COMMITTEE REPORT

March 8, 2018

**H. 4112**

Introduced by Reps. Bedingfield, Fry, Henderson, Huggins, Rutherford and Stringer

S. Printed 3/8/18--H.

Read the first time April 6, 2017.

**THE COMMITTEE ON MEDICAL,**

**MILITARY, PUBLIC AND MUNICIPAL AFFAIRS**

To whom was referred a Bill (H. 4112) to amend the Code of Laws of South Carolina, 1976, by adding Section 44‑53‑363 so as to require the Department of Health and Environmental Control to develop, 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, SECTION 1, by striking Section 44-53-363(A)(1) and inserting:

/ (A)(1) In consultation with the Board of Medical Examiners and the Board of Pharmacy, the department shall develop and publish a uniform voluntary nonopioid directive form which may be used by a patient to deny or refuse the administering or prescribing of a controlled substance containing an opioid by a practitioner. The voluntary nonopioid directive form must provide a reference for receiving evidenced‑based nonpharmaceutical treatment for pain including, but not limited to, acupuncture treatment, chiropractic care, osteopathic manipulation, and physical therapy. /

Renumber sections to conform.

Amend title to conform.

LEON HOWARD for Committee.

**STATEMENT OF ESTIMATED FISCAL IMPACT**

**Explanation of Fiscal Impact**

**Introduced on April 6, 2017**

**State Expenditure**

This bill requires the Department of Health and Environmental Control (DHEC), in consultation with the Board of Medical Examiners and the Board of Pharmacy, to develop and publish a downloadable document form that could be used by a patient to refuse administration of an opioid drug by a practitioner. The bill requires DHEC to promulgate regulations for implementation of the voluntary non-opioid directive form. Additionally, the bill provides immunity from criminal and civil penalties for practitioners, pharmacists, and persons acting as a representative or an agent pursuant to a health care proxy. The bill also allows for professional discipline when practitioners act recklessly or negligently when failing to comply with a patient’s non-opioid directive.

**Department of Health and Environmental Control**. The department reports that the requirement to develop and publish the new form and the promulgation of regulations can be accomplished by existing staff and within the department’s appropriated resources. This bill would not have an expenditure impact on the general fund, federal funds, or other funds.

**Depart of Labor, Licensing and Regulation**. The department reports that assistance to the Department of Health and Environmental Control regarding the development of the new non-opioid directive form can be provided at no additional cost. Any additional work requested by DHEC can be conducted at regularly scheduled board meetings. This bill would not have an expenditure impact on the general fund, federal funds, or other funds.

Frank A. Rainwater, Executive Director

Revenue and Fiscal Affairs Office

**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, BY ADDING SECTION 44‑53‑363 SO AS TO REQUIRE THE DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL TO DEVELOP A VOLUNTARY NONOPIOID DIRECTIVE FORM TO ALLOW A PERSON TO DENY OR REFUSE THE ADMINISTERING OR PRESCRIBING OF A CONTROLLED SUBSTANCE CONTAINING AN OPIOID BY A PRACTITIONER, TO REQUIRE THE DEPARTMENT TO PROMULGATE REGULATIONS AND DEVELOP GUIDELINES, TO PROVIDE CERTAIN IMMUNITIES FROM CIVIL AND CRIMINAL LIABILITY FOR PHARMACISTS, PRACTITIONERS, AND OTHERS, AND TO PROVIDE FOR PROFESSIONAL DISCIPLINE IN LIMITED CIRCUMSTANCES.

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

SECTION 1. Article 3, Chapter 53, Title 44 of the 1976 Code is amended by adding:

“Section 44‑53‑363. (A)(1) In consultation with the Board of Medical Examiners and the Board of Pharmacy, the department shall develop and publish a uniform voluntary nonopioid directive form which may be used by a patient to deny or refuse the administering or prescribing of a controlled substance containing an opioid by a practitioner.

