

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

DEPARTMENT OF VETERANS AFFAIRS

Independent Review of VA's
Fiscal Year 2021 Detailed
Accounting and Budget
Formulation Compliance
Reports to the Office of
National Drug Control Policy

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Abbreviations

FY Fiscal Year

OIG Office of Inspector General

ONDCP Office of National Drug Control Policy

VHA Veterans Health Administration



DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL





March 22, 2022

MEMORANDUM

TO: Chief Financial Officer

Veterans Health Administration (104)

FROM: Assistant Inspector General

Office of Audits and Evaluations (52)

SUBJECT: Independent Review of VA's Fiscal Year 2021 Detailed Accounting and

Budget Formulation Compliance Reports to the Office of National Drug

Control Policy

- 1. The OIG has reviewed the assertions made by management of the Department of Veterans Affairs, Veterans Health Administration (VHA), that are required by the Office of National Drug Control Policy (ONDCP) Circular: *National Drug Control Program Agency Compliance Reviews*, dated September 9, 2021 (the Circular). These assertions are found in the attached Detailed Accounting Report and Budget Formulation Compliance Report for the year ended September 30, 2021, under the heading, "B. Assertions," on pages 20 and 37 of this report.
- 2. VHA management is responsible for the preparation of the Detailed Accounting Report and the Budget Formulation Compliance Report and the assertions contained therein, in conformity with the requirements of the Circular. VHA officials who signed these two reports are identified on pages 21 and 37 of this report. The OIG's responsibility is to express a conclusion on VHA management's assertions based on its review.
- 3. The OIG's review was conducted in accordance with generally accepted government auditing standards, which incorporate the attestation standards established by the American Institute of Certified Public Accountants. Those standards require that the OIG plan and perform the review to obtain limited assurance about whether any material modifications should be made to management's assertions for them to be fairly stated. A review is substantially less in scope than an examination, the objective of which is to obtain reasonable assurance about whether management's assertions are fairly stated, in all material respects, to express an opinion. Accordingly, the OIG does not express such an opinion. The OIG believes this review provides a reasonable basis for its conclusion.

- 4. In the Detailed Accounting Report, VHA management reported three material weaknesses, two significant deficiencies, and five matters concerning noncompliance with laws and regulations, as identified in the OIG report, *Audit of VA's Financial Statements for Fiscal Years 2021 and 2020* (Report No. #21-01052-33, November 15, 2021). These conditions are listed in the Detailed Accounting Report in the section, "Material Weaknesses or Other Findings," found on pages 19 and 20 of this report. A material weakness is a deficiency, or combination of deficiencies, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented or detected and corrected on a timely basis. A significant deficiency is a control deficiency, or a combination of control deficiencies, that is less severe than a material weakness, yet important enough to merit attention by those charged with governance.
- 5. Based on the OIG's review, except for the effects, if any, of the matters described in the preceding paragraph, the OIG is not aware of any material modifications that should be made to VHA management's assertions for them to be fairly stated.
- 6. The OIG provided VHA with the draft report for review and comment. The VHA chief of staff concurred with the report with one comment. For purposes of clarity, the chief of staff requested adding information to footnote 2 that accompanies the chart in VA's Budget Formulation Compliance Report on page 24 of this report. As requested, the OIG added, "Agency budget estimates are not final and subject to change following the budget appropriations process." This change is the responsibility of VHA. It does not affect the OIG's conclusion in the preceding paragraph. The chief of staff's response follows on page three of the OIG's report.

LARRY M. REINKEMEYER Assistant Inspector General for Audits and Evaluations

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Attachments

VA Management Response

Department of Veterans Affairs Memorandum

Date: March 15, 2022

From: Veterans Health Administration, Chief of Staff (10B)

Subj: OIG Draft Report, Independent Review of VA's Fiscal Year 2021 Detailed Accounting and Budget Formulation Compliance Reports to the Office of National Drug Control Policy (Project No. 2021-03164-AE-0154)

To: Assistant Inspector General for Audits and Evaluations (52)

- 1. Thank you for the opportunity to review the subject Office of Inspector General (OIG) draft report. I concur with OIG's draft report with comment.
- 2. For purposes of clarity, the Veterans Health Administration asks OIG to include information for the reader that Agency budget estimates are not final and subject to change following the budget appropriations process. This information seems relevant to existing footnote 2, page 2, accompanying the chart in the Budget Formulation Compliance report.

The OIG removed point of contact information prior to publication.

(Original signed by)

Jon M. Jensen

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

Attachment 1: Detailed Accounting Report

Statement of Disclosures and Assertions for FY 2021 Drug Control Obligations Submitted to Office of National Drug Control Policy (ONDCP) for Fiscal Year Ending September 30, 2021

In accordance with ONDCP's Circular, National Drug Control Program Agency Compliance Reviews, dated September 09, 2021, the Veterans Health Administration asserts that the VHA system of accounting, use of obligations, and systems of internal controls provide reasonable assurance that:

Obligations are based upon the actual expenditures as reported by the Decision Support System (DSS), which is the designated Managerial Cost Accounting (MCA) System of the Department of Veterans Affairs.

The methodology used to calculate obligations of budgetary resources is reasonable and accurate in all material respects and as described herein was the actual methodology used to generate the costs.

Accounting changes are as shown in the disclosures that follow.

DEPARTMENT OF VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION Annual Reporting of FY 2021 Drug Control Funds

A. Detailed Accounting Submission

1. Table of FY 2021 Drug Control Obligations

(In Millions)	
	FY 2021
Description	Actual
Drug Resources by Budget Decision Unit:	
Medical Care	\$973.649
Medical & Prosthetic Research	\$25.418
Total	\$999.067
Drug Resources by Drug Control Function:	
Treatment	\$973.649
Research & Development	\$25.418
Total	\$999.067

2. <u>Drug Control Methodology</u>

The obligation tables for the FY 2021 Drug Control Obligations (above) and the Resource Summary (page 19) showing obligations and FTE (Full-Time Equivalent) for substance use disorder (SUD) treatment in Veterans Health Administration (VHA) are based on specific patient encounters. The specific patient encounters include all inpatient and outpatient episodes of care either provided by VHA staff or purchased in the community. The source data for VHA inpatient care is the Patient TreatmentFile (PTF). For outpatient care, it is the National Patient Care Database Encounter file (SEFILE). For contract care, it is either the PTF or the hospital payment file. For traditional outpatient medical care in the Community (MCC) and Provider Agreements (PA), it is the Provider Payment file. For Third Party Agreements (TPA) Choice, it is the expedited payments from the Office of Community Care (OCC) that are stored in the Corporate Data Warehouse (CDW).

All patient encounters have an associated diagnosis. The primary diagnosis is considered the reason the patient is being treated and is used to determine whether the treatment provided is a substance use disorder treatment and which type of substance use disorder. A list of the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) and International Statistical Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis groups used for substance use disorders are shown in the following table:

Diagnosis Code	Description (DSM-5 and ICD-10-CM)
F11xx	Opioid Related Disorders
F12xx	Cannabis Related Disorders
F13xx	Sedative Hypnotic/Anxiolytic Related Disorders
F14xx	Cocaine Related Disorders
F15xx	Other Stimulant Related Disorders
F16xx	Hallucinogen Related Disorders
F19xx	Other Psychoactive Substance Related Disorders

It should be noted that Prescriptions and Lab tests do not have linkages to a specific diagnosis and are not included in the report.

The cost of VHA provided services is calculated by the Managerial Cost Accounting (MCA) System of the Department of Veterans Affairs (VA). MCA cost data is used at all levels of the VA for important functions, such as cost recovery (billing), budgeting and resource allocation. Additionally, the system contains a rich repository of clinical information, which is used to promote a more proactive approach to the care of high risk (i.e., diabetes and acute coronary patients) and high-cost patients. VA MCA data is also used to calculate and measure the productivity of physicians and other care providers.

The basic unit of MCA cost is the product. For VHA a product can range from a prescription fill made through a mail-out pharmacy, to an outpatient dental exam, to a bed-day of care in an Intensive Care Unit. Every product that is delivered is fully costed. This means that all direct labor, direct supply, and associated indirect costs (to include local and national overhead costs) are applied. Once they are fully costed, products are then assigned to the applicable patient encounter.

MCA costs are the basis for the obligations displayed in the ONDCP report. The Allocation ResourceCenter (ARC) develops ARC cost, which is computed by taking the MCA cost and removing the non-patient specific costs, such as Operating costs for Headquarters, Veterans Integrated Service Network (VISN) Support, National Programs, and Capital and State Home costs, and adding in the community care payments.

For budget purposes, ARC costs are transformed into obligations to account for the entire VHA Budget.It is a multi-step methodology that is implemented to compute obligations.

- The ARC costs are divided into their appropriations using cost centers identified in their Monthly Program Cost Report (MPCR), which is a MCA Account Level Budget (ALB) based report that accounts for all the costs that comprise the MCA system.
- A facility specific ratio of obligations to ARC cost for non-capital costs is created and multiplied by the expenditures to create medical center specific obligations.
- Assign the medical center capital obligations to VHA services proportional to cost.
- Aggregate the national overhead obligations by cost center into their appropriations and assign them to patient services proportional to cost.
- Balance the final obligations nationally to the SF133 Report on Budget Execution total proportionately.

MEDICAL CARE

Year in Review

In FY 2021, 244,564 Veterans who received services within VHA were diagnosed with a drug use disorder. Of these Veterans, VHA provided services by mental health clinicians in a variety of settings and modalities, including outpatient, clinical video telehealth or telephone care to nearly 86 percent (209,456) of Veterans with any diagnosis of a drug use disorder. Among Veterans receiving treatment within VHA in FY 2021, approximately 16 percent (38,199) used amphetamines, around 25 percent (61,152) used cocaine, around 27 percent (66,993) used opioids, and around 54 percent (13,779) used cannabis. (These categories are not mutually exclusive.)

Data for FY 2020 reflected a decline in utilization of VHA services by Veterans experiencing substance use concerns believed to be related to the pandemic. The decrease in the number of Veterans with a SUD diagnoses served is not believed to be reflective of a change in demand for SUD services. VHA moved rapidly to ensure sustainment of treatment services, rapidly transitioning SUD specialty services to telehealth platforms. VHA also worked closely with the Substance Abuse and Mental Health Services Administration (SAMHSA) to ensure continued access to medications for the treatment of opioid use disorder (M-OUD). In FY 2021 VHA saw a slight increase in utilization. In reviewing available data on utilization of SUD specialty services, Veterans are gradually re-engaging with SUD services. Consistent with expansion in use of telehealth since the start of the pandemic, VHA continued to utilize telehealth (telephone only and audio/visual) to support provision of SUD specialty treatment.

As requested, VHA is exploring available data that would allow for more precise information related to Veteran requests for SUD treatment and subsequent engagement in care. At the current time, this information is not available. Development of SUD specific content for the new electronic health record is continuing with the expectation that this information will be available in the future.

The proposed FY 2023 budget is aligned with several Biden-Harris Drug Policy Priorities which include 1) Expanding access to evidence-based treatment; 2) Advancing racial equity in our approach to drug policy; 3) Enhancing evidence-based harm reduction efforts; 4) Advancing recovery-ready workplaces and expanding the addiction workforce; and 5) Expanding access to recovery support services.

Expanding Access to Evidence-Based Treatment

VHA SUD Service Care Delivery

National policy and expectations for the management of SUD within VHA is guided by VHA Handbook 1160.04 and the VA / Department of Defense (DoD) Clinical Practice Guidelines for the Management of SUD (http://www.healthquality.va.gov/). VHA is a leader in the prevention and treatment of SUD and uses a stepped care approach to SUD treatment. Patients with at-risk alcohol use or the least severe SUDs may be treated with evidence-based brief interventions and/or medical management in primary care or general mental health. For those with more severe disorders, specialty SUD treatment programs provide intensive services including withdrawal management, evidence-based psychosocial treatments, SUD medication, case management and relapse prevention. In an effort to better identify and engage Veterans in SUD treatment, VHA is drafting a proposal to provide universal drug screening through primary care as it already does for alcohol use disorder. As an integrated healthcare system, VHA is uniquely situated to address the needs of Veterans diagnosed witha SUD, including providing supports to address co-occurring medical, mental health, and psychosocial needs (e.g., housing, employment). Treatment for SUD occurs across settings and with policy defining expectations for access to SUD treatment, including expectations for access through Community Based Outpatient Clinics (CBOC) and Health Care Centers (HCC).

