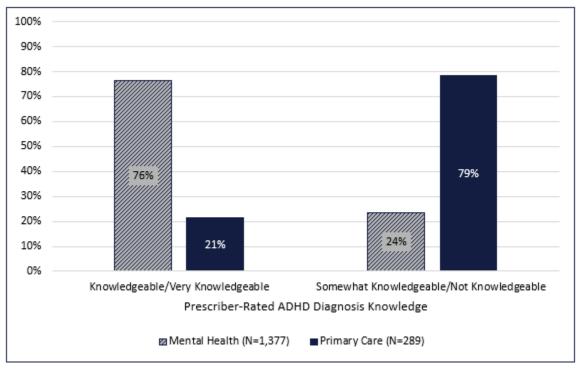
part of their medical residency or clinical training, and fewer reported practice-based, non-VHA, and VHA training (see table 4.)

Questionnaire Response	Mental Health Respondents (N=1076)	Percent	Primary Care Respondents (N=96)	Percent
Medical Residency/Clinical Training	985	91	86	90
Practice-Based Training	363	34	32	33
Non-VHA Training	197	18	25	26
VHA Training	68	6	2	2

#### Table 4. Prescribers' ADHD Diagnostic Training

Source: OIG prescriber questionnaire

Additionally, the OIG found that 24 percent of mental health and 79 percent of primary care prescribers reported being *somewhat knowledgeable* or *not knowledgeable* about ADHD diagnosis (see figure 8). When asked to provide written feedback or comments related to ADHD diagnostic challenges or barriers, 16 percent of mental health prescribers and 9 percent of primary care prescribers indicated a need for additional diagnostic training.

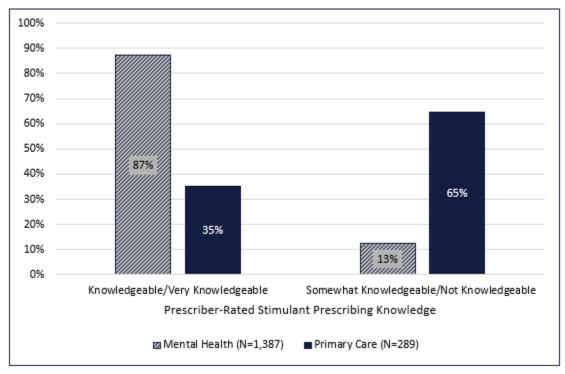


## *Figure 8. Prescriber level of knowledge diagnosing ADHD. Source: OIG analysis of prescriber questionnaire.*

Note: Diagnosis is not within the scope of practice of 'clinical pharmacy specialist' resulting in the exclusion of 10 mental health clinical pharmacy specialist responses.

Approximately one-third of questionnaire respondents reported not having received ADHD diagnosis training and perceived being only *somewhat knowledgeable* or *not knowledgeable* about ADHD diagnosis.

In response to the OIG questionnaire, more than 90 percent of mental health prescribers reported having received stimulant prescribing training, while fewer than 50 percent of primary care prescribers reported having received stimulant prescribing training. When the OIG asked for comments or feedback related to stimulant prescribing, 15 percent of questionnaire respondents identified the need for training with comments such as, "prescribers in the VA will benefit from additional training and resources for prescribing stimulants." Additionally, 87 percent of mental health and 35 percent of primary care respondents reported being *knowledgeable* or *very knowledgeable* about prescribing stimulants for treatment of ADHD. In contrast, 13 percent of mental health and 65 percent of primary care respondents reported being *somewhat knowledgeable* or *not knowledgeable* about stimulant prescribing for ADHD (see figure 9).



*Figure 9. Prescriber level of knowledge for prescribing stimulants for ADHD. Source: OIG analysis of prescriber questionnaire results.* 

The OIG questionnaire asked prescribers to provide additional feedback or comment related to stimulant prescribing. Among respondents, 17 percent indicated a need for prescribing guidance with prescribers indicating it "would be prudent to have [urine drug screen] guidelines, [echocardiogram] guidelines and other things needed to safely prescribe," and "I think with simulants [*sic*] being controlled substances we want to be extra careful to do no harm however we also do not want to withhold indicated treatment because of provider discomfort."

Lack of training and knowledge related to ADHD diagnosis and stimulant prescribing may contribute to insufficient diagnostic assessment, inappropriate prescribing of Schedule IIN controlled substances, and compromise patient safety. The OIG determined that although VHA policy authorizes primary care providers to treat "uncomplicated" mental health conditions, lack of clarity regarding the referral expectations for "complex" mental health conditions may contribute to patients not receiving referrals for mental health care to establish accurate diagnosis and treatment.