(2) The voluntary nonopioid directive form developed by the department pursuant to item (1) must indicate to all prescribing practitioners and health care facilities that the named patient must not be offered, prescribed, supplied with, or otherwise administered a controlled substance containing an opioid.

(3) The voluntary nonopioid directive form must be posted in a downloadable format on the department’s publicly accessible website.

(B)(1) A patient may execute and file a voluntary nonopioid directive form with a practitioner. Each practitioner shall sign and date the form in the presence of the patient as evidence of acceptance and shall provide a signed copy of the form to the patient.

(2) The patient executing and filing a nonopioid directive form with a practitioner shall sign and date the form in the presence of the practitioner or a designee of the practitioner. In the case of a patient who is unable to execute and file a voluntary nonopioid directive form, the patient may designate a duly authorized guardian or health care proxy to execute and file the form in accordance with item (1).

(3) A patient may revoke the voluntary nonopioid directive form for any reason and may do so by written or oral means.

(C) The department shall promulgate regulations for the implementation of the voluntary nonopioid directive form which must include, but not be limited to:

(1) a standard form for the recording and transmission of the voluntary nonopioid directive form, which must include verification by the patient’s practitioner and which must comply with the written consent requirements of the Public Health Service Act, 42 U.S.C. Section 290dd‑2(b), and 42 C.F.R. Part 2, relating to confidentiality of alcohol and drug abuse patient records, provided that the voluntary nonopioid directive form also must provide the basic procedures necessary to revoke the voluntary nonopioid directive form;

(2) procedures to record the voluntary nonopioid directive form in the patient’s medical record or, if available, the patient’s interoperable electronic medical record;

(3) requirements and procedures for a patient to appoint a duly authorized guardian or health care proxy to override a previously filed voluntary nonopioid directive form and circumstances under which an attending practitioner may override a previously filed voluntary nonopioid directive form based on documented medical judgment, which must be recorded in the patient’s medical record;

(4) procedures to ensure that any recording, sharing, or distributing of data relative to the voluntary nonopioid directive form complies with all federal and state confidentiality laws; and

(5) appropriate exemptions for practitioners and other health care providers and emergency medical personnel to prescribe or administer a controlled substance containing an opioid when, in their professional medical judgment, a controlled substance containing an opioid is necessary.

The department shall develop and publish guidelines on its publicly accessible website, which must address, at a minimum, the content of the regulations promulgated pursuant to this subsection.

(D) A written prescription that is presented at an outpatient pharmacy or a prescription that is electronically transmitted to an outpatient pharmacy is presumed to be valid for the purposes of this section, and a pharmacist in an outpatient setting may not be held in violation of this section for dispensing a controlled substance in contradiction to a voluntary nonopioid directive form, except upon evidence that the pharmacist acted knowingly against the voluntary nonopioid directive form.

(E)(1) A practitioner or an employee of a practitioner acting in good faith is not subject to criminal or civil liability and may not be considered to have engaged in unprofessional conduct for failing to offer or administer a prescription or medication order for a controlled substance containing an opioid under the voluntary nonopioid directive form.

(2) A person acting as a representative or an agent pursuant to a health care proxy is not subject to criminal or civil liability for making a decision under subsection (C)(3) in good faith.

(3) Notwithstanding another provision of law, a professional licensing board in its discretion may limit, condition, or suspend the license of, or assess fines against, a practitioner who recklessly or negligently fails to comply with a patient’s voluntary nonopioid directive form.

(F) For purposes of this section:

(1) ‘Health care facility’ means any facility or institution licensed or otherwise permitted to distribute, dispense, conduct research with, or prescribe or administer a controlled substance containing an opioid or other controlled substance in the course of professional practice or research in the State.

(2) ‘Patient’ means a person under the medical care of a practitioner.

(3) ‘Practitioner’ means an individual authorized pursuant to state and federal law to prescribe controlled substances.”

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

‑‑‑‑XX‑‑‑‑