VHA also continues to improve service delivery and efficiency by integrating services for mental health disorders, including SUD, into primary care settings. Veterans from Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn/Operation Inherent Resolve (OEF/OIF/OND/OIR) and Veterans from other eras are served in primary care teams (Patient Aligned Care Teams: PACTs) that have co-located mental health staff to identify and address potential mental health and substance use treatment needs. Secondary prevention services include diagnosis and assessment of possible substance use disorders in patients presenting medical problems that suggest elevated risk of substance use disorders (e.g., treatment for Hepatitis C, prescribed opioid medications). Recognizing the importance of PACT-based care, VHA is implementing the Behavioral Health Interdisciplinary Program – Collaborative Chronic Care Model (BHIP-CCM) at every VHA facility. Implementation of BHIP – CCM teams within general mental health further supports VA's commitment to providing access to chronic disease management and treatment for substance use disorders beyond specialty SUD treatment settings.

Most Veterans with substance use disorders are treated in outpatient programs. Outpatient withdrawal management is available for patients who are medically stable and who have sufficient social support systems to monitor their status. Standard outpatient programs typically treat patients one or two hours per session and patients are generally seen once or twice a week. Intensive SUD outpatient programs generally provide at least three hours of service per day and patients attend three or more days per week.

Considering the frequent co-occurrence of substance use disorders with posttraumatic stress disorder, VHA has also assigned a SUD specialist to each of its hospital-level posttraumatic stress disorder services or teams. The staff person is an integral member of the posttraumatic stress disorder clinical services team and works to integrate substance use disorder care with all other aspects of posttraumatic stress disorder-related care. Among the specialists' responsibilities are identification and treatment of Veterans with co-occurring SUD and posttraumatic stress disorder. Specialists also promote preventive services for Veterans with posttraumatic stress disorder who are at risk for developing a substance use disorder.

VHA provides two types of 24-hour care to patients with severe, complex, or acute substance use disorders. These include inpatient withdrawal management, and stabilization in numerous medical and general mental health units, equivalent to Level 4, Medically Managed Intensive Inpatient Treatment as specified by the American Society of Addiction Medicine Patient Placement Criteria, and provision of care in Mental Health Residential Rehabilitation Treatment Programs (otherwise referred to as Domiciliary beds). VHA offers care in Mental Health Residential Rehabilitation Treatment Programs (MH RRTPs) to Veterans with complex, co-occurring mental health, substance use, medical, and psychosocial needs. Specialty Domiciliary SUD programs provide treatment equivalent to Level 3.7, Medically Monitored Intensive Inpatient Services as specified by the American Society of Addiction Medicine Patient Placement Criteria. At the end of FY 2021, 70 Domiciliary SUD programs were in operation with more than 1,800 beds focused specifically on intensive, medically monitored residential SUD treatment. In addition to those MH RRTPs formally designated as Domiciliary SUD programs, additional SUD specialized services are offered through tracks in other MH RRTPs and the majority of Veterans served by MH RRTPs are diagnosed with a substance use disorder. Several new Domiciliary SUD programs are under development with the number of programs expected to grow over the next few years.

Programs to end homelessness among Veterans are encouraged to have SUD specialists as a part of their multidisciplinary teams. There are SUD specialists working in the Department of Housing and Urban Development – VA Supportive Housing (HUD-VASH), Grant and Per Diem (GPD) and the Health Care for Homeless Veterans (HCHV) programs; however, the use of SUD specialists can vary locally based on site-specific needs. These specialists emphasize early identification of substance use disorders as a risk for maintaining permanent housing, promote engagement or re-engagement in SUD specialty care programs, provide SUD treatment services such as Contingency Management, and serve as linkages between homeless and SUD programs.

Methamphetamine

VA recognizes the emerging threat that methamphetamine poses to our nation's Veterans. Specific data on the rates of methamphetamine use disorder are not available. However, the overall rates of amphetamine use disorder have been increasing over the past several years. The number of Veterans who received care for amphetamine use disorder decreased somewhat due to the pandemic with 38,199 Veterans who received care in VHA during FY 2021 having an amphetamine use disorder diagnosis. VA's commitment to provision of evidence-based treatment has positioned VA well to respond to this emerging threat. Contingency Management (CM) is an evidence-based treatment with demonstrated efficacy in treating stimulant use disorder. VHA implemented CM in 2011, and through September 2021, VHA has provided contingency management services to over 5,700 Veterans with nearly 92 percent of the greater than 73,000 urine samples testing negative for the target drug(s) (e.g. stimulants or cannabis). In January 2022, VHA plans to launch a stimulant safety initiative that will include a focus on expanding access to evidence-based practice such as CM and Cognitive Behavioral Therapy (CBT) for Veterans with stimulant use disorder.

Opioid Use Disorder

Slightly more than 66,993 Veterans with an opioid use disorder (OUD) diagnosis were seen in VHA in FY 2021. Medication for OUD (M-OUD) has historically been provided in SUD specialty-care clinics, but a significant number of Veterans with clinically diagnosed OUD do not access SUD specialty care. By disseminating evidence-based models for delivery of M-OUD in primary care, mental health, and pain management clinics, Veterans are expected to have timely access to the right treatment at their preferred point of care. VHA launched the Stepped Care for Opioid Use Disorder Train the Trainer (SCOUTT) initiative in August 2018 with the intent of supporting the expansion of M-OUD in level 1 clinics (primary care, general mental health and pain management clinics). Phase 1 sites in each VISN implemented this expansion during FY 2019. From August 2018 through September 2021 there was a 211 percent increase in the number of patients receiving buprenorphine in the Phase 1 level clinics and 194 percent increase in the number of providers prescribing buprenorphine in these clinics. Further, Veterans are being retained in care with 71 percent of Veterans retained on buprenorphine for more than 90 days. A National Virtual SCOUTT conference for Phase 1 sites took place in September 2020 with over 300 attendees. Phase 2 of the SCOUTT initiative was launched in FY 2020 and three regional conferences occurred in April 2021 attracting over 500 participants. Since the launch of Phase 2 in October 2020, there has been a 29 percent increase in the number of patients receiving buprenorphine and a 20 percent increase in the number of providers prescribing buprenorphine. Further, the infrastructure developed to support Phase 1 of the SCOUTT initiative also supports level 1 clinics at facilities that are not formally involved in the SCOUTT initiative.

In FY 2021, evidence-based M-OUD, including office-based treatment with buprenorphine and extended-release injectable naltrexone, was accessible to patients seen at 100 percent of VHA medical centers. VHA operates federally regulated opioid treatment programs that can provide methadone maintenance on-site at 33 larger urban locations and at a growing number of VHA facilities that maintain contractual arrangements or arrange non-VA care for providing care through community- based licensed opioid treatment programs. VHA continues to expand the availability of M-OUD for Veterans. VA monitors the percent of patients with OUD who receive M-OUD (45.8 percent through FY 2021 Quarter 3) as part of the Psychotropic Drug Safety Initiative (PDSI). PDSI is a nationwide psychopharmacology quality improvement (QI) program that supports facility-level QI through quarterly quality metrics, clinical decision support tools, technical assistance for QI strategic implementation, and a virtual learning collaborative. Since 4th quarter FY 2019, VA has seen a 4 percent increase in the number of Veterans that received M-OUD (total of 27,358, for FY 2021). Starting in FY 2021, the PDSI has expanded its focus to include safer prescribing of stimulant medication.

The number of providers with a Drug Enforcement Administration (DEA) X-waiver have also continued to increase since the 4th quarter FY 2020 with over 6,500 providers who have written any prescription issued to the VHA pharmacy (VA employed and community providers serving Veterans) as of December 2021 holding an X-Waiver. This reflects an increase of 19 percent from the same timepoint in FY 2020. VA has realized that it will be critical to go beyond providers obtaining a waiver that allows them to prescribe buprenorphine. The number of providers with a DEA X-waiver that prescribed buprenorphine is significantly lower than the number of providers with an X-waiver with only 21 percent of those providers with an Xwaiver issuing a prescription for buprenorphine as of December 2021. While the number of providers is increasing, VA is focusing efforts to remove barriers to prescribing and to support the initiation of buprenorphine when indicated. VHA Notice 2019-18, Buprenorphine Prescribing for Opioid Use Disorder was published in October 2019 and re-issued in September 2020 by the Undersecretary with the intent of clarifying national policy and tasking facilities to remove potential barriers to prescribing if present. In January of 2021, in an effort to reduce prescribing barriers, VHA also removed the requirement for written consent to provide buprenorphine for the treatment of opioid use disorder. In addition, in July 2020, VA formalized efforts to provide training to support efforts to ensure that all providers eligible to obtain an Xwaiver had access to the training utilizing primarily an 8-hour half and half (four hours online and four hours live training) for physicians and a 24-hour training model for eligible non-physician prescribing providers. Between July 2020 and July 2021 VA offered trainings with over 525 providers trained. Given the changes in training requirements for providers treating 30 or less patients put forward with the new SAMHSA Buprenorphine Guidelines in April 2021, additional trainings are being planned to include the addition of shorter focused trainings for providers and other interdisciplinary staff who support M-OUD. VA has also started offering "office hour" sessions for M-OUD treatment consultation with SMEs where providers can discuss cases and ask question of subject matter experts (SMEs) in live sessions as well as continuing consultation via e-mail through the VHA "Ask the Expert Program" and direct live patient consultation through the National TeleMental Health Center. VHA also recognizes the importance of capturing more detailed information on providers most likely to prescribe buprenorphine for OUD and has developed tools that will allow for improved understanding of availability of X-waivered providers by practice setting.

In support of interprofessional team-based models of care, VA is leveraging Clinical Pharmacy Specialist (CPS) providers to deliver comprehensive medication management services and improve Veteran access to SUD care. In partnership with the VA Office of Rural Health, the VA Pharmacy Benefits Management (PBM) Clinical Pharmacy Practice Office launched a nationwide initiative in FY2020 to expand the CPS provider workforce focused on SUD care. Since initiation, 51 VA facilities have been awarded funding to hire 64 CPS providers across Mental Health, Pain Management, Primary Care and Specialty Care settings with a focus of expanding access to OUD and alcohol use disorder (AUD) care for rural Veterans. As part of this project, three regional train the trainer clinical pharmacy boot camps were held virtually in June and July 2020 and trained 234 VA-CPS providers in OUD and AUD care. The training focused on advancing CPS provider practice in SUD care and risk mitigation across level 1 clinics, in alignment with the SCOUTT initiative and offered subsequent office hours to further support CPS practice growth in SUD care. All boot camp participants completed 24-hour DEA X-waiver training prior to the boot camp in anticipation that future legislation may include pharmacist practitioners as potential providers of buprenorphine-based therapy, furthering access to M-OUD. As of the 4th quarter FY 2021, 212 VA CPS providers are routinely delivering OUD care with 47,150 encounters in FY 2021. This represents a 76.8 percent growth in CPS provider practice in OUD care delivery since the implementation of the SCOUTT initiative; significant CPS practice growth in SUD care is expected in FY 2022.

Advancing racial equity and diversity in our approach to drug policy

In June 2021 VHA brought together a workgroup to better understand gender/ethnic/racial, Lesbian Gay Bisexual Transgender Questioning and others (LGBTQ+) SUD healthcare disparities in VHA with the goal of piloting target interventions for the largest gaps in FY 2022 and then based on the results of these pilots disseminating best practices to the field in FY 2023.

Mental Health residential treatment services, including SUD residential services for women Veterans are available in every VISN. Across the residential programs that serve women Veterans, 70 percent offer gender specific mental health services and 56 percent offer a separate, secure wing or unit for women Veterans. For those women Veterans requesting a residential program for women Veterans only, there are currently 11 programs that serve as national resources available to meet that need. Five of the women-only programs provide intensive specialty treatment for substance use. Further, about 37 percent of VA facilities offer women-only outpatient SUD or PTSD-SUD treatment, and all of VA facilities offer individual SUD or SUD-PTSD treatment for women Veterans. Finally, VA is developing at least 2 additional women only residential SUD treatment programs that will serve as national referral resources for women Veterans.

