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Office of Inspector General**

Office of Healthcare Inspections

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Healthcare Inspection

**Opioid Agonist Treatment Program
Concerns**

**VA Maryland Health Care System
Baltimore, Maryland**

October 19, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations made by a confidential complainant in 2015 regarding the Opioid Agonist Treatment Program (OATP) at the Baltimore VA Medical Center, one of three VA Maryland Health Care System campuses, located in Baltimore, MD. The complainant alleged the OATP lacked quality controls necessary to ensure patients received treatment planning and monthly counseling as required, which resulted in patient deaths.

We substantiated that the OATP lacked effective quality controls necessary to ensure patients consistently received required treatment planning and monthly counseling. We did not substantiate that OATP patients died because of this condition. We also determined the program lacked a clear policy on cardiac risk management and quality controls to ensure recommended cardiac monitoring and that the OATP Medical Director's responsibilities did not include ensuring compliance with all applicable Federal, State, and local laws as required.

Opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. Opioid treatment programs (OTP)¹ are one option that can provide medication-assisted treatment for people diagnosed with an opioid use disorder. OTP patients can receive opioid agonists, which are medications such as methadone and buprenorphine. OTPs are governed by Title 42 of the United States Code of Federal Regulations Part 8 (42 CFR § 8) and guidance provided by the Substance Abuse and Mental Health Services Administration (SAMHSA). Veterans Health Administration (VHA) Handbook 1160.04 requires its OTPs to meet the requirements for certification outlined in 42 CFR Part § 8.²

To respond to the allegations regarding OATP patient treatment planning and monthly counseling sessions, we reviewed the electronic health records (EHRs) of all 272 identified patients who were enrolled in the OATP during the first quarter of fiscal year (FY) 2016 (October 1 through December 31, 2015). We reviewed the EHRs of those patients for treatment planning and documentation of monthly counseling sessions that occurred during the interval from April 1, 2015 to March 30, 2016 allowing us to review the care provided in the year leading up to our site visit.

42 CFR § 8.12 (f)(4) requires that OTP patients receive initial and periodic assessments and that treatment plans based on the assessments are prepared, reviewed, and updated. Of the 272 EHRs reviewed, 64 (24 percent) did not contain evidence of compliance with treatment planning requirements. 42 CFR § 8.12(f)(5) requires that

¹ Federal regulations and SAMHSA guidance refer to programs that treat opioid dependence with medications as OTP. We use the acronym OATP in reference to the Baltimore VAMC opioid dependence treatment program and we use OTP in reference to opioid dependence treatment programs generally.

² VHA Handbook 1160.04, *VHA Programs for Veterans With Substance Use Disorders (SUD)*, March, 2012. This Handbook was scheduled to be recertified on or before the last working day of March 2017 and has not yet been recertified.

OTPs provide adequate substance abuse counseling to each patient as clinically necessary and OATP policy required counseling sessions at least monthly. Of the 272 EHRs reviewed, two-thirds (183) did not contain evidence that patients were provided with even 90 percent of the required monthly sessions. We determined the failure to provide consistent treatment planning and monthly counseling was due to lack of counseling staff supervision. We determined the lack of supervision occurred because OATP counselors reported to their respective discipline's department head, not the Program Manager. Consequently, the Program Manager did not have supervisory authority over the counseling staff. As of January 2017, the Program Manager had supervisory oversight of OATP addiction counselors and social workers who served as counselors.

To respond to the allegation regarding OATP patient deaths, we identified 39 patients whose death occurred during or after receiving OATP treatment in FYs 2014 and 2015, and the first quarter of FY 2016. We conducted clinical reviews of the EHRs and, in none of the cases, could we establish a link between deficient individual counseling and the patient's death.

Although not a part of the original allegation, we determined the program lacked a clear policy on cardiac risk management and quality controls to ensure cardiac monitoring as recommended by SAMHSA guidelines and OATP informal policy. Of the 272 OATP patients reviewed, 241 (89 percent) received methadone. We reviewed the EHRs of these 241 patients for electrocardiogram (ECG) documentation. All 241 patient EHRs contained at least one ECG; however, the ECGs were not all completed at least annually as recommended by SAMHSA and the OATP's informal cardiac risk management plan. Specifically, 48 (20 percent) of the 241 patients did not have a documented annual ECG. Overdue ECG days ranged from 3 to 368 days with a median of 33.5 days.

We identified a concern related to the role of the OATP Medical Director. 42 CFR § 8.12 (b) and SAMHSA require that the medical director is responsible for ensuring regulatory compliance with all applicable Federal, State, local laws, and regulations. However, the OATP policy describing the medical director's duties did not include regulatory compliance responsibility or define a sufficient number of hours to ensure regulatory compliance.

We recommended that the VA Maryland Health Care System Director ensure that OATP:

- Counselors provide treatment planning consistent with 42 CFR § 8, SAMHSA guidelines, and local policy requirements.
- Counselors provide counseling sessions consistent with 42 CFR § 8, SAMHSA guidelines, and local policy requirements.
- Leaders consider implementing clear policies regarding the management of cardiac risk that include annual ECG assessment consistent with SAMHSA guidelines.

