

DHEC's Oversight of Methadone Clinics

Background and Federal Oversight

The federal Substance Abuse and Mental Health Services Administration ("SAMSHA") implements federal regulations governing medicinal treatment of opioid dependence and accreditation and certification of opioid treatment programs ("OTPs"). The federal oversight also incorporates state-level regulation of OTPs. Specifically, OTPs must be licensed by the state in which they operate, have controlled substances registrations from the Drug Enforcement Administration (DEA) and as required by state law, and meet any other state-specific requirements.

OTPs provide Medication-Assisted Treatment ("MAT") for individuals diagnosed with an opioid use disorder. Federal law requires patients who receive treatment in an OTP to receive counseling services and social support in addition to prescribed medication. Federal law also limits OTP treatment to agonist medications approved by the Food and Drug Administration (FDA). Currently, methadone, levomethadyl acetate (LAAM), and buprenorphine are the FDA-approved opioid agonist medications for treatment of opioid use disorder under federal regulations. Though methadone is just one of the medications used in MAT, OTPs that use methadone are commonly referred to as "methadone clinics."

DHEC's Role

DHEC is the state agency in South Carolina charged with licensing methadone clinics and issuing their state controlled substances registrations. OTPs are one of six types of substance abuse treatment facilities that are licensed by DHEC, and are referred to as "narcotic treatment programs"¹ ("NTPs") under state law.

Certificate of Need (CON)

DHEC's Certificate of Need ("CON") program administers regulations executing the State Certification of Need and Health Facility Licensure Act ("the Act") set forth in S.C. Code Sections 44-7-110 to 44-7-230. The purpose of the Act is to: promote cost containment, prevent duplication of health care facilities and services, guide the establishment of health facilities and services which will best serve public need, and ensure high-quality services are provided in health facilities in this state. S.C. Code Section 44-7-120. While not applicable to all types of health facilities and services, the Act specifies projects requiring a CON in S.C. Code Section 44-7-160. OTPs fall within the types of health care facilities requiring a CON.

DHEC calculates the need for health care facilities and services throughout the state within the State Health Plan ("the Plan") and recently published an updated 2017-2018 edition of the Plan. In the previous

¹The State Certification of Need and Health Facility Licensure Act lists "narcotic treatment programs" in the definition of "health care facility," but does not otherwise define the term in statute. See S.C. Code §44-7-110(10). However, federal regulations use the term "opioid treatment program, or "OTP," and define it to mean "a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1)." 42 CFR §8.2. According to DHEC Regulation 61-93, §101.00, a "narcotic treatment program" is, in part, "an outpatient psychoactive substance abuse/dependence program using methadone or other narcotic treatment medication such as LAAM, and offering a range of treatment procedures and services for the rehabilitation of persons dependent on opium, morphine, heroin, or any derivative or synthetic drug of that group." For the purposes of this memo, the terms "opioid treatment program" or "OTP" and "narcotic treatment program" or "NTP" are used interchangeably. The term "methadone clinic" refers to an OTP or NTP where methadone is used in Medication-Assisted Treatment or "MAT".

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Plan, the need for an OTP was specified by the applicant; **in the current Plan, the need for a NTP is at least one facility per county, with priority in counties with no programs. In addition, the current Plan provides increased opportunities for expanded health care services for treating addiction**, including the following language on page 53:

Due to the increasing number of opioid deaths in South Carolina, additional facilities are needed for the services to be accessible within thirty (30) minutes' travel time for the majority of state residents. The benefits of improved accessibility will outweigh the adverse effects of the duplication of this existing service.

There are currently two pending CON applications for OTPs in Sumter County and Anderson County. CON application updates are published monthly on the DHEC website:
<http://www.scdhec.gov/Health/docs/CON%20Update.pdf>.