VHA also has pursued educational efforts to promote culturally competent SUD care, e.g., its Best SUDCare Anywhere webinar series has convened webinars on SUD care for women (in FY 2019), culturally competent SUD care (in FY 2020), and is convening a webinar on SUD care for Native Americans in January 2022.

Enhancing evidence-based harm reduction efforts

Opioid Safety Initiative

VHA continues to pursue a comprehensive strategy to promote safe prescribing of opioids when indicated for effective pain management. The purpose of the Opioid Safety Initiative (OSI) is to ensure pain management is addressed thoughtfully, compassionately, and safely. The OSI makes the totality of opioid use visible at all levels in the organization. Based on comparisons of national data between the quarter beginning in Quarter 4, FY 2012 (beginning in July 2012) to Quarter 4, FY 2021 (ending in September 2021), many aspects of the OSI continue to show positive results. Fewer than 377,679 Veterans were on long-term opioids. The average dose of selected opioids has continued to decline as 60,652 fewer patients were receiving morphine equivalent daily doses greater than or equal to 90 milligrams, demonstrating that prescribing and consumption behaviors are changing. The desired results of OSI have been achieved during a time that VHA has seen a 6.2 percent increase in Veterans that have utilized VHA outpatient pharmacy services.

According to the Centers for Disease Control and Prevention (CDC), 50 million adults in the United States have chronic daily pain, with 19.6 million adults experiencing high-impact chronic pain that interferes with daily life or work activities. Chronic pain is a national public health problem as outlined in the 2011 study by the Institute of Medicine (IOM). The IOM study describes in detail many concerns of pain management, including system-wide deficits in the training of our Nation's health care professionals in pain management and substance use disorders prevention and management, and the problems caused by a fragmented health care system. The over-use and misuse of opioids for pain management in the United States is a consequence of a health care system that until recently was less than fully prepared to respond to these challenges.

VHA has identified and broadly responded to the many challenges of pain management through policies supporting clinical monitoring, education and training of health professionals and teams, and expansion of clinical resources and programs. VHA's Pain Management Directive defines and describes policy expectations and responsibilities for the overall National Pain Management Strategy and Stepped Care pain model, which is evidence-based and has been adopted by the DoD as well.

Our approach to managing opioid over-use fits into this plan, and the VA has employed broad strategies to address the opioid epidemic: education, pain management, risk mitigation, and addiction treatment. First, VHA addressed the problem of clinically inappropriate high dose prescribing of opioids through the VA's national program, OSI. Second, VHA developed an effective system of interdisciplinary, patient-aligned pain management with the competency to provide safe and effective pain control and quality of life for Veterans for the remainder of their lives.

VHA has reduced the reliance on opioid medication for pain management by more than 60 percent since 2012, largely by starting fewer patients newly on long-term opioid therapy and by offering pain care options that are safer and more effective in the long run. Most of the decline in VHA opioid prescriptions is not due to Veterans "getting by" with fewer opioids, but by following a Stepped Care Model for Pain treatment addressing the causes of pain with fewer Veterans requiring the initiation of long-term opioid therapy. VHA has been recognized by many as a leader in the pain management field for the responsible use of opioids. Notably, VHA has organized many types of interdisciplinary pain care teams to help with medication safety, patient education, pain schools, cognitive behavioral therapy and helping patients transition from a biomedical to a biopsychosocial model of pain care. As VHA continues its efforts to address opioid overuse, non-opioid treatments, and complementary and integrative medicine treatments (such as massage therapy, yoga, meditation, occupational therapy, physical therapy, recreational therapy, acupuncture, tai chi, etc.) are an important component to VHA's Pain Management Strategy.

To further strengthen OSI and keep this trend moving in the right direction, VHA has deployed state- of-the-art tools to help protect Veteran patients using high doses of opioids or with medical risk factors that put them at an increased risk of complications from opioid medications including overdose. These tools include the Stratification Tool for Opioid Risk Mitigation (STORM), which is available to all clinical staff in the VHA. These tools include information about the dosages of opioids and other sedative medication, significant medical problems that could contribute to an adverse reaction and monitoring data to aid in the review and management of complex patients. The STORM allows VHA providers to view information about risk factors for opioid overdose, suicide-related events and other harms and recommends patient-specific risk mitigation strategies. To address overdose and suicide risk, VHA required that patients identified as very high risk per the STORM predictive model receive a case review by an interdisciplinary team including pain, addiction, and mental health expertise. Preliminary findings from a randomized policy evaluation of this new clinical program found that patients targeted for case review had lower rates of all-cause mortality and medical record documented adverse events, such as motor vehicle accidents and overdose.

Additionally, VHA has formalized a system-wide Academic Detailing program that is in process of being implemented throughout the organization. Academic Detailing provides specialty teams to visit facilities and provide on-site support and education to providers to further enhance pain management efforts. The Academic Detailing program is another important step to improve mental health, substance use disorder, and pain management medication therapy across all VHA medical centers. As of September 30, 2021, academic detailers (specially trained VA Pharmacists) have held 76,183 outreach visits related to Opioid Safety, Overdose Education and Naloxone Distribution, opioid use disorder, and suicide prevention.

As VHA continues its efforts to address opioid over-use, complementary and integrative medicine treatments are an important component to VHA's Pain Management Strategy. VHA currently offers many complementary and integrative medicine treatments, many of which may be useful in chronic pain. These treatments include acupressure, acupuncture, biofeedback, chiropractic services, exercise, heated pool therapy, hypnosis/hypnotherapy, massage therapy, meditation, occupational therapy, physical therapy, recreational therapy, relaxation, tai chi, transcutaneous electrical nerve stimulation, yoga, and other services.

VHA has several other programs that are complementary to the Opioid Safety Initiative and include: 9 of 19

- State Prescription Drug Monitoring Programs (PDMP): Fifty (50) States, the District of Columbia, and Puerto Rico are activated for outgoing transmission of VA controlled substances prescription data. 50 of 54 individual states/regional/territories PDMPs are currently participating in the VA's new integrated PDMP query solution. Since the solution was deployed across VA on November 9, 2020, over 2 million queries have been executed with the PDMP button to help guide treatment solutions. This does not include queries that are done manually, for example, from those states that are not yet integrated into the PDMP solution.
- Medication Take-Back Program: VA offers free medication take back services to Veterans through mail-back envelopes and on-site receptacles compliant with Drug Enforcement Administration (DEA) regulations. As of September 30, 2021, Veterans have returned over 250 tons of unwanted or unneeded medication using these services.

Opioid Overdose Education and Naloxone Distribution

The VA Opioid Overdose Education and Naloxone Distribution (OEND) program aims to decrease opioid-related overdose deaths among VHA patients by providing education on opioid overdose prevention, recognition of opioid overdose, and training on the rescue response, including provision of naloxone. All three Food and Drug Administration (FDA)-approved forms of naloxone (injectable, nasal spray and auto-injector) that the FDA states can be considered as options for community distribution were added to the VA National Formulary as soon as they were available. The nasal spray formulation is currently available through every VHA facility. VHA assembled injectable (intramuscular) naloxone kits as part of its initial OEND program. These were replaced by the auto-injector—specifically designed for layperson use—when that formulation became available. However,the auto-injector was abruptly discontinued by the pharmaceutical manufacturer on September 30, 2020. In response, VHA has started re-assembling the injectable (intramuscular) naloxone kits. VHA recommends offering OEND to Veterans prescribed or using opioids who are at increased risk for opioid overdose or whose provider deems it clinically indicated. Given the increase in opioid-involved stimulant overdoses, VHA also recommends offering OEND to Veterans with stimulant use disorders. Academic Detailing has promoted OEND through individualized, evidence-based educational outreach visits and consultation for clinicians by clinicians.

In July 2016, Congress took the important step of eliminating copayment requirements for opioid antagonists (e.g., naloxone) furnished to Veterans at high risk for overdose and for education on their use (per P. L. 114-98, title IX, the Jason Simcakoski Memorial and Promise Act). This change has been implemented throughout VHA and a final rule has been published in the Federal Register that amended two of VA's copayment regulations, 38 CFR 17.108 and 17.110, to accurately implement these changes into the Code of Federal Regulations. The proposed rule also defines who VHA considers to be at high risk for overdose. This definition will assist in the implementation of the public law and facilitate identification of high-risk Veterans. Early identification of these Veterans can facilitate provision of lifesaving opioid antagonist medication. Since implementation of the OEND program in 2014, over 36,700 VHA prescribers, representing all VHA facilities, have prescribed naloxone, and more than 650,000 naloxone prescriptions have been dispensed to over 328,100 Veterans (as of December 2021). Through December 2021, as documented through spontaneous reporting of overdose reversal events as well as through a national note, over 2,000 overdose reversals with naloxone have been reported.

As of April 2021, 129 VHA facilities had equipped 3,552 VA Police officers with naloxone, with 136 reported opioid overdose reversals with VA Police naloxone, and 77 VHA facilities had equipped 1,095 Automated External Defibrillator (AED) cabinets with naloxone, with 10 reported opioid overdose reversals with AED cabinet naloxone. VHA's Rapid Naloxone Initiative received the 2020 John M. Eisenberg National Level Innovation in Patient Safety and Quality Award.

This prestigious award from The Joint Commission (TJC) and National Quality Forum recognizes those who have made significant and long-lasting contributions to improving patient safety and health care quality. Notably, in 2018 VHA dispensed a naloxone prescription for 1 in 6 patients on high dose opioids, as compared to 1 in 69 patients in the private sector.

Finally, as part of the broader OEND effort, VHA has established a community of practice for sharing innovative and promising practices which has included discussion of post-overdose engagement in treatment. Materials developed in support of the OEND initiative also are available to Veterans, their family members, and the broader public.

Syringe Service Programs

In May of 2021 the Assistant Under Secretary for Clinical Services issued interim guidance on Syringe Services Programs (SSPs) recommending that VA medical Centers develop SSPs or otherwise ensure Veterans enrolled in VHA care have access to SSPs where such programs are not prohibited under state, county, or local law. In addition to providing access to sterile needles, syringes and other supplies, SSPs facilitate safe disposal of used syringes and provide the opportunity to link to other important services, such as buprenorphine induction, and programs such as OEND, screening and treatment for viral hepatitis and HIV, screening for sexually transmitted infections and referral to social, mental health, and other medical services. VHA is currently in the process of drafting a directive supporting the establishment of SSPs in VHA Medical Centers where not prohibited by under state, county, or local law.

In FY 2022, VHA will implement a national electronic medical record note template for SSPs that will facilitate documentation of screening for infectious diseases associated with injection drug use, vaccinations, referrals for services, and prescriptions for syringes. VHA plans to develop a standard VHA SSP kit for VA facilities standing up SSPs, facilitating consistent practices in assembling, prescribing, and dispensing a specified set of essential sterile items to Veterans who inject drugs. VHA also plans to develop Talent Management System (TMS) training to enhance provider knowledge about harm reduction and SSPs and give them the information they need to educate Veterans on safer injection practices and safer drug use. At the start of FY 2022, there were four (4) VA facilities operating SSPs, with another 18 VA facilities close to standing up and implementing SSPs. By the end of FY 2022 and continuing into FY 2023, VHA expects the number of programs to increase significantly with implementation of the SSP Directive and of the standard VHA SSP kits. FY 2023 efforts will focus on assisting programs with implementation via data tools and other supportive resources. VHA will promote innovative practices demonstrated to have benefit, such as distribution of fentanyl test strips, and work to disseminate proven innovations to the maximum extent possible consistent with variations in legal and regulatory requirements throughout the U.S.

In FY 2022, VHA plans to implement a national electronic medical record note template for SSPs which include screening for infectious diseases, vaccinations, referrals for services, and prescription for syringes. VHA is also planning to centrally develop SSP kits that facilities developing SSPs can prescribe in order to provide essential sterile equipment to Veterans who inject drugs. VHA also plans to develop a Talent Management System (TMS) training module to enhance provider knowledge about harm reduction and SSPs and give them the information they need to educate Veterans on safer injection practices, safe disposal of used syringes, and safer drug use. At the start of FY 2022, there were four VA-SSPs operating in the enterprise and 18 programs close to implementation. By the end of the fiscal year and into FY 2023 we expect the number of programs to increase significantly with the implementation of the directive and national kits. Fiscal Year 2023 efforts will focus on assisting programs with implementation which will include supportive tools like data resources. VHA will work to promote innovative practices including distributing fentanyl test strips and work to scale up innovations as much as possible given variations in law throughout the country.