- Policies assign regulatory compliance responsibilities consistent with 42 CFR § 8 and SAMHSA guidelines.
- Medical Director is present at the program a sufficient number of hours to ensure regulatory compliance consistent with 42 CFR § 8 and SAMHSA guidelines.

Comments

The Veterans Integrated Service Network and System Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes A and B, pages 19–23, for the Directors’ comments.) We will follow up on the recently implemented actions proposed for all recommendations to ensure they have been effective and sustained.



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Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations made regarding the Opioid Agonist Treatment Program (OATP)³ at the Baltimore VA Medical Center (VAMC), located in Baltimore, MD.

Background

Baltimore VAMC is one of three VA Maryland Health Care System (system) campuses. It is part of Veterans Integrated Service Network (VISN) 5, and provides acute medical, surgical, specialty, and outpatient services.

Opioids: Opioids are a class of drugs that include prescription pain relievers such as oxycodone, hydrocodone, morphine, codeine, and fentanyl, as well as the illicit drug heroin. In addition to relief of pain, opioids can produce feelings of extreme well being referred to as euphoria. Common side effects include drowsiness, constipation, nausea/vomiting, and dizziness. At high doses, opioids can cause respiratory depression and other physiological actions that can lead to death. With prolonged use, physical and/or psychological dependence can occur.⁴

Opioid Use Disorder: Opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. Opioid use disorder symptoms include:

*...a strong desire for opioids, inability to control or reduce use, continued use despite interference with major obligations or social functioning, use of larger amounts over time, development of tolerance, spending a great deal of time to obtain and use opioids, and withdrawal symptoms that occur after stopping or reducing use, such as negative mood, nausea or vomiting, muscle aches, diarrhea, fever, and insomnia.*⁵

Opioid Treatment Programs: Opioid treatment programs (OTP) are one option that can provide medication-assisted treatment (MAT) for people diagnosed with an opioid use disorder.⁶ OTP patients can receive opioid agonists, which are medications such as methadone and buprenorphine. Opioid agonists bind to the body's opioid receptors and assist with reducing opioid withdrawal symptoms and cravings. Such treatment has proven successful in reducing opioid use. In some cases, OTPs provide MAT with an

³ Federal regulations and SAMHSA guidance refer to programs that treat opioid dependence with medications as OTP. Consequently, we use the acronym OATP in reference to the Baltimore VAMC opioid dependence treatment program and we use OTP in reference to opioid dependence treatment programs generally.

⁴ National Institute on Drug Abuse, Prescription Drug Abuse, <http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids>. Accessed March 18, 2016.

⁵ Substance Abuse and Mental Health Services Administration, Opioid Use Disorder, <https://www.samhsa.gov/disorders/substance-use>. Accessed January 5, 2017.

⁶ MAT is the use of medication, counseling, and behavioral therapies in combination to treat substance use disorders. <https://www.samhsa.gov/medication-assisted-treatment> Accessed December 16, 2016.

opioid antagonist, which is a medication that can help maintain sobriety by blocking opioid receptors.⁷

An alternative setting for patients to receive MAT, not under the auspices of an OTP, is office-based treatment by an individual provider. Currently, only buprenorphine is approved by Federal regulatory authorities for such treatment.

In the United States, OTPs are governed by Title 42 of the Code of Federal Regulations Part 8 (42 CFR § 8).⁸ Veterans Health Administration (VHA) Handbook 1160.04 requires its OTPs to meet the requirements for certification outlined in 42 CFR § 8.⁹ Under these regulations, OTPs must have current Substance Abuse and Mental Health Services Administration (SAMHSA) certification.¹⁰ To obtain SAMHSA certification, OTPs must successfully complete an accreditation process and meet other requirements of 42 CFR § 8. Pertinent to this review, OTPs must comply with the following federal regulations as a condition of SAMHSA certification:¹¹

- *42 CFR § 8.12 (b). Administrative and organizational structure. An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction, which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP complies with all applicable Federal, State, and local laws and regulations.*
- *42 CFR § 8.12 (f). Required services. (1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.*
- *42 CFR § 8.12 (f)(4). Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify*

⁷ Management of Substance Use Disorder, VA/DoD Clinical Practice Guideline (2015).

⁸ Certification of Opioid Treatment Programs, 42 CFR § 8. (2007).

⁹ VHA Handbook 1160.04, *VHA Programs for Veterans With Substance Use Disorders (SUD)*, March, 2012. This Handbook was scheduled to be recertified on or before the last working day of March 2017 and has not yet been recertified.

¹⁰ SAMHSA is an agency within the U.S. Department of Health and Human Services whose mission is to reduce the impact of substance abuse and mental illness.