#### 4. Absence of VHA Policy and Clinical Practice Guidance

The OIG determined that VHA has no established policies or clinical practice guidance related to the assessment, diagnosis, and treatment of ADHD. In interviews with the OIG, both Office of Mental Health and Suicide Prevention and Office of Primary Care leaders acknowledged a lack of formal policy or guidance. Office of Mental Health and Suicide Prevention leaders told the OIG that "guidance to the field would be to use the DSM-5." Office of Primary Care leaders stated VA qualification standards require providers to have the skills to diagnose mental health disorders in general. A leader from the Office of Primary Care also stated that there is "tension" on who "takes the lead on these issues," and indicated an expectation that mental health should take the lead because "they're the people we're going to be going to, to do this for primary care."

Office of Mental Health and Suicide Prevention leaders explained to the OIG that a workgroup was formed in 2022 to "better set expectations and support ADHD assessment," and that the workgroup focused on (1) developing EHR templates "to support screening, diagnosis, and treatment," (2) providing consultation through an "Ask the Expert – ADHD" email group, and (3) developing outpatient guidance related to ADHD treatment flow. VHA Pharmacy Benefits Management's Office of Academic Detailing provided OIG additional educational materials related to ADHD diagnosis and treatment that are available to staff on an internal website, including a clinician guide and a factsheet.<sup>59</sup> Although VHA has made optional resources related to ADHD assessment, diagnosis, and treatment available, the OIG concluded that VHA's lack of ADHD-related policies and clinical practice guidance may contribute to limited awareness of clinical expectations and resources to determine a patient's need for comprehensive mental health evaluation.

<sup>&</sup>lt;sup>59</sup> VHA Pharmacy Benefits Management Academic Detailing Services, "Identification and Management of Attention-Deficit/Hyperactivity Disorder (ADHD) in Adults: Academic Detailing Clinician Guide," July 2022. The clinician guide is a tool for VHA prescribers that includes general recommendations and instructs that "specific clinical decisions should be made by the treating provider based on an individual patient's clinical condition"; VHA Pharmacy Benefits Management Academic Detailing Services, "Attention-Deficit/Hyperactivity Disorder (ADHD) in Adults: Academic Detailing Quick Reference Guide," July 2022; VHA Pharmacy Benefits Management Academic Detailing Services, "ADHD in Adults FAQs," July 2022.

## Conclusion

The VA OIG conducted this national review to evaluate VHA's ADHD diagnostic assessment practices, stimulant prescribing practices, training requirements and expectations, and policies. The OIG identified an increase in ADHD diagnosis and stimulant prescriptions within VHA from October 1, 2018, through September 30, 2022.

The OIG found most EHRs did not contain documentation that patients met all ADHD diagnostic criteria, but 72 percent of mental health and 64 percent of primary care EHRs included documentation that the patient met at least one DSM diagnostic criterion. Among EHRs that did not included documentation of any ADHD DSM diagnostic criteria, 43 percent of mental health and 60 percent of primary care EHRs indicated that a stimulant was prescribed to facilitate continuity of care and documented the patient's reported history of ADHD diagnosis and treatment. However, 50 percent of mental health and 46 percent of primary care prescribers did not document an attempt to verify the prior diagnosis.

Most EHRs included documentation of a diagnostic interview, while fewer included documentation of other potentially important assessment methods, such as information from family members or friends, symptom checklists, or standardized testing instruments. In response to an OIG questionnaire item soliciting feedback or comments related to diagnosing ADHD, 28 percent of respondents indicated a need for more support related to diagnostic testing. The OIG would expect VHA prescribers to document assessment of diagnostic criteria to support an ADHD diagnosis. The absence of an accurate ADHD diagnosis may contribute to inappropriate or unnecessary treatment due to a limited understanding of a patient's symptoms.

In EHR reviews, 64 percent of mental health and 97 percent of primary care EHRs included documentation of cardiac risk monitoring. Providers documented urine toxicology testing in 41 percent of mental health EHRs and 46 percent of primary care EHRs. Documentation of a prescription drug monitoring program query prior to the initiation of a stimulant was included in 92 percent of mental health and 83 percent of primary care EHRs. Given the importance of considering cardiac risk and potential substance misuse to inform treatment decisions, mitigate risk, and promote safe patient care, the OIG would expect prescribers to assess and document risks and contraindications prior to initiating stimulant medication to treat ADHD. Additionally, the OIG would expect the prescription drug monitoring program query goal for new controlled substance prescriptions to meet or exceed the goal established for active prescriptions.