Post-Overdose Care

During FY 2019, VHA implemented a process for documenting accidental and severe adverse effect overdoses as a component of suicide prevention efforts. Implementation of the Suicide Behavior and Overdose Report (SBOR) note template provides a foundation for VHA to implement strategies designed specifically to address the myriad of overdose risk factors from a patient-centered perspective and to support Veteran engagement in timely treatment following a non-fatal overdose (opioid and non-opioid related). In July 2021, VHA mandated use of a national medical record note template to report overdose (e.g., SBOR), with a focus on improving post-overdose care. As past non-fatal overdoses increase the risk of future overdose events, VHA also mandated facilities have a process to ensure that overdose events are reviewed with a focus on engaging patients in treatment. In general, VHA is aligning the required processes for reporting non-fatal overdoses with the already required reporting and post-event treatment interventions for Veterans who make a suicide attempt. This initiative involves a national medical record note template designed to standardize and streamline the process of overdose reporting across VHA, enhancing the visibility of accidental overdoses within the Veteran's medical record, improving clinical care after the suicide/overdose event, and facilitating real-time tracking of overdose event data, for use in clinical decision support tools and local/national aggregate reports.

Advancing recovery-ready workplaces and expanding the addiction workforce/ Expanding access to recovery support services.

Implementation of the FY 2022 and 2023 SUD budgets focus on expanding and scaling up the addiction workforce and advancing the recover-ready workplace as well as access to recovery services through:

- Expanding the addiction workforce to support residential and general SUD care delivery (including funding for new SUD providers in our General Mental Health Clinics, Primary Care-Mental Health Integration Programs and through the addition of telehealth providers in our Clinical Resource Hubs)
- Enhancing employment opportunities for Veterans in recovery by funding SUD specific supported employment staff at VA Medical Centers
- Increasing Peer Support Services by increasing the number of SUD-Specific Peer Specialists at VA Medical Centers. Specific training in SUD is being planned for Peer Specialists. Strategies to help support hiring of Peer Specialists with bilingual skills will be initiated.

Other Initiatives

Veterans Justice Programs

The Uniform Mental Health Services Handbook affirmed that "Police encounters and pre-trial court proceedings are often missed opportunities to connect Veterans with VA mental health services as a negotiated alternative to incarceration or other criminal sanctions." VA medical centers provide outreach to justice-involved Veterans in the communities they serve.

VA services for justice-involved Veterans are provided through two dedicated national programs, both prevention-oriented components of VA's Homeless Programs: Health Care for Reentry Veterans (HCRV) and Veterans Justice Outreach (VJO). Known collectively as the Veterans Justice Programs (VJP), HCRV and VJO facilitate access to needed VA health care and other services for Veterans at all stages of the criminal justice process, from initial contact with law enforcement through community reentry following extended incarceration.

HCRV Specialists provide outreach to Veterans approaching release from state and Federal prisons. They briefly assess reentry Veterans' probable treatment needs, help Veterans plan to access responsive services upon release, and provide post-release follow-up as needed to ensure that Veterans are engaged with needed services. Most HCRV Specialists are based at VA medical centers, but they typically serve Veterans across a large area, often conducting outreach to prison facilities in at least one entire state, and sometimes an entire VISN.

VJO Specialists serve Veterans at earlier stages of the criminal justice process, with a three-pronged focus on outreach to community law enforcement, jails, and courts. VJO Specialists at each VA medical center work with Veterans in the local criminal courts (including but not limited to the Veterans Treatment Courts, or VTCs), conduct outreach in local jails, and engage with local law enforcement by delivering VA-focused training sessions and other informational presentations. Each VA medical center has at least one VJO Specialist, who serves as a liaison between VA and the local criminal justice system.

Public Law 115-240, The Veterans Treatment Court Improvement Act of 2018, signed September 17, 2018, required VA to hire 50 new Veterans Justice Outreach Specialists to serve in VTCs, in addition to their other outreach duties. VA medical centers have filled all positions, as well as an additional 15 positions added in FY 2020.

Veterans who are seen by HCRV and VJO Specialists access VA mental health and substance use treatment at high rates. Most Veterans seen in the VJO program have a mental health (72 percent) or substance use disorder (56 percent) diagnosis, or both (48 percent). Within one year of their VJO outreach visit, 92 percent of Veterans with mental health diagnoses had had at least one VHA mental health visit. Within the same timeframe, 66 percent of Veterans with substance use disorder diagnoses had had at least one VHA substance use disorder visit; these Veterans had an average of 12 outpatient visits that year. Veterans seen by HCRV Specialists have a similar profile, with 43 percent with a mental health diagnosis, 23 percent with a substance use disorder diagnosis and 18 percent with both. Veterans in HCRV access VHA care at high rates, but slightly lower than those in VJO with 86 percent of those with a mental health diagnosis having at least one visit, an average of 11 outpatient visits within one year of their HCRV outreach visit. For those with a substance use disorder, 52 percent had at least one visit, and an average of 6 outpatient visits within one year of their HCRV outreach visit. Improving access to treatment and care for this segment of the Veteran population is in direct alignment with the identified agency goals.

In communities where justice programs relevant to Veterans exist (Veterans courts, drug courts, mental health courts, and police crisis intervention teams), VA has taken the initiative in building working relationships to ensure that eligible justice-involved Veterans get needed care. In communities where no such programs exist, VA has reached out to potential justice system partners (judges, prosecutors, police, and jail administrators) to connect eligible justice-involved Veterans with needed VA services including addiction treatment. VJO specialists currently serve Veterans in 601 Veterans Treatment Courts and other Veteran-focused courts, with more planned. Their duties in a Veterans Treatment Court include linkage to VHA treatment services. These specialists also educate and advocate for the availability of evidence-based SUD treatments, especially MOUD, in criminal justice settings and in preparation for transition of patients from those settings to community living.

In communities without Veterans Treatment Courts, VA medical centers have established relationships with a range of justice system and community partners, including police and sheriffs' departments, local jail administrators, judges, prosecutors, public defenders, probation officers, and community mental health providers.

Collaboration with Federal Partners

VHA is committed to working collaboratively with other Federal Partners in support of the National Drug Control Strategy and will continue to share insights of VHA efforts and input into the national drug strategy agenda to address SUD care with ONDCP and other interagency partners. With the support of ONDCP, VHA provided an update on VHA peer support services through a webinar in September 2020. Furthermore, VHA is working collaboratively with the Indian Health Service (IHS) and the Department of Defense (DoD) on joint training opportunities in the SUD lane including overdose prevention, opioid safety and evidence-based SUD practice. VHA is also collaborating actively with Health and Human Services (HHS)/ Substance Abuse and Mental Health Services Administration on education related to Contingency Management and oversight of the VA Opioid Treatment programs. VHA also recently worked with HHS in FY 2020 to provide access for staff from IHS and the Bureau of Prisons to join the Clinical Pharmacy Boot Camps to support expansion of SUD services supported by Clinical Pharmacy Specialists with 32 Public Health Service partners participating in this virtual program. VHA is currently working collaboratively with the Department of Defense (DoD) to share lessons learned across the agencies to support access to M-OUD, particularly for transitioning service members and in FY 2021 VHA along with DoD updated the VA/DoD ClinicalPractice Guidelines for the Management of Substance Use Disorders.

The accompanying Department of Veterans Affairs Resource Summary (page 19) was prepared in accordance with the following ONDCP circulars (a) National Drug Control Program Agency Compliance Reviews dated September 9, 2021, (b) Budget Formulation, dated September 9, 2021, and (c) Budget Execution, dated September 9, 2021. In accordance with the guidance provided in the Office of National Drug Control Policy's letter of September 7, 2004, VA's methodology only incorporates Specialized Treatment costs.

Specialized Treatment Costs (Dollars in Millions)

Specialized Treatment	VHA Obligations	Care in the Community Obligations	Total Obligations	FTE
Inpatient	\$229.622	\$136.330	\$365.952	879
Outpatient	\$342.709	\$35.554	\$378.263	1,227
Residential Rehabilitation & Treatment	\$229.434	\$0.000	\$229.434	992
Total	\$801.765	\$171.884	\$973.649	3,098

VA does not track obligations by ONDCP function. In the absence of such capability, obligations by specialized treatment costs have been furnished, as indicated.

MEDICAL & PROSTHETIC RESEARCH

VHA research supports the generation of new knowledge to improve prevention, diagnosis, and treatment of substance use disorders (SUD) (e.g., opioids, alcohol, tobacco, cocaine, cannabis, methamphetamine, etc.), as well as the development and testing of innovative, non-opioid approaches for chronic pain management for Veterans.

The VA patient population has experienced many of the problems of at-risk opioid and addiction that have made this a major clinical and public health issue in the U.S. Opioids are used to treat pain, but they are associated with dangerous side effects including depressed breathing, cognitive impairment, and the potential for addiction.

The second State of the Art (SOTA) Conference on Effective Management of Pain and Addiction: Strategies to Improve Opioid Safety was held on September 11-12, 2019. This conference focused on three areas: 1) Managing Opioid Use Disorder (OUD), 2) Long Term Opioid Therapy and Tapering; and 3) Substance Use Disorder and Pain. Findings from the SOTA were published in the Journal of General Internal Medicine (Becker WC et al., J Gen Intern Med. 2020). Three areas of focus included managing opioid use disorder, tapering of long-term opioid therapy for pain when risk outweighs benefit, and co-occurring pain and substance use disorder. Recommendations made by SOTA participants included testing implementation strategies in the Veterans Health Administration for: 1. Expanding access to medication treatment for OUD, 2. Testing collaborative tapering programs for patients prescribed long-term opioids, and 3. Larger trials of behavioral and exercise/movement interventions for pain among patients with substance use disorders. In accordance with goals identified in the SOTA, VA's Health Services Research and Development (HSR&D) released a new research solicitation in Fall 2020 that will fund focused research to inform, improve, and/or implement evidence-based practices to improve opioids safety and management of OUD. This research solicitation adheres to cross-cutting principles aimed at expanding our understanding of care for older Veterans, developing more effective strategies for reducing racial and ethnic disparities, and examining the effects of the COVID-19 pandemic in the treatment and management of pain and OUD. The solicitation will focus research on numerous priority areas including:

- a) Implementation of evidence-based medications for opioid use disorder (M-OUD)
- b) Identification and development of appropriate and successful strategies for opioid tapering and discontinuation
- c) Examination of the potential role of buprenorphine/naloxone and non-pharmacological interventions in managing pain in patients with a history of OUD
- d) Development of more effective approaches to monitor patient outcomes for guiding treatment
- e) Development of new approaches for sustaining patient engagement in treatment including use of telehealth platforms
- f) Study of the management of acute pain among patients on M-OUD, including issues in emergency department care and best practices involving patients with acute pain who are at risk for relapse

Further, in recognition of the rising rates of stimulant use disorder and stimulant overdoses across the country and within the VA, HSR&D also added research on stimulant use disorder to its parent Request for Application (RFA)'s list of research priorities in Fall 2020. (Note: The Parent RFA is the main funding opportunity announcement VA investigators apply to for research funding.)

In addition, the Clinical Science Research & Development (CSR&D) Service has a long-standing focus on research on pain mechanisms and treatment alternatives to opioids, and health-risk behaviors (e.g., substance use, addictive disorders) as priority areas in their parent Merit RFA.

Lastly, both the Basic Laboratory Research & Development (BLR&D) and Rehabilitation Research & Development Services have mutual interest on the relationship between Traumatic Brain Injury (TBI) and substance/opioid misuse. This special emphasis area is included in the parent Merit RFAs for both services.