¹¹ Text underlined by OIG to highlight key requirements salient to this review.

the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

- *42 CFR § 8.12 (f)(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.*

Baltimore VAMC OATP: The OATP is a specialty service that is a component part of the overall Substance Abuse Treatment Program (SATP) within the Mental Health Clinical Center (MHCC), which is overseen by the Chief of MHCC.¹² The OATP is managed by the SATP Program Manager and patient care is coordinated by the OATP Program Coordinator. Interdisciplinary program staff are responsible for ongoing medical assessments, psychiatric medication management, and overall management of opioid agonist dosing issues. Counselors are responsible for providing regular individual and/or group therapy and case management, which includes treatment planning. At the time of our April 2016 onsite visit, the OATP possessed current SAMHSA certification and Joint Commission accreditation and reported 264 enrolled patients. In December 2016, the OATP reported 300 enrolled patients.

OATP Management and Staffing: At the time of our April 2016 onsite visit, the SATP Program Manager had been in the role for 3 weeks and the Acting Medical Director was concurrently serving as Medical Director of the Inpatient and Outpatient Post Traumatic Stress Disorder (PTSD) programs (a job that he reported required 36 hours per week of his time). The Program Coordinator had been in the role since 2008.

In April 2016, OATP counseling staff consisted of two addiction therapists, two social workers, and one psychologist. Staffing also included a nurse practitioner and program support staff. A higher level of counseling staff was in place during December 2016, when OATP counseling staff comprised three addiction therapists, three social workers, and two psychologists.¹³

Phases of Treatment: The OATP policy recognizes five phases of treatment.¹⁴ Each phase has specific requirements for individual counseling and medication (methadone or buprenorphine) administration. The phases range from those new to the program (0 to 3 months) to those patients who have been in sobriety for a year or more. At a minimum, the OATP policy requires that counselors provide individual counseling sessions monthly except in unusual circumstances (such as if a patient is hospitalized

¹² Although the Baltimore VAMC organization chart refers to this group as the Addiction Treatment Program (ATP), the historical name of the group is the Substance Abuse Treatment Program (SATP) and EHR notes use the abbreviation SATP in the title.

¹³ Facility managers reported plans to add another OATP addiction therapist in January 2017, bringing the total to four addiction therapists.

¹⁴ OATP Policies and Procedures, *Treatment Planning and Components of Treatment*, Reviewed January 2016.

or traveling out of the area) to all OATP patients, regardless of the phase of treatment. The policy also requires that counselors complete treatment planning within 30 days of admission to the OATP and treatment plan updates every 6 months at a minimum for all patients, regardless of the phase of treatment. The treatment plans must be interdisciplinary in nature and include patient participation.

Methadone and Buprenorphine Administration: Facility policy requires OATP patients new to the program (0 to 3 months) to report to the OATP pharmacy for daily observed dosing Monday through Saturday (daily reporting) and pharmacists provide one dose to be taken Sunday. As patients progress through the program, the status may expand and can range from reporting 5 days per week with take-home doses for Saturday and Sunday, to reporting biweekly for take-home doses to last 2 weeks (biweekly reporting). In all cases, patients must report to the OATP in person at least biweekly to receive methadone or buprenorphine.

Prior Relevant Baltimore OATP-Specific VA OIG Publications: Prior to receiving the allegations discussed below, VA OIG had not published any OATP specific reviews.

Allegations: In September 2015, the OIG Office of Investigations referred the following allegations, made by a confidential complainant, to the OIG Office of Healthcare Inspections.

- The OATP lacked quality controls necessary to ensure patients received treatment planning and monthly counseling as required.
- The lack of OATP quality controls as noted above resulted in patient deaths.

Scope and Methodology

We initiated our review in January 2016 and conducted a site visit April 26–27, 2016. We interviewed Baltimore VAMC leaders, the Chief of MHCC, the Acting OATP Medical Director, the SATP Program Manager, and the OATP Program Coordinator. We also interviewed the OATP Nurse Practitioner, other clinical staff (psychologist, social workers, and addiction specialists) as well as program support staff. We also communicated with a SAMHSA compliance officer.¹⁵

We reviewed relevant VHA and Baltimore VAMC policies and procedures related to the OATP. We reviewed applicable Federal law, SAMHSA guidance, and Joint Commission OATP accreditation standards. To identify OATP patient electronic health records (EHR) for review, we used data extracted from the Corporate Data Warehouse (CDW), which is a centralized data repository that contains VHA clinical, administrative, and financial data.

Treatment Planning and Monthly Counseling Sessions: To respond to the allegations regarding OATP patient treatment planning/updating and monthly counseling sessions,

¹⁵ SAMHSA compliance officers determine OTP certification.

we reviewed the EHRs of all 272 identified patients (study population) who were enrolled in the OATP during the first quarter of fiscal year (FY) 2016 (October 1 through December 31, 2015).¹⁶ We reviewed the EHRs of those patients for treatment planning/updating and documentation of monthly counseling sessions that occurred during the interval from April 1, 2015 to March 30, 2016, (study period) allowing us to review the care provided in the year leading up to our site visit.¹⁷ For those patients without treatment plans or updates completed within the study period, we reviewed the EHR prior to the study period until we identified the date of the most recent treatment plan or update.

Opportunity and Missed Opportunity: Not all study population patients were enrolled in the program for the entire study period and some patients experienced lengthy hospital stays, which prevented OATP participation during part or parts of the study period. For those patients, the requirement for OATP monthly counseling sessions was reduced to reflect the number of monthly opportunities available to provide services.