Health Facility and Service Licensure

In addition to administering the state's CON program, DHEC establishes and enforces standards for the licensure, maintenance, and operation of health facilities and services to ensure the safe and adequate treatment of persons served. S.C. Code Section 44-7-250. To be licensed by DHEC, OTPs must be in compliance with the applicable provisions of Regulation 61-93, *Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence*, including staffing, client admissions, services, client physical examinations, medication management, and other facility-related requirements. **DHEC conducts routine licensing inspections of OTPs on an annual basis and follow-up inspections and investigations when necessary. There are currently 21 licensed OTPs in 16 counties across the state.**

Controlled Substances Registration

State law provides DHEC with exclusive control over the controlled substance methadone and establishes restrictions for the use of methadone. S.C. Code Ann. Section 44-53-710, *et seq.* **Methadone is restricted to use in treatment, maintenance, or detoxification programs approved by DHEC;** dispensing by hospital for analgesia, pertussis, and detoxification treatment as approved by DHEC; and dispensing by a retail pharmacy for analgesia as provided for by Regulation 61-4, *Controlled Substances*. *Id.* Regulation 61-4 further provides for the specified approved use and dispensing of methadone in accordance with state law.

DHEC also enforces the South Carolina Controlled Substances Act, which requires every person who manufactures, distributes, prescribes, or dispenses any controlled substance to register with DHEC, unless exempted by law. **An OTP is required to obtain a state controlled substances registration from DHEC as a "narcotic treatment program" and the practitioner that is the medical director of the facility is to sign the controlled substances registration application.** The OTP must also obtain a federal controlled substances registration from the DEA.

Controlled substances registrants are required to be in compliance with Regulation 61-4, which establishes requirements necessary to ensure appropriate safety, authority, and accountability with regard to the possession, manufacture, dispensing, administering, use, and distribution of controlled substances. **Registrants are subject to an annual inventory (May 1) and are inspected on a three-year cycle, or more frequently, when necessary.**

Exploring Additional Oversight Options

In response to the increase in opioid addiction across our state and nation, DHEC has been closely examining our role in the oversight of methadone clinics and working with state and federal partners to identify potential additional oversight options to help combat the problem.

Addressing Methadone Diversion

Some of DHEC's concerns about methadone clinics were **addressed in the 2015 Joint Advisory Opinion issued by the State Boards of Medical Examiners, Nursing, and Pharmacy**. The joint opinion states that a methadone clinic should have a pharmacist onsite during hours when methadone is dispensed for either administration onsite or at home and that dispensing occurs any time product selection, which includes dosage selection, occurs. **This opinion addressed regulatory compliance concerns DHEC previously had about a pharmacist often not being present during all dosing hours of a methadone clinic.** However, the 2015 Joint Advisory Opinion does not fully resolve the issue of diversion that DHEC continues to encounter in the state's methadone clinics. DHEC is committed to continuing to work with our state and federal partners to explore additional oversight options to address diversion of opioids in these clinics.

Improving Awareness of and Access to Treatment

During the recent agency regulation review, DHEC determined that Regulation 61-93, which includes NTP (or OTP) licensure, can be better organized to improve awareness and access to treatment at these facilities and programs. DHEC will seek input from the Department of Alcohol and Other Drug Abuse Substances and other stakeholders to explore updating this regulation.

DHEC is also looking at ways to improve access to Medication Assisted Treatment for individuals diagnosed with an opioid use disorder. The use of medication in combination with counseling and behavioral therapies for treatment of opioid abuse can help sustain recovery.

Through the federal Drug Addiction Treatment Act (DATA) of 2000, qualified physicians may treat opioid dependency with approved narcotic medications in settings beyond OTPs, such as methadone clinics. Qualified physicians are permitted to dispense or prescribe approved Schedule III, IV, and V narcotic medications that have a lower risk for abuse, like buprenorphine, beyond traditional treatment program settings.

Initially, DATA-waived physicians (DWP) may treat a maximum of 30 patients at a time. After one year, the DWP may seek approval to treat up to 100 patients at a time. DWP who have had a waiver to treat 100 patients for at least one year can now apply to treat up to 275 patients at a time under new federal regulations.

The federal 2016 Comprehensive Addiction and Recovery Act (CARA) expands access to substance abuse treatment services and overdose reversal medications by extending the privilege of prescribing buprenorphine in office-based settings to qualifying nurse practitioners and physician assistants.

DHEC would like to update Regulation 61-93 to ensure that practitioners are not unduly limited or restrained by our state regulatory requirements when prescribing the approved narcotic medications in authorized settings. In particular, the regulation should be revised to include a section on the administration of opioid medication in a private physician's office where the physician orders separate counseling provided by a licensed counselor, and clarification of when a license is required.