In summary, all of ORD's services have demonstrated commitment to placing substance/opioid use disorders as an area of high priority in funding opportunity announcements in the hopes of stimulating the field to develop, test and implement novel strategies towards the treatment of SUD. As VHA continues to reduce excessive reliance on opioid medication, VA will maintain efforts in 2022 on pain-management research in areas responsive to the Jason Simcakoski Memorial and Promise Actand the President's Commission on Combating Drug Addiction and the Opioid Crisis. Towards this goal, VA identified the following areas to invest in:

- Non-pharmaceutical strategies for painful conditions: VA will continue to test and develop novel non-pharmaceutical strategies for painful conditions including cognitive behavioral therapy (CBT), traditional complementary and integrative health approaches (e.g., yoga, Taichi, and activity-based therapies), device-based (e.g., electrical stimulation), and even cell therapies for musculoskeletal conditions.
- Safer medications to treat pain: VA will continue to focus research on understanding the benefits and risks of non-opioid medications for pain management and alleviation. An example is targeting mutations in sodium and other ion channels which have been shown to cause pain associated with phantom limb pain, corneal neuralgia, chemotherapy-induced pain, diabetes, small fiber neuropathy, erythromelalgia, and burns.
- Develop and test technologies providing access to treatment for chronic pain and opioid misuse: VA is testing the use of telehealth, smart-apps, web- and phone-based technology to provide outreach and care to Veterans living in rural areas. These interventions include peer coaching, treatment for OUD, provision of biobehavioral approaches, as well as establishing best practices for delivery of care using these modalities.

	Obligations	Drug Control	
Specialized Function	(Millions)	Related Percent	FTE
Research & Development	\$25.418	N/A	N/A

- 3. Methodology Modifications In accordance with the guidance provided in the Office of National Drug Control Policy's letter of September 7, 2004, VA's methodology for calculating Substance Abuse Treatment Costs only incorporates Specialized Treatment costs and does not takes into consideration Other Related Treatment costs. Drug control methodology detailed in A.1 was the actual methodology used to generate the Resource Summary (page 19).
- 4. Material Weaknesses or Other Findings CliftonLarsonAllen LLP provided an unmodified opinion on VA's FY 2021 consolidated financial statements. They identified three material weaknesses, two significant deficiencies, and certain conditions regarding noncompliance with laws and regulations. The material weaknesses relate to: 1) Controls over Significant Accounting Estimates (Repeat); 2) Financial Systems and Reporting (Repeat); and 3) Information Technology (IT) Security Controls (Repeat). Also, CLA identified two significant deficiencies, which were previously reported as material weaknesses in FY 2020. The two significant deficiencies are: 1) Obligations, Undelivered Orders (UDOs), and Accrued Expenses; and 2) Entity Level Controls including CFO Organizational Structure. Reducing these material weaknesses to significant deficiencies is a major VA/VHA accomplishment.

The conditions regarding noncompliance with laws and regulations include findings of noncompliance in: a) Federal Financial Management Improvement Act (FFMIA) (repeat comment); b) Federal Managers' Financial Integrity Act (FMFIA) (repeat comment); c) Noncompliance with 38 USC 5315 -collection of interest on debt owed by Veterans to VBA (repeat comment); d) Anti-deficiency Act (repeat comment); e) Payment Integrity Information Act (PIIA) for FY 2020, as reported by the Office of Inspector General (repeat comment).

- 5. <u>Reprogrammings or Transfers There were no reprogramming of funds or transfers that adjusted</u> drug control-related funding because drug control expenditures are reported based on patients served in various VA clinical settings for specialized substance abuse treatment programs.
- 6. Other Disclosures This budget accounts for drug control-related costs for VHA Medical Care and Research. It does not include all drug-related costs for the agency. VA incurs costs related to accounting and security of narcotics and other controlled substances and costs of law enforcement related to illegal drug activity; however, these costs are assumed to be relatively small and would not have a material effect on the reported costs.

B. Assertions

- 1. Obligations by Budget Decision Unit VA asserts that the obligations reported by budget decision unit are the actual obligations from VA's accounting system and are consistent with the application of the approved methodology as required by ONDCP Circular, Budget Formulation, dated September 9, 2021.
- 2. <u>Drug Methodology</u> VA asserts that the methodology used to calculate FY 2021 drug control obligations by function and budget decision unit is reasonable and accurate based on the criteria set forth in the ONDCP Circular, Budget Formulation, dated September 9, 2021.
- 3. <u>Application of Methodology</u> VA asserts the methodology described in Section A.2 above was used to prepare the obligations contained in this report.
- 4. <u>Material Weaknesses or Other Finding</u> VA asserts that all material weaknesses or finding by independent sources, or other known weaknesses have been disclosed.
- 5. <u>Methodology Modifications</u> VA asserts no modifications were made to methodology for reporting drug control resources.
- 6. <u>Reprogrammings or Transfers</u> VA asserts no changes were made to VA's Financial Plan that required ONDCP approval per the ONDCP Circular, Budget Execution, dated September 9, 2021.
- 7. Fund Control Notices The data presented are associated with obligations against a financial plan that was based upon a methodology in accordance with all Fund Control Notices issued by the Director under 21 U.S.C. §1703 (f) and Section 9 of the ONDCP Circular, Budget Execution, dated September 9, 2021.

Subj: Statement of Disclosures and Assertions for FY 2021 Drug Control Obligations Submitted to Office

of National Drug Control Policy (ONDCP) for Fiscal Year Ending September 30, 2021

Resource Management (104B)

/s/ digitally signed by Rachel Mitchell on December 19, 2021

Laura Duke Date
Chief Financial Officer
VHA Office of Finance (104)

/s/ digitally signed on December 17, 2021

Jeff Nechanicky Date
Associate Chief Financial Officer
Resource Management (104B)

/s/ digitally signed on December 16, 2021

Charles Stepanek Date
Director of Budget Services

Department of Veterans Affairs Resource Summary Obligations (In Millions)

	2021
Medical Care:	Actual ¹
Specialized Treatment	
	\$365.952
Inpatient	*****
Outpatient	\$378.263
Residential Rehabilitation & Treatment	\$229.434
Specialized Treatment	\$973.649
Medical & Prosthetics Research:	
Research & Development	\$25.418
Drug Control Resources by Function & Decision Unit, Total	\$999.067
Drug Control Resources Personnel Summary	
Total FTE	3,098
Total VHA Enacted Appropriations ²	\$108,932
Drug Control Percentage	0.92%
Diag Condoi i cicentage	0.9270
Total VA Enacted Appropriations ³	\$265,034
Drug Control Percentage	0.38%

¹Numbers may not add due to rounding

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

²Includes VHA Medical Care Appropriations and Medical and Prosthetic Research Appropriation account, including supplemental appropriations only.

³Includes all VA appropriations, including supplemental appropriations.

Attachment 2: Budget Formulation Compliance Report

Statement of Disclosures and Assertions for FY 2023 Budget Formulation Compliance Report Submitted to Office of National Drug Control Policy (ONDCP) for Fiscal Year Ending September 30, 2021

In accordance with ONDCP's Circular, National Drug Control Program Agency Compliance Reviews, dated September 9, 2021, the Veterans Health Administration asserts that the VHA system of accounting, use of obligations, and systems of internal controls provide reasonable assurance that:

Obligations are based upon the actual expenditures as reported by the Decision Support System (DSS), which is the designated Managerial Cost Accounting (MCA) System of the Department of Veterans Affairs.

The methodology used to calculate obligations of budgetary resources is reasonable and accurate in all material respects and as described herein was the actual methodology used to generate the costs.

Accounting changes are as shown in the disclosures that follow.

DEPARTMENT OF VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION

Annual Budget Formulation Compliance Report of ONDCP Funds

BUDGET FORMULATION COMPLIANCE REPORT

A. Summer Budget Information

1. Summer Budget Transmittal – Summer drug budget was submitted to ONDCP on August 2, 2021 in accordance with ONDCP Circular, Budget Formulation, Section 9.a (1), dated September 9, 2021.

2. Resource Summary Table

	The Part of the Pa	Budget Authority ((in Millions)	
	FY 2020 Actuals	FY 2021 Current Estimate	FY 2022 Request	FY 2023 Request
Drug Resources by Budget Decision 1	U nit /1			
Medical Care	\$835.571	\$868.158	\$909.830	\$946.223
Medical & Prosthetic Research	19.320	\$20.000	20.000	20.000
Total Funding	\$854.891	\$888.158	\$929.830	\$966.223
Drug Resources by Budget Function				
Treatment	\$835.571	\$868.158	\$909.830	\$946.223
Research and Development	19.320	\$20.000	20.000	20.000
Total Funding	\$854.891	\$888.158	\$929.830	\$966.223

Drug Resources Personnel Summary				
Total FTEs (direct only)	3,284	3,345	3,407	3,470
Drug Resources as a Percent of Budget	t			
Total Agency Budget (in billions) /2	\$100.673	\$109.386	\$102.382	\$130.135
Drug Resources Percentage	.85%	0.81%	0.91%	0.74%

^{1/}VA does not have a discrete ONDCP appropriation; VA forecasts obligations anticipated to support substances use disorder treatment programs, including opioid use disorder treatment programs, for Veterans.

PROGRAM SUMMARY

MISSION

The Veterans Health Administration's (VHA) mission statement is "Honor America's Veterans by providing exceptional care that improves their health and well-being." Care for Veterans with mental illnesses and substance use disorders is an important part of overall health care.

^{2/} Agency budget for FY 2021 includes appropriation provided under P.L. 117-2, American Rescue Plan. Agency budget estimates are not final and subject to change following the budget appropriations process.

The goal of VHA's Office of Mental Health and Suicide Prevention (OMHSP) is to provide effective, safe, efficient, recovery-oriented, and compassionate care for those with substance use disorders and mental illness, those who are vulnerable to substance use disorders (SUD) and those who are in continuing care to sustain recovery.

METHODOLOGY

Costs that are scored as drug-related include those associated with any treatment when a primary diagnosis of drug use disorder is documented including treatment administered in a general medical or general mental health setting. Estimates are based on specific patient encounters and include all inpatient and outpatient episodes of care either provided by VHA staff or purchased in the community. All encounters have an associated diagnosis. The primary diagnosis is considered the reason the patient is being treated and is used to determine whether the treatment provided is drug use disorder treatment and which type of drug use disorder. It should be noted that prescriptions and lab tests do not have linkages to a specific diagnosis and are not included in the report.

The cost of VHA provided services is calculated by the Managerial Cost Accounting (MCA) System of the Department of Veterans Affairs (VA). MCA cost data is used at all levels of the VA for important functions, such as cost recovery (billing), budgeting and resource allocation. Additionally, the system contains a rich repository of clinical information, which is used to promote a more proactive approach to the care of high risk (i.e., diabetes and acute coronary patients) and high-cost patients. VA MCA data is also used to calculate and measure the productivity of physicians and other care providers.

The basic unit of MCA cost is the product. For VHA a product can range from a prescription fill made through a mail-out pharmacy, to an outpatient dental exam, to a bed-day of care in an Intensive Care Unit. Every product that is delivered is fully costed. This means that all direct labor, direct supply and associated indirect costs (to include local and national overhead costs) are applied. Once they are fully costed, products are then assigned to the applicable patient encounter.

MCA costs are the basis for the obligations displayed in the ONDCP report. The Allocation Resource Center (ARC) develops ARC cost, which is computed by taking the MCA cost and removing the non-patient specific costs, such as Operating costs for Headquarters, Veterans Integrated Service Network (VISN) Support, National Programs, and Capital and State Home costs, and adding in the community care payments.

BUDGET SUMMARY

In FY 2023, VHA requests \$946.223 for drug control activities, an increase of \$36.34 million above the FY 2022 current estimate.¹

Medical Care

FY 2023 Request: \$946.223 million (\$36.393 million above the FY 2022)

¹ FY 2023 estimates based on FY 2020 actuals. Updated estimates based on FY 2021 actuals will be included in the FY 2023 ONDCP Detailed Accounting Submission.

The Uniform Mental Health Services Handbook, approved by the Under Secretary for Health (USH) on September 11, 2008, specifies SUD services that must be made available to all Veterans in need of them. The Handbook commits VA to providing SUD treatment services to every eligible Veteran regardless of where he or she lives. To further enhance access to SUD treatment, clinics offering these services must offer extended clinic hours during the week and on weekends and all facilities must provide same-day access for emergent need for SUD treatment.