We defined an “opportunity” as any month during which a patient received methadone or buprenorphine. We defined a “missed opportunity” as any month during which a patient received methadone or buprenorphine, but did not receive required services, such as counseling and treatment planning. We used the first day of the month of the patient’s most recent OATP “opportunity” during the study period to look back 180 days for minimum treatment planning requirements and, in patients receiving methadone, 365 days for minimum annual electrocardiograph (ECG) documentation.

Patient Death Reviews: To respond to the allegation regarding OATP patient deaths, we analyzed CDW data to identify patients who had a recorded date of death that occurred during or after receiving OATP treatment in FYs 2014 and 2015, and the first quarter of FY 2016. We conducted clinical reviews of these patients’ EHRs to determine whether the cause of death could be related to substance use or the patients’ OATP treatment.¹⁸ Cases without cause of death documentation, or that suggested the cause of death could possibly be related to substance use or OATP treatment were referred to an OIG senior physician who conducted in-depth EHR reviews of the identified patients’ EHRs.¹⁹ The senior physician also reviewed relevant death certificates and medical examiner reports.

Cardiac Monitoring of Patients Receiving Methadone: Patients receiving methadone comprised 89 percent of the study population (241 of 272). We reviewed the EHRs of these 241 patients for ECG documentation. To find the latest ECG in cases without such testing in the past year, we reviewed the records in reverse chronological order

¹⁶ We selected this cohort of patients in order to capture enough opportunities (at least 4 months) for counseling and treatment planning to be able to make assertions regarding the adequacy of these required services.

¹⁷ All study population patients were in the OATP a sufficient amount of time to have required a documented treatment plan (30 days).

¹⁸ The initial clinical reviews were conducted by a registered nurse or by a health system specialist under the supervision of a registered nurse.

¹⁹ Examples of causes of death that did not receive in-depth physician review included complications arising from metastatic lung cancer and chronic liver, lung, and cardiac disease.

starting from March 31, 2016, until we found documentation of an ECG. We then compared the one year anniversary of this testing to the date of the most recent appointment opportunity to determine the number of days an ECG was overdue.

VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders (SUD)*, March 2012 cited in this report was scheduled to be recertified on or before the last working day of March 2017 and has not yet been recertified.

We considered this policy to be in effect as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),²⁰ the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."²¹ The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."²²

We substantiate allegations when the facts and findings support that the alleged events or actions took place. We do not substantiate allegations when the facts show the allegations are unfounded. We cannot substantiate allegations when there is no conclusive evidence to either sustain or refute the allegation.

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

²⁰ VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

²¹ VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

²² *Ibid.*

Inspection Results

Issue 1: Treatment Planning and Counseling

We substantiated that the OATP lacked effective quality controls necessary to ensure patients consistently received required treatment planning and monthly counseling. We based this conclusion on our review of EHRs indicating that patients did not uniformly receive treatment planning and counseling services.

Treatment Planning

42 CFR § 8.12 (f)(4) requires that OTP patients receive initial and periodic assessments and that treatment plans based on the assessments are prepared, reviewed, and updated. SAMHSA's *Federal Guidelines for Opioid Treatment Programs* (guidelines) state that OTPs must design individualized treatment plans, which must be evaluated (updated) at regular intervals.²³ The OATP treatment plan policy required treatment plan development within 30 days of a patient's admission to the program and that, at a minimum, treatment plans were to be updated every 6 months. The policy required that treatment plans incorporate interdisciplinary elements and patient participation in the development of the plan.

Of the 272 EHRs reviewed, 64 (24 percent) did not contain evidence of compliance with 42 CFR § 8.12 (f)(4) and OATP policy. Nine of these EHRs did not contain a documented initial treatment plan. Eight of the patients without a documented initial treatment plan had been OATP patients for the entire study period and the remaining patient entered the program in October 2015.

The remaining 55 EHRs did not contain evidence that the treatment plan had been updated within 6 months (180 days) of the OATP's most current opportunity during the study period. Days overdue for the delinquent treatment plan updates ranged from 7 to 647 days with a median of 157 days.

Counseling

42 CFR § 8.12(f)(5) requires that OTPs provide adequate substance abuse counseling to each patient as clinically necessary. Because the federal regulations and SAMHSA guidelines do not define "adequate," we asked a SAMHSA official how OTPs satisfy certification requirements for adequacy of counseling services. The SAMHSA official advised us there is not a specific frequency for counseling services and stated OTPs should have a standardized assessment process to identify the specific needs of each patient.

The OATP policy, "*Treatment Planning and Components of Treatment*," listed minimum individual counseling frequency requirements, which were based on phases of

²³ *The Federal Guidelines for Opioid Treatment Programs*, developed and published by SAMHSA, guides OTP programs in implementing OTP programs that comply with federal regulations.

treatment and treatment intensity levels. Treatment requirements ranged from twice weekly (intensive phase) to monthly (supportive and maintenance phases). The policy allowed counselors to place holds on medication to facilitate appointment attendance for those patients who had a pattern of missing appointments.