In response to an OIG questionnaire, 70 percent of all respondents, including 78 percent of mental health and 33 percent of primary care prescribers, indicated receiving ADHD diagnostic assessment training. Approximately one-third of questionnaire respondents reported not having received ADHD diagnosis training and perceived being only *somewhat knowledgeable* or *not knowledgeable* about ADHD diagnosis. More than 90 percent of mental health and fewer than 50 percent of primary care prescribers reported receiving stimulant prescribing training.

Additionally, 13 percent of mental health and 65 percent of primary care respondents reported being *somewhat knowledgeable* or *not knowledgeable* about prescribing stimulant medication for treatment of ADHD. Lack of training and knowledge related to ADHD diagnosis and stimulant medication prescribing may contribute to insufficient diagnostic assessment, inappropriate prescribing of stimulant medication, and compromise patient safety.

Office of Mental Health and Suicide Prevention and Office of Primary Care leaders acknowledged a lack of formal policy or guidance related to the assessment, diagnosis, and treatment of ADHD. VHA has made optional resources related to ADHD assessment, diagnosis, and treatment available. However, the OIG concluded that VHA's lack of ADHD-related policies and clinical practice guidance may contribute to limited awareness of clinical expectations and resources to determine a patient's need for comprehensive mental health evaluation.

## **Recommendations 1–5**

- 1. The Under Secretary for Health ensures Veterans Health Administration prescribers establish a diagnosis based on a complete and documented assessment prior to initiation of a stimulant to treat attention deficit hyperactivity disorder.
- 2. The Under Secretary for Health ensures Veterans Health Administration prescribers assess risks and contraindications associated with stimulant prescribing.
- 3. The Under Secretary for Health evaluates the prescription drug monitoring program query adherence goal for initial stimulant prescribing and takes action as warranted.
- 4. The Under Secretary for Health evaluates the adequacy of the referral processes related to complex mental health disorders, such as attention deficit hyperactivity disorder, and takes action as warranted.
- 5. The Under Secretary for Health considers establishing policy and clinical practice guidance related to attention deficit hyperactivity disorder diagnostic assessment and treatment with a stimulant and takes action as warranted.

## Appendix A: Office of the Under Secretary for Health Memorandum

#### **Department of Veterans Affairs Memorandum**

Date: February 26, 2024

- From: Under Secretary for Health (10)
- Subj: Office of Inspector General (OIG) Draft Report, Deficiencies in ADHD Diagnostic Assessment, Evaluation of Stimulant Medication Risks, and Policy Guidance (VIEWS 11391254)
- To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the draft report regarding Veterans Health Administration's (VHA) Attention Deficit Hyperactivity Disorder (ADHD) diagnostic assessment and stimulant prescribing practices. VHA concurs with the recommendations.

2. VHA will review our screening and diagnostic tools for ADHD. We continue to partner with the Department of Defense to ensure that medications prescribed during military service continue when service members transition to Department of Veterans Affairs care when clinically appropriate. VHA continues to monitor emerging research related to substance use disorders and any risks associated with ADHD stimulant treatments.

3. Thank you again for partnering with VHA to ensure Veterans receive the high-quality health care they deserve. Comments regarding this memorandum may be directed to the GAO OIG Accountability Liaison Office at VACOVHA10BGOALOIG@va.gov

(Original signed by:) Shereef Elnahal, M.D., MBA

## **Office of the Under Secretary for Health Response**

#### VETERANS HEALTH ADMINISTRATION (VHA) Action Plan Deficiencies in Attention Deficit Hyperactivity Disorder Diagnostic Assessment, Evaluation of Stimulant Medication Risks, and Policy Guidance

# <u>Recommendation 1.</u> The USH ensures prescribers complete assessment and documentation to establish a diagnosis prior to initiation of a stimulant to treat attention deficit hyperactivity disorder.

#### VHA Comments: Concur

VHA concurs that all providers should complete an adequate assessment and provide adequate documentation to establish a mental health diagnosis or provisional diagnosis prior to the initiation of treatment, including the prescription of controlled substances such as stimulant medications for diagnoses such as attention deficit hyperactivity disorder (ADHD). ADHD may be assessed and treated by a full range of providers with VA facility privileges to diagnose and treat Veterans with mental health disorders. VA providers complete an adequate assessment and documentation for the diagnosis of mental health disorders.