In FY 2020, 243,254 Veterans who received services within VHA were diagnosed with a drug use disorder. Of these Veterans, VHA provided services by mental health clinicians in a variety of outpatient settings to nearly 82 percent (198,444) of Veterans with any diagnosis of a drug use disorder. Among Veterans receiving treatment within VHA in FY 2020, approximately 16 percent (39,240) used amphetamines, around 27 percent (65,717) used cocaine, around 28 percent (68,174) used opioids, and around 52 percent (127,671) used cannabis. (These categories are not mutually exclusive.)

Data for FY 2020 reflect a decline in utilization of VHA services by Veterans experiencing substance use concerns believed to be related to the pandemic. The decrease in the number of Veterans with a SUD diagnoses served is not believed to be reflective of a change in demand for SUD services. VHA moved rapidly to ensure sustainment of treatment services, rapidly transitioning SUD specialty services to telehealth platforms. VHA also worked closely with the Substance Abuse and Mental Health Services Administration (SAMHSA) to ensure continued access to medications for the treatment of opioid use disorder (M-OUD). In reviewing available data on utilization of SUD specialty services, Veterans are gradually re-engaging with SUD services. Since the start of the pandemic, VHA has seen a significant increase in the utilization of telehealth (telephone only and audio/visual) to support provision of SUD specialty treatment with the overall number of telehealth SUD specialty encounters increasing from slightly more than 12,000 in October 2019 to slightly more than 108,000 in October 2020.

As requested, VHA is exploring available data that would allow for more precise information related to Veteran requests for SUD treatment and subsequent engagement in care. At the current time, this information is not available. Development of SUD specific content for the new electronic health record is continuing with the expectation that this information will be available in the future.

The FY 2023 proposed budget is aligned with several Biden-Harris Drug Policy Priorities which include 1) Expanding access to evidence-based treatment; 2) Advancing racial equity in our approach to drug policy; 3) Enhancing evidence-based harm reduction efforts; 4) Advancing recovery-ready workplaces and expanding the addiction workforce; and 5) Expanding access to recovery support services.

Expanding Access to Evidence-Based Treatment

VHA SUD Service Care Delivery

National policy and expectations for the management of SUD within VHA is guided by VHA Handbook 1160.04 and the VA / Department of Defense (DoD) Clinical Practice Guidelines for the Management of SUD (http://www.healthquality.va.gov/). VHA is a leader in the prevention and treatment of SUD and uses a stepped care approach to SUD treatment. Patients with at-risk alcohol use or the least severe SUDs may be treated with evidence-based brief interventions and/or medical management in primary care or general mental health. For those with more severe disorders, specialty SUD treatment programs provide intensive services including withdrawal management, evidence-based psychosocial treatments, SUD medication, case management and relapse prevention. As an integrated healthcare system, VHA is uniquely situated to address the needs of Veterans diagnosed with a SUD, including providing supports to address co-occurring medical, mental health, and psychosocial needs (e.g., housing, employment).

Treatment for SUD occurs across settings and with policy defining expectations for access to SUD treatment, including expectations for access through Community Based Outpatient Clinics (CBOC) and Health Care Centers (HCC).

VHA also continues to improve service delivery and efficiency by integrating services for mental health disorders, including SUD, into primary care settings. Veterans from Operation Enduring Freedom/Operation Freedom/Operation Iraqi New Dawn/Operation Inherent Resolve (OEF/OIF/OND/OIR) and Veterans from other eras are served in primary care teams (Patient Aligned Care Teams: PACTs) that have co-located mental health staff to identify and address potential mental health and substance use treatment needs. Secondary prevention services include diagnosis and assessment of possible substance use disorders in patients presenting medical problems that suggest elevated risk of substance use disorders (e.g., treatment for Hepatitis C, prescribed opioid medications). Recognizing the importance of team-based care, VHA is implementing the Behavioral Health Interdisciplinary Program – Collaborative Chronic Care Model (BHIP-CCM) at every VHA facility. Implementation of BHIP - CCM teams within general mental health further supports VA's commitment to providing access to chronic disease management and treatment for substance use disorders beyond specialty SUD treatment settings.

Most Veterans with substance use disorders are treated in outpatient programs. Outpatient withdrawal management is available for patients who are medically stable and who have sufficient social support systems to monitor their status. Standard outpatient programs typically treat patients one or two hours per session and patients are generally seen once or twice a week. Intensive SUD outpatient programs provide at least three hours of service per day and patients attend three or more days per week.

Considering the frequent co-occurrence of substance use disorders with posttraumatic stress disorder, VHA has also assigned a SUD specialist to each of its hospital-level posttraumatic stress disorder services or teams. The staff person is an integral member of the posttraumatic stress disorder clinical services team and works to integrate substance use disorder care with all other aspects of posttraumatic stress disorder-related care. Among the specialists' responsibilities are identification and treatment of Veterans with co-occurring SUD and posttraumatic stress disorder. Specialists also promote preventive services for Veterans with posttraumatic stress disorder who are at risk for developing a substance use disorder.

VHA provides two types of 24-hour care to patients with severe, complex, or acute substance use disorders. These include inpatient withdrawal management and stabilization in numerous medical and general mental health units and provision of care in Mental Health Residential Rehabilitation Treatment Programs (otherwise referred to as Domiciliary beds). VHA offers care in Mental Health Residential Rehabilitation Treatment Programs (MH RRTPs) to Veterans with complex, co-occurring mental health, substance use, medical, and psychosocial needs. Specialty Domiciliary SUD programs provide treatment equivalent to Level 3.7, Medically Monitored Intensive Inpatient Services as specified by the American Society of Addiction Medicine Patient Placement Criteria. At the end of FY 2020, 68 Domiciliary SUD programs were in operation with more than 1,800 beds focused specifically on intensive, medically monitored residential SUD treatment. In addition to those MH RRTPs formally designated as Domiciliary SUD programs, additional SUD specialized services are offered through tracks in other MH RRTPs and the majority of Veterans served by MH RRTPs are diagnosed with a substance use disorder.

Programs to end homelessness among Veterans are encouraged to have SUD specialists as a part of their multidisciplinary teams. There are SUD specialists working in the Department of Housing and Urban Development – VA Supportive Housing (HUD-VASH), Grant and Per Diem (GPD) and the Health Care for Homeless Veterans (HCHV) programs; however, the use of SUD specialists can vary locally based on site-specific needs.

These specialists emphasize early identification of substance use disorders as a risk for maintaining permanent housing, promote engagement or re-engagement in SUD specialty care programs and serve as linkages between homeless and SUD programs.

Methamphetamine

VA recognizes the emerging threat that methamphetamine poses to our nation's Veterans. Specific data on the rates of methamphetamine use disorder are not available. However, the overall rates of amphetamine use disorder have been increasing over the past several years. The number of Veterans who received care for amphetamine use disorder decreased somewhat due to the pandemic with 39,240 Veterans who received care in VHA during FY 2020 having an amphetamine use disorder diagnosis. VA's commitment to provision of evidence-based treatment has positioned VA well to respond to this emerging threat. Contingency Management (CM) is an evidence-based treatment with demonstrated efficacy in treating stimulant use disorder. VHA implemented CM in 2011, and through September 2020, VHA has provided contingency management services to over 5,400 Veterans with over 92 percent of the greater than 7,000 urine samples testing negative for the target drug(s) (e.g., stimulants or cannabis). In January 2022, VHA plans to launch a stimulant safety initiative that will include a focus on expanding access to evidence-based practice such as CM and Cognitive Behavioral Therapy (CBT) for Veterans with stimulant use disorder.

Opioid Use Disorder

Slightly more than 68,100 Veterans with an opioid use disorder (OUD) diagnosis were seen in VHA in FY 2020. Medication for OUD (M-OUD) has historically been provided in SUD specialty-care clinics, but a significant number of Veterans with clinically diagnosed OUD do not access SUD specialty care. By disseminating evidence-based models for delivery of M-OUD in primary care, mental health, and pain management clinics, Veterans are expected to have timely access to the right treatment at their preferred point of care. VHA launched the Stepped Care for Opioid Use Disorder Train the Trainer (SCOUTT) initiative in August 2018 with the intent of supporting the expansion of M-OUD in level 1 clinics (primary care, general mental health and pain management clinics). Phase 1 sites in each VISN implemented this expansion during FY 2019. From August 2018 through September 2020 there was a 136 percent increase in the number of patients receiving buprenorphine in the initial Phase 1 level One clinics and 163 percent increase in the number of providers prescribing buprenorphine in these clinics. Further, Veterans are being retained in care with 71 percent of Veterans retained on buprenorphine for more than 90 days. A National Virtual SCOUTT conference for Phase 1 sites took place in September 2020 with over 300 attendees. Phase 2 of the SCOUTT initiative was launched in FY 2020 and three regional conferences occurred in April 2021 attracting over 500 participants. Phase 2 teams from new facilities in each VISN are now implementing efforts. Further, the infrastructure developed to support the SCOUTT initiative also supports efforts by facilities across the country to expand access to MOUD in level 1 clinics with a 51 percent increase in the number of Veterans receiving buprenorphine in any level 1 clinic between August 2018 and September 2020 and an 82 percent increase in the number of providers prescribing buprenorphine in those clinics.

In FY 2020, evidence-based M-OUD, including office-based treatment with buprenorphine and extended-release injectable naltrexone, was accessible to patients seen at 100 percent of VHA medical centers. VHA operates federally regulated opioid treatment programs that can provide methadone maintenance on-site at 33 larger urban locations and at a growing number of VHA facilities that maintain contractual arrangements or arrange non-VA care for providing care through community-based licensed opioid treatment programs. VHA continues to expand the availability of M-OUD for Veterans. VA monitors the percent of patients with OUD who receive M-OUD (44.4 percent during FY 2020) as part of the Psychotropic Drug Safety Initiative (PDSI).

PDSI is a nationwide psychopharmacology quality improvement (QI) program that supports facility-level QI through quarterly quality metrics, clinical decision support tools, technical assistance for QI strategic implementation, and a virtual learning collaborative. Since 4th quarter FY 2019, VA has seen a 4 percent increase in the number of Veterans that received M-OUD (total of 27,571, 4 FY 2020).

The number of providers with a Drug Enforcement Administration (DEA) X-waiver have also continued to increase since the 4th quarter FY 2019 with over 5,500 providers who have written any prescription issued to the VHA pharmacy (VA employed and community providers serving Veterans) in September 2020 holding an X-Waiver. This reflects an increase of 27 percent from the same time point in FY 2019. VA has realized that it will be critical to go beyond providers obtaining a waiver that allows them to prescribe buprenorphine. The number of providers with a DEA X-waiver that prescribed buprenorphine during FY 2020 was significantly lower than the number of providers with an X-waiver with only 24 percent of those providers with an X-waiver issuing a prescription for buprenorphine in September 2020. While the number of providers is increasing, VA is focusing efforts to remove barriers to prescribing and to support the initiation of buprenorphine when indicated. VHA Notice 2019-18, Buprenorphine Prescribing for Opioid Use Disorder was published in October 2019 and re-issued in September 2020 by the Undersecretary with the intent of clarifying national policy and tasking facilities to remove potential barriers to prescribing if present. In January of 2021, in an effort to reduce prescribing barriers, VHA also removed the requirement for written consent to provide buprenorphine for the treatment of opioid use disorder. In addition, in July 2020, VA formalized efforts to provide training to support efforts to ensure that all providers eligible to obtain an X-waiver had access to the training utilizing primarily an 8 hour half and half (4 hours online and 4 hours live training) for physicians and a 24 hour training model for eligible non-physician prescribing providers. Between July 2020 and July 2021 VA offered trainings with over 525 providers trained. Given the changes in training requirements for providers treating 30 or less patients put forward with the new SAMHSA Buprenorphine Guidelines in April 2021, additional trainings are being planned to include the addition of shorter focused trainings for providers and other interdisciplinary staff who support M-OUD. VA has also started offering "office hour" sessions for M-OUD treatment consultation with SMEs where providers can discuss cases and ask question of subject matter experts (SMEs) in live sessions as well as continuing consultation via e-mail through the VHA "Ask the Expert Program" and direct live patient consultation through the National TeleMental Health Center. VHA also recognizes the importance of capturing more detailed information on providers most likely to prescribe buprenorphine for OUD and has developed tools that will allow for improved understanding of availability of X-waivered providers by practice setting.