According to the Chief of MHCC, the expectation was that OATP counselors should meet with patients at least monthly. The SATP Program Manager, Program Coordinator, and counseling staff we interviewed verbalized awareness of the monthly counseling minimum expectation. OATP Mental Health Treatment Plans, documented in patients' EHRs, also addressed monthly counseling. An example is below:

Treatment plan:

Problem: "I have found it hard to stay clean for long periods of time."

Goal: "To stay clean so I can focus on other goals."

Objective: I will: Meet with my counselor at least 1x/month; continue attending recovery groups; structure my day and avoid idle time; spend more time with family.

Intervention: Monthly 1:1 therapy and case management, [counselor's name]

Table 1 presents the number and corresponding percentage of patients grouped according to the percentage of the required monthly sessions that they received (compliance).

Table 1: OATP Required Minimum Monthly Individual Counseling Occurrences/Opportunities April 1, 2015 through March 31, 2016.

| Compliance with Required Minimum Monthly Counseling Sessions (percentage) | Number of Patients | Percentage of Patients* |
|--|---------------------------|--------------------------------|
| 100 | 50 | 18 |
| 90-99 | 39 | 14 |
| 80-89 | 42 | 15 |
| 70-79 | 47 | 17 |
| 60-69 | 31 | 11 |
| 50-59 | 24 | 9 |
| 40-49 | 20 | 7 |
| 30-39 | 10 | 4 |
| 20-29 | 3 | 1 |
| 10-19 | 5 | 2 |
| 0-9 | 1 | <1 |

*Source: OIG data analysis results. * Rounded to the nearest whole number.*

As the data in Table 1 shows, of the 272 EHRs reviewed, two thirds (183) did not contain evidence that patients were provided with even 90 percent of the monthly sessions needed for compliance with 42 CFR § 8.12(f)(5) and OATP policy. In one extreme example, a patient’s EHR contained evidence of 2 counseling sessions and 10 opportunities missed during the 12-month study period. The patient’s 2015 Mental Health Treatment Plan stated the counselor would meet with the patient once per month for the next 6 months. The patient received a counseling session one month later, but the EHR did not contain another documented counseling session for 8 months.

We also analyzed the documented reasons for missed opportunities and grouped the reasons into four categories: No Appointment Scheduled, Patient No-Show, Cancelled By Clinic, Cancelled By Patient. The No Appointment Scheduled category was by far the most common reason, accounting for 70 percent of the counseling session missed opportunities and representing a contribution to missed opportunities that was about three times higher than patient no-shows. (See Table 2.)

Table 2: Breakdown of Counseling Session Missed Opportunities by Type with Corresponding Proportion

| Type of Missed Opportunity | Proportion of Total Missed Opportunities (percentage) |
|----------------------------|---|
| No Appointment Scheduled | 70 |
| Patient No-Show | 23 |
| Cancelled By Clinic | 3 |
| Cancelled By Patient | 3 |

Source: OIG data analysis results

The Chief of MHCC, SATP Program Manager, and Acting Medical Director believed noncompliance with monthly counseling sessions was caused, in part, by inadequate counseling staff supervision. We were told the counselors’ supervisory reporting system was complicated and difficult because “everyone reports to someone else.” We learned that OATP counselors reported to their respective discipline’s department head, not the SATP Program Manager. For example, counseling staff whose discipline was in social work reported to the Chief of Social Work, who was not a part of the OATP. Consequently, the SATP Program Manager did not have supervisory authority over the counselors.

Counseling Session and Treatment Planning Concerns Identified by OATP Leaders and Acted on Prior to OIG’s Review

The SATP Program Manager we interviewed was appointed in February 2016, replacing a prior SATP Program Manager. In March, the SATP Program Manager conducted a quality audit of OATP patients’ EHRs, which showed that counselors did not consistently provide treatment plan updating and monthly counseling sessions to OATP patients as required. As a result of the audit findings, the Chief of MHCC and SATP Program Manager followed up with each counselor and their supervisor to ensure

compliance with regulations from that point forward. In April 2016, to ensure counseling sessions occurred as required, the SATP Program Manager developed tracking spreadsheets for each counselor.

Appointment Scheduling Concerns Identified by OATP Leaders and Acted on Prior to OIG's Review

We learned that prior to the new SATP Program Manager's tenure, the OATP was run more like a walk-in clinic and that appointments were not routinely scheduled in advance. The Chief of MHCC expressed the belief that scheduling appointments in advance would improve monthly counseling session compliance. Given that our data analysis showed counseling session appointments were not scheduled for 70 percent of the missed appointment opportunities, this seems a reasonable approach. (See Table 2.)

The Chief of MHCC instituted OATP process changes to improve accountability and supervision. In March 2016, the Chief of MHCC held a mandatory meeting with all OATP counseling staff to discuss program requirements. A follow-up email to the staff reiterated the following expectations that were discussed during the meeting.

- Counselors and/or therapists were to see patients at least monthly.
- Counselors and/or therapists were to ensure patients received appointments.
- Counselors and/or therapists were to follow up with patients who missed appointments.
- Counselors and/or therapists were to add a note for the pharmacist to withhold medication dosing for patients who were not making contact with counselors and/or therapists until the patient checked in with the assigned counselor and/or therapist.

