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Indicates New Matter

COMMITTEE REPORT

February 20, 2020

**H. 4355**

Introduced by Reps. Fry, Yow, Hewitt, Bailey, Wooten, Erickson, Pendarvis, Weeks and Dillard

S. Printed 2/20/20--H.

Read the first time March 28, 2019.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (H. 4355) to amend Section 44‑53‑720, Code of Laws of South Carolina, 1976, relating to restrictions on the use of methadone, so as to authorize pharmacists and, etc., respectfully

**REPORT:**

That they have duly and carefully considered the same and recommend that the same do pass with amendment:

Amend the bill, as and if amended, by striking all after the enacting words and inserting:

/ SECTION 1. Section 44‑53‑720 of the 1976 Code is amended to read:

“Section 44‑53‑720. (A) Methadone and its salts are restricted to:

(1) use in treatment, maintenance, or detoxification programs as approved by the Department of Health and Environmental Control~~.~~;

(2) dispensing by a hospital for analgesia, pertussis, and detoxification treatment as approved by the Department of Health and Environmental Control~~.~~; and

(3) dispensing by a retail pharmacy for analgesia as provided for by R. 61‑4, Section ~~507.5~~ 1012.

(B)(1) This section does not prevent a licensed practitioner, as defined in Section 40‑43‑30, from dispensing a drug or device for a patient of a narcotic treatment program (NTP) if a drug dispensed by the NTP is properly labeled in accordance with state and federal law.

(2) As it pertains to an NTP without a retail pharmacy, the NTP must obtain and maintain an NTP permit as designated by this section, and:

(a) monthly shall conduct and submit to the Board of Pharmacy self inspections and maintain written checklists that are readily available to the Board of Pharmacy for on‑site visits; and

(b) designate a pharmacist duly licensed by and in good standing with the Board of Pharmacy as a consultant pharmacist to be responsible for the duties stated in this section at the NTP permit holder’s location. A consultant pharmacist shall sign a new or renewal application along with the NTP permit holder and agree in writing to assume the responsibilities of a consultant pharmacist. The consultant pharmacist shall perform and maintain written quarterly inspections that are readily available. The NTP permit holder and consultant pharmacist shall notify the Board of Pharmacy in writing within ten days of a change of consultant pharmacist. A designation of an individual as a consultant pharmacist or delegation of duties to a consultant pharmacist by a holder of an NTP permit may not relieve the permit holder of the NTP permit holder’s duties under federal laws or regulations.

(3) As it pertains to an NTP with a permitted pharmacy,

(a) the NTP’s pharmacy must be permitted pursuant to Section 40‑43‑83;

(b) the NTP must obtain and maintain an NTP permit for its affiliated health center delivery sites without an on‑site pharmacy. An affiliated delivery site is subject to the inspection requirements outlined in this subsection, and the NTP pharmacist may serve as the consultant pharmacist for the NTP’s affiliated delivery sites; and

(c) with prior approval of the Board of Pharmacy, the NTP pharmacist may serve as the pharmacist-in-charge for more than one pharmacy at a time and need not be physically present in the pharmacy to serve as its pharmacist-in-charge.

(C) Methadone or any other narcotic treatment medication that is approved by the Food and Drug Administration pursuant to 21 U.S.C. Section 355 for use in the treatment of opioid use disorder may be dispensed and administered by a practitioner licensed by the State Board of Medical Examiners and registered under state and federal law to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by or under the order of the licensed practitioner when the program contracts or employs a consultant pharmacist in accordance with Section 44‑53‑720(B). The agent must be a pharmacist, physician, physician assistant, advanced practice registered nurse, registered nurse, or licensed practical nurse and employed or contracted by the NTP dispensing the treatment medication.

(D) An NTP that dispenses and administers methadone or any narcotic treatment medication shall comply with the security control requirements of Title 21 Code of Federal Regulations Chapter II.

(E) The Board of Pharmacy shall promulgate regulations needed to effectuate the purposes of this section.

(F) For purposes of this section,

(1) ‘Narcotic treatment program’, ‘NTP’, ‘opioid treatment program’, or ‘OTP’ means a program licensed by the Department of Health and Environmental Control that dispenses and administers methadone or other narcotic treatment medications. OTP and NTP shall be used interchangeably and given the same meaning throughout this section.

(2) ‘Health center delivery site’ means a physical location where a licensed practitioner duly employed by or under contract with an NTP provides treatment, maintenance, or detoxification pursuant to Section 44‑53‑720(A) to patients of that NTP. An NTP may have multiple health center delivery sites.”

SECTION 2. This act takes effect upon approval by the Governor. /

Renumber sections to conform.

Amend title to conform.

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Explanation of Fiscal Impact**

**Introduced on March 28, 2019**

**State Expenditure**

The bill requires that methadone or any other opioid agonist treatment medication for use in the treatment of opioid use disorder must be administered or dispensed by a practitioner licensed by the State Board of Medical Examiners and registered under state and federal law to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by or under the order of the licensed practitioner. Licensure requirements for agents are also outlined.

**Department of Alcohol and Other Drug Abuse Services (DAODAS).** DAODAS indicates that its detoxification facilities are not licensed as Narcotic Treatment Programs, and therefore do not administer methadone to patients. Further, if a patient chooses methadone as part of their Medication Assisted Treatment, the individual is referred to a licensed Narcotic Treatment Program. As such, the bill has no impact on DAODAS.

**Department of Mental Health (DMH).** DMH indicates thatits mental health centers do not administer methadone to patients in the outpatient setting. DAODAS further indicates that, in the inpatient setting, methadone is administered in the manner described in the bill. The bill will have no impact to the general fund, other funds, or federal funds for DMH, as DMH is in compliance with the provisions of the bill.

**Local Expenditure**

Counties and municipalities were surveyed to determine what, if any, expenditure impact the passage of the bill will have on community hospitals. The counties of Florence and Lancaster provided responses. The Revenue and Fiscal Affairs Office (RFA) received no responses from counties whose community hospitals are not affiliated with larger medical systems, who may be impacted by the bill. However, RFA does not anticipate that conformity with the licensure requirements outlined in the bill will result in additional local expenditures.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND SECTION 44‑53‑720, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO RESTRICTIONS ON THE USE OF METHADONE, SO AS TO AUTHORIZE PHARMACISTS AND NURSES TO ADMINISTER OR DISPENSE METHADONE OR OTHER OPIOID AGONIST TREATMENT MEDICATIONS IN CERTAIN CIRCUMSTANCES.

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. Section 44‑53‑720 of the 1976 Code is amended to read:

“Section 44‑53‑720. (A) Methadone and its salts are restricted to:

(1) use in treatment, maintenance, or detoxification programs as approved by the Department of Health and Environmental Control~~.~~;

(2) dispensing by a hospital for analgesia, pertussis, and detoxification treatment as approved by the Department of Health and Environmental Control~~.~~; and

(3) dispensing by a retail pharmacy for analgesia as provided for by R. 61‑4, Section ~~507.5~~ 1012.

(B) Methadone or any other opioid agonist treatment medication that is approved by the Food and Drug Administration pursuant to 21 U.S.C. Section 355 for use in the treatment of opioid use disorder must be administered or dispensed only by a practitioner licensed by the State Board of Medical Examiners and registered under state and federal law to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by or under the order of the licensed practitioner. The agent must be a pharmacist, registered nurse, or licensed practical nurse authorized by federal and state law to administer or dispense opioid drugs and employed by the program, hospital, or pharmacy dispensing the treatment medication.”

SECTION 2. This act takes effect upon approval by the Governor.

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