In support of interprofessional team-based models of care, VA is leveraging Clinical Pharmacy Specialist (CPS) providers to deliver comprehensive medication management services and improve Veteran access to SUD care. In partnership with the VA Office of Rural Health, the VA Pharmacy Benefits Management (PBM) Clinical Pharmacy Practice Office launched a nationwide initiative in FY 2020 to expand the CPS provider workforce focused on SUD care. Since initiation, 51 VA facilities have been awarded funding to hire 64 CPS providers across Mental Health, Pain Management, Primary Care and Specialty Care settings with a focus of expanding access to OUD and alcohol use disorder (AUD) care for rural Veterans. As part of this project, three regional train the trainer clinical pharmacy boot camps were held virtually in June and July 2020 and trained 234 VA-CPS providers in OUD and AUD care. The training focused on advancing CPS provider practice in SUD care and risk mitigation across level 1 clinics, in alignment with the SCOUTT initiative and offered subsequent office hours to further support CPS practice growth in SUD care. All boot camp participants completed 24-hour DEA X-waiver training prior to the boot camp in anticipation that future legislation may include pharmacist practitioners as potential providers of buprenorphine-based therapy, furthering access to M-OUD.

As of the 4th quarter FY 2020, 141 VA CPS providers are routinely delivering OUD care with 32,566 encounters in FY 2020. This represents a 35.6 percent growth in CPS provider practice in OUD care delivery since the implementation of the SCOUTT initiative; significant CPS practice growth in SUD care is expected in FY 2021.

Advancing racial equity and diversity in our approach to drug policy

In June 2021 VHA brought together a workgroup to better understand gender/ethnic/racial, Lesbian Gay Bisexual Transgender Questioning and others (LGBTQ+) SUD healthcare disparities in VHA with the goal of piloting target interventions for the largest gaps in FY 2022 and then based on the results of these pilots disseminating best practices to the field in FY 2023.

Mental Health residential treatment services, including SUD residential services for women Veterans are available in every VISN. Across the residential programs that serve women Veterans, 70% offer gender specific mental health services and 56% offer a separate, secure wing or unit for women Veterans. For those women Veterans requesting a residential program for women Veterans only, there are currently 11 programs that serve as national resources available to meet that need. Five of the women-only programs provide intensive specialty treatment for substance use. Further, about 37 percent of VA facilities offer women-only outpatient SUD or PTSD-SUD treatment, and all of VA facilities offer individual SUD or SUD-PTSD treatment for women Veterans. Finally, VA is developing at least 2 additional women only residential SUD treatment programs that will serve as national referral resources for women Veterans.

Enhancing evidence-based harm reduction efforts

Opioid Safety Initiative²

VHA continues to pursue a comprehensive strategy to promote safe prescribing of opioids when indicated for effective pain management. The purpose of the Opioid Safety Initiative (OSI) is to ensure pain management is addressed thoughtfully, compassionately, and safely to make the totality of opioid use visible at all levels in the organization. Based on comparisons of national data between the quarter beginning in Quarter 4, FY 2012 (beginning in July 2012) to Quarter 4, FY 2020 (ending in September 2020), many aspects of the OSI continue to show positive results. Despite an increase of 230,286 Veterans who were dispensed any medication from a VHA pharmacy, 349,388 fewer Veterans were on long-term opioids. The average dose of selected opioids has continued to decline as 58,123 fewer patients were receiving morphine equivalent daily doses greater than or equal to 90 milligrams, demonstrating that prescribing and consumption behaviors are changing. The desired results of OSI have been achieved during a time that VHA has seen a 5.8 percent increase in Veterans that have utilized VHA outpatient pharmacy services.

Chronic pain is a national public health problem as outlined in the 2011 study by the Institute of Medicine (IOM). At least 100 million Americans suffer from some form of chronic pain.

² FY 2022 Annual Budget Submission, Vol. II, Medical Programs and Information Technology Programs for additional detail for additional budget detail and estimates on VA's Opioid Safety Initiative, including VA's efforts to address P.L. 114-198, title IX, the Jason Simcakoski Memorial and Promise Act.

The IOM study describes in detail many concerns of pain management, including system-wide deficits in the training of our Nation's health care professionals in pain management and substance use disorders prevention and management, and the problems caused by a fragmented health care system. The over-use and misuse of opioids for pain management in the United States is a consequence of a health care system that until recently was less than fully prepared to respond to these challenges.

VHA has identified and broadly responded to the many challenges of pain management through policies supporting clinical monitoring, education and training of health professionals and teams, and expansion of clinical resources and programs. VHA's Pain Management Directive defines and describes policy expectations and responsibilities for the overall National Pain Management Strategy and Stepped Care pain model, which is evidence-based and has been adopted by the DoD as well. Our approach to managing opioid over-use fits into this plan, and the VA has employed broad strategies to address the opioid epidemic: education, pain management, risk mitigation, and addiction treatment. First, VHA addressed the problem of clinically inappropriate high-dose prescribing of opioids through the VA's national program, OSI. Second, VHA developed an effective system of interdisciplinary, patient-aligned pain management with the competency to provide safe and effective pain control and quality of life for Veterans for the remainder of their lives.

VHA has reduced the reliance on opioid medication for pain management by more than 60 percent since 2012, largely by starting fewer patients newly on long-term opioid therapy and by offering pain care options that are safer and more effective in the long run. The majority of the decline in VHA opioid prescriptions is not due to Veterans "getting by" with fewer opioids, but by following a Stepped Care Model for Pain treatment addressing the causes of pain with fewer Veterans requiring the initiation of long-term opioid therapy. VHA has been recognized by many as a leader in the pain management field for the responsible use of opioids. Notably, VHA has organized many types of interdisciplinary pain care teams to help with medication safety, patient education, pain schools, cognitive behavioral therapy and helping patients transition from a biomedical to a biopsychosocial model of pain care. As VHA continues its efforts to address opioid over-use, non-opioid treatments and complementary and integrative medicine treatments (such as massage therapy, yoga, meditation, occupational therapy, physical therapy, recreational therapy, acupuncture, tai chi, etc.) are an important component to VHA's Pain Management Strategy.

To further strengthen OSI and keep this trend moving in the right direction, VHA has deployed state-ofthe-art tools to help protect Veteran patients using high doses of opioids or with medical risk factors that put them at an increased risk of complications from opioid medications including overdose. These tools, referred to as the Opioid Therapy Risk Report (OTRR) and the Stratification Tool for Opioid Risk Mitigation (STORM), are available to all clinical staff in the VHA. These tools include information about the dosages of narcotics and other sedative medications, significant medical problems that could contribute to an adverse reaction and monitoring data to aid in the review and management of complex patients. The OTRR allows VHA providers to review all pertinent clinical data related to pain treatment in one place, providing a comprehensive Veteran-centered and more efficient level of management not previously available to primary care providers. The STORM allows VHA providers to view information about risk factors for opioid overdose, suicide-related events and other harms and recommends patient-specific risk mitigation strategies. Both tools are part of VHA's broader efforts to prevent opioid overdose deaths. To address overdose and suicide risk, VHA required that patients identified as very high risk per the STORM predictive model receive a case review by an interdisciplinary team including pain, addiction and mental health expertise. Preliminary findings from a randomized policy evaluation of this new clinical program found that patients targeted for case review had lower rates of all-cause mortality and medical record documented adverse events, such as motor vehicle accidents and overdose.

Additionally, VHA has formalized a system-wide Academic Detailing program that is in process of being implemented throughout the organization. Academic Detailing provides specialty teams to visit facilities and provide on-site support and education to providers to further enhance pain management efforts. The Academic Detailing program is another important step to improve mental health, substance use disorder, and pain management medication therapy across all VHA medical centers. As of September 30, 2020, academic detailers (specially trained VA Pharmacists) have held 61,627 outreach visits related to Opioid Safety, Overdose Education and Naloxone Distribution, opioid use disorder, and suicide prevention.

As VHA continues its efforts to address opioid over-use, complementary and integrative medicine treatments are an important component to VHA's Pain Management Strategy. VHA currently offers many complementary and integrative medicine treatments, many of which may be useful in chronic pain. These treatments include acupressure, acupuncture, biofeedback, chiropractic services, exercise, heated pool therapy, hypnosis/hypnotherapy, massage therapy, meditation, occupational therapy, physical therapy, recreational therapy, relaxation, tai chi, transcutaneous electrical nerve stimulation, yoga and other services.

VHA has several other programs that are complementary to the Opioid Safety Initiative and include:

- <u>State Prescription Drug Monitoring Programs (PDMP):</u> 49 States, the District of Columbia, and Puerto Rico are activated for VA data transmission. From Quarter 3, Fiscal Year 2013 (ending in June 2013) to Quarter 4, Fiscal Year 2020 (ending September 2020), VA providers have documented over 7.9 million queries to State Prescription Drug Monitoring Programs to help guide treatment decisions.
- Medication Take-Back Program: VA offers free medication take back services to Veterans through mail-back envelopes and on-site receptacles compliant with Drug Enforcement Administration (DEA) regulations. As of September 30, 2020, Veterans have returned over 203.5 tons of unwanted or unneeded medication using these services.

Opioid Overdose Education and Naloxone Distribution

The VA Opioid Overdose Education and Naloxone Distribution (OEND) program aims to decrease opioid-related overdose deaths among VHA patients by providing education on opioid overdose prevention, recognition of opioid overdose, and training on the rescue response, including provision of naloxone. All three Food and Drug Administration (FDA)-approved forms of naloxone (injectable, nasal spray and auto-injector) that the FDA states can be considered as options for community distribution were added to the VA National Formulary as soon as they were available. The nasal spray formulation is currently available through every VHA facility. VHA assembled injectable (intramuscular) naloxone kits as part of its initial OEND program. These were replaced by the auto-injector—specifically designed for layperson use—when that formulation became available. However, the auto-injector was abruptly discontinued by the pharmaceutical manufacturer on September 30, 2020. In response, VHA is currently working on reassembling the injectable (intramuscular) naloxone kits. VHA recommends offering OEND to Veterans prescribed or using opioids who are at increased risk for opioid overdose or whose provider deems it clinically indicated. Academic Detailing has promoted OEND through individualized, evidence-based educational outreach visits and consultation for clinicians by clinicians.

In July 2016, Congress took the important step of eliminating copayment requirements for opioid antagonists (e.g., naloxone) furnished to Veterans at high risk for overdose and for education on their use (per P. L. 114-98, title IX, the Jason Simcakoski Memorial and Promise Act). This change has been implemented throughout VHA and a proposed rule has been published in the Federal Register to amend two of VA's copayment regulations, 38 CFR 17.108 and 17.110, to accurately implement these changes into law. The proposed rule also defines who VA considers to be at high risk for overdose.

This definition will assist in the implementation of the public law and to facilitate the identification of such Veterans. Early identification of these Veterans can facilitate provision of lifesaving opioid antagonist medication. Since implementation of the OEND program in 2014, over 28,100 VHA prescribers, representing all VHA facilities, have prescribed naloxone, and more than 450,000 naloxone prescriptions have been dispensed to over 254,800 Veterans (as of the end of September 2020). Through the end of FY 2020, as documented through spontaneous reporting of overdose reversal events as well as through the national note, over 1,500 overdose reversals with naloxone have been reported.

In an effort to ensure timely access to naloxone for emergency responding, VHA launched the Rapid Naloxone Initiative in September 2018 consisting of three elements: (1) OEND to VHA patients at-risk for opioid overdose, (2) VHA Police Naloxone, and (3) Automated External Defibrillator (AED) Cabinet Naloxone. As documented through spontaneous reporting of overdose reversal events as well as through a national medical record note, over 1,500 overdose reversals with naloxone have been reported through FY 2020. In 2018 VHA dispensed a naloxone prescription for 1 in 5 patients on high dose opioids, as compared to 1 in 69 patients in the private sector.