In April 2016, the Chief of MHCC began the process of transferring supervisory responsibility for OATP addiction counselors and social workers to the SATP Program Manager. As of January 2017, the SATP Program Manager had supervisory oversight of all OATP addiction counselors and social workers who serve as counselors.

Issue 2: Patient Deaths Allegedly Occurred Because the OATP Lacked Quality Controls for Care Provided

We did not substantiate that OATP patients died because the OATP lacked quality controls necessary to ensure patients received monthly meetings with counselors and treatment planning as required. We identified and reviewed records of 39 patients who had a recorded date of death during or after receiving OATP treatment in FYs 2014 and 2015, and the first quarter of FY 2016. Eighteen of these cases (46 percent) either lacked cause of death documentation or had evidence that suggested the cause of death could possibly be related to substance use or OATP treatment. These deaths occurred throughout the time period inspected, specifically between January 3, 2014 and March 5, 2016.

Of the 18 reviewed patient deaths, four patients were either discharged from OATP more than one year before they died, or were referred but not enrolled in OATP during the year before they died, and so we excluded treatment deficiencies as potentially contributing to their deaths. Another eight patients were treated with office-based buprenorphine, and so OATP treatment practices would not pertain to their situations. Of the remaining six patients, all of whom were treated in OATP during the year before they died, two died from reasons judged to be unrelated to misuse of opioids (and so outside the scope of OATP treatment). The remaining four patient deaths were either likely or definitely due to opioid misuse. We found deficiencies in the OATP-provided treatment for three of these four patients, specifically with respect to the frequency of individual counseling sessions. However, these patients were actively engaged in other elements of OATP treatment. In none of these cases could we establish a link between deficient individual counseling and the patient's death.

Other Issues: Cardiac Risk Management and OATP Medical Director

Although not a part of the original allegation, we determined the program lacked a clear policy on cardiac risk management and quality controls to ensure cardiac monitoring as recommended by SAMHSA guidelines and OATP informal policy. We also identified a concern related to the role of the OATP Medical Director.

Cardiac Risk Management

Because studies have demonstrated that methadone can cause life threatening cardiac rhythm disturbances,²⁴ SAMHSA Guidelines recommend that programs have "clear policies" regarding managing cardiac risk that include ECG assessment. The OATP did not have a formal cardiac risk management policy; however, the Chief of MHCC stated that the OATP had an informal cardiac risk management plan, which included annual ECG cardiac monitoring for patients receiving methadone. In addition, the Acting Medical Director stated that it was his understanding that ECGs were required annually for patients receiving methadone.

Of the 272 OATP patients reviewed, 241 received methadone. All 241 patient EHRs contained at least one ECG; however, the ECGs were not all completed at least annually as required by the informal cardiac risk management plan. Specifically, 48 (20 percent) of the 241 patients did not have a documented annual ECG. Overdue ECG days ranged from 3 to 368 days with a median of 33.5 days.

While we determined that 34 (71 percent) of the 48 overdue ECGs were less than 60 days overdue, some ECGs were significantly more overdue. In one case, the patient's ECG was 368 days overdue. The patient's most recent ECG during the study period was performed in February 2014. In June 2015, a physician assistant noted the ECG was overdue and the Acting Medical Director acknowledged receiving the information

²⁴ Van Noord C, Eijgelsheim M, Stricker. *Drug- and Non-Drug-Associated QT Interval Prolongation*. British Journal of Clinical Pharmacology. 2010;70(1):16–23.

the same day. However, as of March 31, 2016, the patient had not received another ECG.²⁵

OATP Medical Director

42 CFR § 8.2 defines medical director as follows: “Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director’s direct supervision.”

42 CFR § 8.12 (b) requires that the medical director is responsible for monitoring and supervising all medical and nursing services provided by the OTP and ensuring regulatory compliance with all applicable Federal, State, and local laws and regulations. SAMHSA guidelines state, “The medical director should be present at the program a sufficient number of hours to assure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation.”

The system’s Opioid Agonist Administrative Policy did not include the responsibility for ensuring regulatory compliance. The system’s policy stated the following: “Medical Director of the OATP is charged with the medical oversight of the clinic and is responsible for supervising the medical assessment and management of Veterans in the OATP.” The policy did not address the number of hours it determined was sufficient to assure regulatory compliance.²⁶

The OATP Acting Medical Director was appointed to the position in December 2014, after the prior OATP Medical Director retired. The Acting Medical Director was also the Director of the Inpatient and Outpatient PTSD programs and told us that he spent most of his time (36 hours per week) with the PTSD programs. The Acting Medical Director also stated that most of his OATP involvement was through phone calls and treatment planning meetings one day a week.

SAMHSA guidelines do not define the “sufficient number of hours” regarding presence in the program to satisfy this Medical Director requirement. However, based on the noncompliance concerns discussed in this report, we determined that the 4 hours that the Acting Medical Director stated he was present at the program was not sufficient to enable him to properly perform the obligations required of a Medical Director.