VHA developed and implemented tools to improve ADHD screening and diagnosis in the electronic medical record. These new screening and diagnostic tools for ADHD are currently undergoing evaluation to ensure they are used as intended by providers.

The Office of the Assistant Under Secretary for Health for Clinical Services will identify and ensure that VA providers are provided with assessment and documentation standards for ADHD in adults. This guidance will include information on the use of validated self-report measures and cognitive testing by psychologists. This guidance may be updated as information from ADHD clinical practice guidelines becomes available.

VHA will also evaluate provider use of screening and diagnostic tools for ADHD recently published in the electronic medical record (EMR). Additional education will be provided regarding these tools as warranted.

Status: In progress Target completion: February 2025

## <u>Recommendation 2.</u> The USH ensures prescribers assess risks and contraindications associated with stimulant prescribing.

#### VHA Comments: Concur

VHA concurs that prescribers should assess and communicate with patients the risks, benefits, and potential contraindications of stimulant medications prior to prescribing.

The presence of a substance use disorder is not a contraindication to ADHD treatment, nor is it an absolute contraindication for treatment with stimulants. Providers must have the flexibility to assess and treat individual Veterans using evidence-based treatment practices informed by an ever-expanding body of evidence and Veteran preferences.

In 2023, VHA initiated efforts to improve evaluation and documentation associated with the prescription of controlled substances through a national controlled substance template. This template is currently in the concurrence and evaluation process. The template will apply to stimulant medication prescriptions as well as other controlled substances.

The Office of the Assistant Under Secretary for Health for Clinical Services will identify and ensure that appropriate VA providers receive assessment and documentation standards for the prescription of stimulant medications. This guidance may be updated as information from ADHD clinical practice guidelines becomes available.

VHA will also review a report on the evaluation of the national controlled substance template performance as well as recommendations from the national controlled substance template workgroup to determine if and how this template should be utilized across the system to assess the risks and potential contraindications of controlled substances, including stimulant medications.

Status: In progress Target completion: February 2025

# <u>Recommendation 3.</u> The USH evaluates the PDMP query adherence goal for initial stimulant prescribing and takes action as warranted.

#### VHA Comments: Concur

VHA requires prescribers to query and review a patient's prescription history to inform clinical practice. Prescription drug monitoring programs (PDMP) enable VHA providers to identify patients who are receiving controlled substances from multiple sources, which can be helpful in providing the best care for Veterans and preventing diversion of controlled substances.

The Office of the Assistant Under Secretary for Health for Clinical Services, in collaboration with associated program offices, will evaluate the PDMP query adherence goals of 75% for new and 95% for ongoing controlled substance prescriptions as listed in current VHA guidance.

Status: In progress Target completion: August 2024

<u>Recommendation 4.</u> The USH evaluates the adequacy of the referral processes related to complex mental health disorders, such as ADHD, and takes action as warranted.

#### VHA Comments: Concur

VHA concurs with evaluating the referral processes related to complex mental health disorders such as ADHD. VHA acknowledges that Veterans should receive referrals to the level of care appropriate to their needs.

The Office of the Assistant Under Secretary for Health for Clinical Services will review the referral processes and take action as warranted.

Status: In progress Target completion: August 2024

<u>Recommendation 5.</u> The USH considers establishing policy and clinical practice guidance related to ADHD diagnostic assessment and treatment with a stimulant and takes action as warranted.

#### VHA Comments: Concur

VHA concurs with the need to establish clinical practice guidance related to the assessment and treatment of ADHD in adults. There are national groups currently developing clinical practice guidelines for adult ADHD and there is VA evidence synthesis that will be reviewed when data is available.

The Office of the Assistant Under Secretary for Health for Clinical Services, in collaboration with associated program offices, will review products associated with national evidence synthesis initiatives related to ADHD in adults and make recommendations to VA providers as warranted.

Status: In progress

Target completion: February 2025

## **OIG Contact and Staff Acknowledgments**

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Amber Singh, PhD, Director Marsha Alishahi, LCSW Christine Micek, MSN, RN Jill Murray, LCSW Sarah Reading, MD Laura Savatgy, BA, MPA Tammra Wood, LCSW-S
Other Contributors	Peter Almenoff, MD Jennifer Christensen, DPM Reynelda Garoutte, MHA, BSN Xuefei Jennewein, MS Brandon LeFlore-Nemeth, MBA Yu-Fang Li, PhD, RN Stephanie Long, LCSW Marie Parry April Terenzi, BA, BS Andrew Waghorn, JD

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