Finally, as part of the broader OEND effort, VHA has established a community of practice for sharing innovative and promising practices which has included discussion of post-overdose engagement in treatment. Materials developed in support of the OEND initiative also are available to Veterans, their family members, and the broader public. During FY 2019, VHA implemented a process for documenting accidental and severe adverse effect overdoses as a component of suicide prevention efforts. Implementation of the Suicide Behavior and Overdose Report (SBOR) note template provides a foundation for VHA to implement strategies designed specifically to engage Veterans in timely treatment following a non-fatal overdose (opioid and non-opioid related). During FY 2021, VHA plans to build on that foundation to require use of the SBOR with a focus on continuing efforts to improvement post-overdose engagement in care.

Syringe Service Programs

In May of 2021 the Assistant Under Secretary for Clinical Services issued interim guidance on Syringe Services Programs (SSPs) recommending that VA medical Centers develop SSPs or otherwise ensure Veterans enrolled in VHA care have access to SSPs where such programs are not prohibited under state, county, or local law. In addition to providing access to sterile needles, syringes and other supplies, SSPs facilitate safe disposal of used syringes and provide the opportunity to link to other important services and programs such as OEND, screening and treatment for viral hepatitis and HIV, screening for sexually transmitted infections and referral to social, mental health, and other medical services. VHA is currently in the process of drafting a directive supporting the establishment of SSPs in VHA Medical Centers.

Post-Overdose Assessment and Care Planning

As past non-fatal overdoses increase the risk of future overdose events, it is anticipated that in August 2021, facilities will be required to provide an interdisciplinary overdose review utilizing a standard note that guides appropriate treatment planning. This will align the required processes for reporting non-fatal overdoses with the already required reporting and post-event treatment interventions for Veterans who make a suicide attempt. The initiative will require a national medical record note template designed to standardize and streamline the process of overdose reporting across VHA, enhance the visibility of accidental overdoses within the Veteran's medical record, improve clinical care after the suicide/overdose event, and facilitate real-time tracking of overdose event data, for use in clinical decision support tools and local/national aggregate reporting needs.

Advancing recovery-ready workplaces and expanding the addiction workforce / Expanding access to recovery support services.

Implementation of the FY 2022 SUD budget will focus on expanding the addiction workforce and advancing the recover-ready workplace as well as access to recovery services through:

- Expanding the addiction workforce to support residential and general SUD care delivery (including funding for new SUD providers in our General Mental Health Clinics, Primary Care-Mental Health Integration Programs and through the addition of telehealth providers in our Clinical Resource Hubs)
- Enhancing employment opportunities for Veterans in recovery by funding SUD specific supported employment staff at VA Medical Centers
- Increasing Peer Support Services by increasing the number of SUD-Specific Peer Specialists at VA Medical Centers.

Other Initiatives

Veterans Justice Programs³

The Uniform Mental Health Services Handbook affirmed that "Police encounters and pre-trial court proceedings are often missed opportunities to connect Veterans with VA mental health services as a negotiated alternative to incarceration or other criminal sanctions." VA medical centers provide outreach to justice-involved Veterans in the communities they serve.

VA services for justice-involved Veterans are provided through two dedicated national programs, both prevention-oriented components of VA's Homeless Programs: Health Care for Reentry Veterans (HCRV) and Veterans Justice Outreach (VJO). Known collectively as the Veterans Justice Programs (VJP), HCRV and VJO facilitate access to needed VA health care and other services for Veterans at all stages of the criminal justice process, from initial contact with law enforcement through community reentry following extended incarceration.

HCRV Specialists provide outreach to Veterans approaching release from state and Federal prisons. They briefly assess reentry Veterans' probable treatment needs, help Veterans plan to access responsive services upon release, and provide post-release follow-up as needed to ensure that Veterans are engaged with needed services. Most HCRV Specialists are based at VA medical centers, but they typically serve Veterans across a large area, often conducting outreach to prison facilities in at least one entire state, and sometimes an entire VISN.

VJO Specialists serve Veterans at earlier stages of the criminal justice process, with a three-pronged focus on outreach to community law enforcement, jails, and courts. VJO Specialists at each VA medical center work with Veterans in the local criminal courts (including but not limited to the Veterans Treatment Courts, or VTCs), conduct outreach in local jails, and engage with local law enforcement by delivering VA-focused training sessions and other informational presentations. Each VA medical center has at least one VJO Specialist, who serves as a liaison between VA and the local criminal justice system.

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³ Please see VA's FY 2022 Annual Budget Submission, Vol. II, Medical Programs and Information Technology Programs for additional budget detail and estimates on VA's Veterans Homelessness Programs, including VA's Justice Outreach Programs.

Public Law 115-240, The Veterans Treatment Court Improvement Act of 2018, signed September 17, 2018, required VA to hire 50 new Veterans Justice Outreach Specialists to serve in VTCs, in addition to their other outreach duties. VA medical centers have filled all of these positions, as well as an additional 15 added in FY 2020.

Veterans who are seen by HCRV and VJO Specialists access VA mental health and substance use treatment at high rates. Most Veterans seen in the VJO program have a mental health (77 percent) or substance use disorder (71 percent) diagnosis, or both (58 percent). Within one year of their VJO outreach visit, 97 percent of Veterans with mental health diagnoses had had at least one VHA mental health visit, and 78 percent had at least six visits. Within the same timeframe, 72 percent of Veterans with substance use disorder diagnoses had had at least one VHA substance use disorder visit, and 54 percent had had at least six. Veterans seen by HCRV Specialists have a similar profile, with 56 percent with a mental health diagnosis, 55 percent with a substance use disorder diagnosis and 39 percent with both. Veterans in HCRV access VA care at high rates, but slightly lower than those in VJO with 93 percent of those with a mental health diagnosis having at least one visit, and 64 percent having at least six visits. For those with a substance use disorder, 57 percent had at least one visit, and 37 percent had at least six. Improving access to treatment and care for this segment of the Veteran population is in direct alignment with the identified agency goals.

In communities where justice programs relevant to Veterans exist (Veterans courts, drug courts, mental health courts, and police crisis intervention teams), VA has taken the initiative in building working relationships to ensure that eligible justice-involved Veterans get needed care. In communities where no such programs exist, VA has reached out to potential justice system partners (judges, prosecutors, police, and jail administrators) to connect eligible justice-involved Veterans with needed VA services including addiction treatment. VJO specialists currently serve Veterans in 561 Veterans Treatment Courts and other Veteran-focused courts, with more planned. Their duties in a Veterans Treatment Court include linkage to VHA treatment services. In communities without Veterans Treatment Courts, VA medical centers have established relationships with a range of justice system and community partners, including police and sheriffs' departments, local jail administrators, judges, prosecutors, public defenders, probation officers, and community mental health providers.

Collaboration with Federal Partners

VHA is committed to working collaboratively with other Federal Partners in support of the National Drug Control Strategy and will continue to share insights of VHA efforts and input into the national drug strategy agenda to address SUD care with ONDCP and other interagency partners. With the support of ONDCP, VHA provided an update on VHA peer support services through a webinar in September 2020. Furthermore, VHA is working collaboratively with the Indian health Service and the Department of Defense on joint training opportunities in the SUD lane including overdose prevention, opioid safety and evidence-based SUD practice. VHA also recently worked with Health and Human Services in FY 2020 to provide access for staff from Indian Health Services and the Bureau of Prisons to join the Clinical Pharmacy Boot Camps to support expansion of SUD services supported by Clinical Pharmacy Specialists with 32 Public Health Service partners participating in this virtual program. VHA is currently working collaboratively with the Department of Defense (DoD) to share lessons learned across the agencies to support access to M-OUD, particularly for transitioning service members.

Research and Development

FY 2023 Request: \$20.0 million (No change from the FY 2022 request)

VHA research supports the generation of new knowledge to improve prevention, diagnosis, and treatment of substance use disorders (e.g., opioids, alcohol, tobacco, cocaine, methamphetamine, etc.), as well as the development and testing of innovative, non-opioid approaches for chronic pain management for Veterans. The VA patient population has experienced many of the problems of at-risk opioid and addiction that have made this a major clinical and public health issue in the U.S. Opioids are used to treat pain, but they are associated with dangerous side effects including depressed breathing, cognitive impairment, and the potential for addiction. Second State of the Art (SOTA) Conference on Effective Management of Pain and Addiction: Strategies to Improve Opioid Safety was held on September 11-12, 2019. This conference focused on three areas: 1) Managing OUD, 2) Long Term Opioid Therapy and Tapering; and 3) Substance Use Disorder and Pain. Findings from the SOTA will be published in an upcoming supplemental issue to the Journal of General Internal Medicine and will include reporting consensus on existing evidence for managing opioid use disorder, tapering of long-term opioid therapy for pain when risk outweighs benefit, and co-occurring pain and substance use disorder. In accordance with goals identified in the SOTA, VA's Health Services Research and Development (HSR&D) released a new research solicitation in Fall 2020 that will fund focused research to inform, improve, and/or implement evidence-based practices to improve opioids safety and management of OUD. This research solicitation adheres to cross-cutting principles aimed at expanding our understanding of care for older Veterans, developing more effective strategies for reducing racial and ethnic disparities, and examining the effects of the COVID-19 pandemic in the treatment and management of pain and OUD. The solicitation will focus research on numerous priority areas including:

- a) Implementation of evidence-based medications for opioid use disorder (M-OUD)
- b) Identification and development of appropriate and successful strategies for opioid tapering and discontinuation
- c) Examination of the potential role of buprenorphine/naloxone and non-pharmacological interventions in managing pain in patients with a history of OUD
- d) Development of more effective approaches to monitor patient outcomes for guiding treatment
- e) Development of new approaches for sustaining patient engagement in treatment including use of telehealth platforms
- f) Study of the management of acute pain among patients on M-OUD, including issues in emergency department care and best practices involving patients with acute pain who are at risk for relapse

Further, in recognition of the rising rates of stimulant use disorder and stimulant overdoses across the country and within the VA, HSR&D also added research on stimulant use disorder to its parent RFA's list of research priorities in Fall 2020, indicating HSR&D's commitment to supporting emerging partner needs.

As VHA continues to reduce excessive reliance on opiate medication, VA will maintain efforts in 2022 on pain-management research in areas responsive to the Jason Simcakoski Memorial and Promise Act and the President's Commission on Combating Drug Addiction and the Opioid Crisis. Towards this goal, VA identified the following areas to invest in:

• Non-pharmaceutical strategies for painful conditions: VA will continue to test and develop novel non-pharmaceutical strategies for painful conditions including traditional complementary and integrative health approaches (e.g. yoga, Tai-chi, and activity-based therapies), device-based (e.g., electrical stimulation), and even cell therapies for musculoskeletal conditions.

- Safer medications to treat pain: VA will continue to focus research on understanding the benefits
 and risks of non-opioid medications for pain management and alleviation. An example is targeting
 mutations in sodium channels which have been shown to cause pain associated with diabetes, small
 fiber neuropathy, erythromelalgia, and burns.
- Develop and test technologies providing access to treatment for chronic pain and opioid misuse: VA is testing the use of telehealth, smart-apps, web- and phone-based technology to provide outreach and care to Veterans living in rural areas. These interventions include peer coaching, treatment for OUD, provision of biobehavioral approaches, as well as establishing best practices for delivery of care using these modalities.

B. Assertions

- 1. Timeliness of Summer Budget Submission VA asserts that the FY 2023 summer drug budget was submitted to ONDCP on the date provided in Section A.1 (page 2) based on the criteria set forth in the ONDCP Circular, Budget Formulation, dated September 9, 2021 and was provided to ONDCP at the same time as the budget request was submitted to superiors in accordance with 21 U.S.C. § 1703(c)(1)(A).
- 2. Funding Levels VA asserts the estimated obligations by Budget Decision Unit represent the funding levels in the budget submission made to the Department without alteration or adjustment by any official at the Department. A correction has been made in this report and subsequent to the Summer Budget Submission Resource Summary Table in the 2022 Revised Request Column Drug Resources by Budget Function Total Funding Level from "\$29.830" to "929.830."

/s/ Digitally signed by Rachel Mitchell on December 16, 2021	
Laura Duke	Date
Chief Financial Officer	
VHA Office of Finance (104)	
/s/ Digitally signed on December 14, 2021	
Jeff Nechanicky	Date
Associate Chief Financial Officer	
Resource Management (104B)	
/s/ Digitally signed on December 14, 2021	
Charles Stepanek	Date
Director of Budget Services	
Resource Management (104B)	

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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Assistant Under Secretary for Health for Clinical Services

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