In April 2016, the Chief of MHCC told us that the OATP Medical Director position was a difficult one to fill. Despite posting the position and interviewing many candidates, some were not good fits and some refused the job offer. In January 2017, the Chief of MHCC advised us that the Medical Director position was in the final stages of being filled. The Chief told us that the selectee possessed prior OTP management experience.

²⁵ The next documented ECG was dated February 15, 2017.

²⁶ VA Maryland Healthcare System, *Opioid Agonist Administrative Policy*, VAMHCS Policy Memorandum 512-116/MH-005, January 2014.

Conclusions

We substantiated that the OATP lacked effective quality controls necessary to ensure patients consistently received required treatment planning and monthly counseling. We determined the failure to provide consistent treatment planning and monthly counseling was due, in part, to lack of counseling staff supervision. We did not substantiate that OATP patients died as a result. We also determined the OATP lacked a clear policy on cardiac risk management and quality controls to ensure appropriate cardiac monitoring.

We determined that the OATP Medical Director's designated responsibilities did not include ensuring compliance with all applicable Federal, State, and local laws as required²⁷ and that the Acting OATP Medical Director's presence in the program was not sufficient to enable him to meet the obligations of that position. Responsibility for this must be shared with the leaders who assigned the Medical Director to competing clinical duties which occupied the majority of his service time, and formulated a policy that did not require the Medical Director to ensure regulatory compliance.

We made five recommendations.

Recommendations

1. We recommended that the VA Maryland Health Care System Director ensure that Baltimore VA Medical Center Opioid Agonist Treatment Program counselors provide treatment planning consistent with Title 42 of the Code of Federal Regulations Part 8, Substance Abuse and Mental Health Services Administration guidelines, and local policy requirements.
2. We recommended that the VA Maryland Health Care System Director ensure that Baltimore VA Medical Center Opioid Agonist Treatment Program counselors provide counseling sessions consistent with Title 42 of the Code of Federal Regulations Part 8, Substance Abuse and Mental Health Services Administration guidelines, and local policy requirements.
3. We recommended that the VA Maryland Health Care System Director ensure that Baltimore VA Medical Center Opioid Agonist Treatment Program leaders consider implementing clear policies regarding the management of cardiac risk that include annual electrocardiographic assessment consistent with Substance Abuse and Mental Health Services Administration guidelines.

²⁷ 42 CFR § 8.2 defines medical director as follows: "Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision."

4. We recommended that the VA Maryland Health Care System Director ensure Opioid Agonist Treatment Program administrative policies assign regulatory compliance responsibilities consistent with Title 42 of the Code of Federal Regulations Part 8 and Substance Abuse and Mental Health Services Administration guidelines.

5. We recommended that the VA Maryland Health Care System Director ensure that the Baltimore VA Medical Center Opioid Agonist Treatment Program Medical Director is present at the program a sufficient number of hours to ensure regulatory compliance consistent with Title 42 of the Code of Federal Regulations Part 8 and Substance Abuse and Mental Health Services Administration guidelines.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

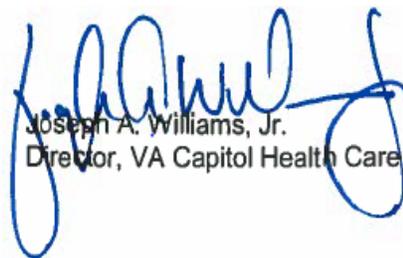
Date: August 14, 2017

From: Director, VA Capitol Health Care Network (10N5)

Subj: **Healthcare Inspection**— Opioid Agonist Treatment Program Concerns, VA Maryland Healthcare System, Baltimore, Maryland

To: Director, Kansas City Office of Healthcare Inspections (54KC)
Director, Management Review Service

1. I would like to express my appreciation to the Office of Inspector General (OIG) Healthcare Inspection Team for their professional and comprehensive review of the Opioid Agonist Treatment Program at the VA Maryland Health Care System (VAMHCS), Baltimore, Maryland.
2. I have reviewed the draft report, and concur with the report and conclusions rendered.
3. Please express my thanks to the Team for their professionalism and assistance to us in our continuing efforts to improve the care we provide to our Veterans.
4. For any further questions regarding this matter, please contact the VISN 5 Quality Management Officer, at (410) 691-1131.



Joseph A. Williams, Jr.
Director, VA Capitol Health Care Network, VISN 5

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 9, 2017
From: Director, VA Maryland Health Care System (512/00)
Subj: **Healthcare Inspection**—Opioid Agonist Treatment Program Concerns, VA Maryland Healthcare System, Baltimore, Maryland
To: Director, VA Capitol Health Care Network (10N5)

1. I would like to express my appreciation to the Office of Inspector General Survey Team for their professional review of the Opioid Agonist Treatment Program Concerns.
2. I have reviewed the draft for the VA Maryland Health Care System, Baltimore, Maryland, and concur with the findings and recommendations.
3. Please express my gratitude to the survey team for their professionalism and assistance to us in our continuing efforts to provide the best care possible to our Veteran patients.


Adam M. Robinson, Jr., M.D.

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the VA Maryland Health Care System Director ensure that Baltimore VA Medical Center Opioid Agonist Treatment Program counselors provide treatment planning consistent with Title 42 of the Code of Federal Regulations Part 8, Substance Abuse and Mental Health Services Administration guidelines, and local policy requirements.

Concur

Target date for completion: Completed as of February 1, 2017, with ongoing monitoring to ensure compliance.

Facility response: Mental Health leadership recognizes the need for internal changes to specifically address treatment plans and how staff manages patient caseloads. To ensure compliance, counselors are required to submit monthly reports to the substance abuse treatment program manager. These reports will indicate dates of completed treatment plans, consistent with Title 42 of the Code of Federal Regulations Part 8, Substance Abuse and Mental Health Services Administration guidelines, and local policy requirements. The Director of the Mental Health Clinical Care Center (MHCCC) will provide oversight of program compliance. A tracking template has been created to monitor treatment plan completion. A goal of 90% compliance as measured by monthly chart audits for three consecutive months has been set. VAMHCS will submit compliance data and will request closure on this recommendation once the goal has been met.

Recommendation 2. We recommended that the VA Maryland Health Care System Director ensure that Baltimore VA Medical Center Opioid Agonist Treatment Program counselors provide counseling sessions consistent with Title 42 of the Code of Federal Regulations Part 8, Substance Abuse and Mental Health Services Administration guidelines, and local policy requirements.

Concur

Target date for completion: Completed as of February 1, 2017, with ongoing monitoring to ensure compliance.

Facility response: As of February 1, 2017, the VA Maryland Health Care System Opioid Agonist Treatment Program counselors submit monthly reports to program management regarding dates of counseling sessions consistent with Title 42 of the Code of Federal Regulations Part 8, Substance Abuse and Mental Health Services

Administration guidelines, and local policy requirements. The substance abuse treatment program manager will review monthly reports to ensure programmatic compliance regarding counseling sessions. The Director of the Mental Health Clinical Care Center (MHCCC) will provide oversight of program compliance. A tracking template has been created to monitor session attendance. A goal of 90% compliance as measured by monthly chart audits for three consecutive months was set. VAMHCS surpassed this threshold (99% compliance) for the months of April, May, and June 2017 and requests closure on this recommendation.

Recommendation 3. We recommended that the VA Maryland Health Care System Director ensure that Baltimore VA Medical Center Opioid Agonist Treatment Program leaders consider implementing clear policies regarding the management of cardiac risk that include annual electrocardiographic assessment consistent with Substance Abuse and Mental Health Services Administration guidelines.

Concur

Target date for completion: Completed August 2017

Facility response: The VA Maryland Health Care System Opioid Agonist Treatment Program leadership created a Cardiac Risk Assessment Standard Operating Procedure which provides clear instruction regarding how often a patient in the Opioid Agonist Treatment Program will receive an annual Electrocardiographic assessment consistent with Substance Abuse and Mental Health Services Administration guidelines. Cardiac risk monitoring has been in place since April 2017 (100% of patients receive cardiac risk monitoring). The Standard Operating Procedure has been completed and is in full implementation since August 2017. A copy of SOP 116-MH-080, Opioid Agonist Treatment Program Cardiac Risk Assessment has been attached with this response. The facility requests closure on this recommendation.

Recommendation 4. We recommended that the VA Maryland Health Care System Director ensure Opioid Agonist Treatment Program administrative policies assign regulatory compliance responsibilities consistent with Title 42 of the Code of Federal Regulations Part 8 and Substance Abuse and Mental Health Services Administration guidelines.

Concur

Target date for completion: Completed August 2017

Facility response: The VA Maryland Health Care System Opioid Agonist Treatment Program leadership reviewed and revised the Opioid Agonist Treatment Program Administrative Policy to clearly assign regulatory compliance responsibilities consistent with Title 42 of the Code of Federal Regulations Part 8 and Substance Abuse and Mental Health Services Administration guidelines. The policy is currently in routing for leadership concurrence. The facility submits the policy and requests closure of this recommendation.

Recommendation 5. We recommended that the VA Maryland Health Care System Director ensure that the Baltimore VA Medical Center Opioid Agonist Treatment Program Medical Director is present at the program a sufficient number of hours to ensure regulatory compliance consistent with Title 42 of the Code of Federal Regulations Part 8 and Substance Abuse and Mental Health Services Administration guidelines.

Concur

Target date for completion: Completed May 2017

Facility response: The Opioid Agonist Treatment Program Medical Director is physically present at the VA Maryland Health Care System on a full time basis to ensure program compliance. The program medical director continues to ensure that high quality care is provided to all Opioid Agonist Treatment Program patients. The Opioid Agonist Treatment Program Medical Director has provided assistance to Mental Health leadership in ensuring adherence to policies and procedures consistent with Title 42 of the Code of Federal Regulations Part 8 and Substance Abuse and Mental Health Services Administration guidelines. The facility requests closure of this recommendation.

OIG Contact and Staff Acknowledgments

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|---------------------------|---|
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