WEST VIRGINIA LEGISLATURE

2024 SECOND EXTRAORDINARY SESSION

Enrolled

Senate Bill 2028

BY SENATORS BLAIR (MR. PRESIDENT) AND WOELFEL

(BY REQUEST OF THE EXECUTIVE)

[Passed October 8, 2024; in effect from passage]

AN ACT to amend and reenact §16-2D-9 of the Code of West Virginia, 1931, as amended; to amend and reenact §30-7-15a of said code; and to amend and reenact §60A-9-4 of said code, all relating to permitting research activities; providing that opioid treatment program may be developed only if part of an approved clinical trial; providing opioid treatment program must have institutional review board approval; describing opioid treatment program to be developed; requiring the opioid treatment program to register with the Board of Pharmacy; specifying the permitted clinical trial; permitting an advanced practice registered nurse who is participating in clinical trial to dispense; limiting the exemption to a one-time use; permitting an advanced practice registered nurse who is participating in a clinical trial to exceed prescription limitations; and requiring clinical trial to be registered with the Board of Pharmacy.

Be it enacted by the Legislature of West Virginia:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 2D. CERTIFICATE OF NEED.

§16-2D-9. Health services that cannot be developed.

Notwithstanding §16-2D-8 and §16-2D-11 of this code, these health services require a certificate of need but the authority may not issue a certificate of need to:

(1) A health care facility adding intermediate care or skilled nursing beds to its current licensed bed complement, except as provided in §16-2D-11 of this code;

(2) A person developing, constructing, or replacing a skilled nursing facility except in the case of facilities designed to replace existing beds in existing facilities that may soon be deemed unsafe or facilities utilizing existing licensed beds from existing facilities which are designed to meet the changing health care delivery system;

(3) Add beds in an intermediate care facility for individuals with an intellectual disability, except that prohibition does not apply to an intermediate care facility for individuals with

intellectual disabilities beds approved under the Kanawha County Circuit Court order of August 3, 1989, civil action number MISC-81-585 issued in the case of *E.H. v. Matin*, 168 W.V. 248, 284 S.E. 2d 232 (1981) including the 24 beds provided in §16-2D-8 of this code;

(4) An opioid treatment program: *Provided*, That an opioid treatment program that is an approved clinical trial, with institutional review board approval, for the study of office-based methadone versus buprenorphine to address retention in medication for opioid use disorder treatment may be developed for the limited purposes of conducting the clinical trial and shall be limited to the time frame set forth in the clinical trial, after registering with the Board of Pharmacy: *Provided, further,* That this exemption only permits one program to participate once in CTN-0131; and

(5) Add licensed substance abuse treatment beds in any county which already has greater than 250 licensed substance abuse treatment beds.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 7. REGISTERED PROFESSIONAL NURSES.

§30-7-15a. Prescriptive authority for prescription drugs.

(a) An advanced practice registered nurse may not prescribe a Schedule I controlled substance as provided in §60A-2-204 of this code.

(b) An advanced practice registered nurse may prescribe up to a three-day supply of a Schedule II narcotic as provided in §60A-2-206 of this code: *Provided*, That an advanced practice registered nurse who is participating in a clinical trial, with institutional review board approval, for the rural expansion of medication-assisted treatment for opioid use disorder may dispense for the time frame of the clinical trial, after registering with the Board of Pharmacy: *Provided, further*, That this exemption only permits one program to participate once in CTN-0102-XR, which is also the same program as provided for in §60A-9-4 of this code.

(c) There are no other limitations on the prescribing authority of an advanced practice registered nurse, except as provided in §16-54-1 *et seq.* of this code.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-4. Required information.

(a) The following individuals shall report the required information to the Controlled Substances Monitoring Program Database when:

(1) A medical services provider dispenses a controlled substance listed in Schedule II, III, IV, or V;

(2) A prescription for the controlled substance or opioid antagonist is filled by:

(A) A pharmacist or pharmacy in this state;

(B) A hospital, or other health care facility, for outpatient use; or

(C) A pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state; and

(3) A pharmacist or pharmacy sells an opioid antagonist.

(b) The above individuals shall, in a manner prescribed by rules promulgated by the Board of Pharmacy pursuant to this article, report the following information, as applicable:

(1) The name, address, pharmacy prescription number, and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;

(2) The full legal name, address, and birth date of the person for whom the prescription is written;

(3) The name, address, and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

(4) The name and national drug code number of the Schedule II, III, IV, and V controlled substance or opioid antagonist dispensed;

(5) The quantity and dosage of the Schedule II, III, IV, and V controlled substance or opioid antagonist dispensed;

(6) The date the prescription was written and the date filled;

(7) The number of refills, if any, authorized by the prescription;

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, information about the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the Board of Pharmacy; and

(9) The source of payment for the controlled substance dispensed.

(c) Whenever a medical services provider treats a patient for an overdose that has occurred as a result of illicit or prescribed medication, the medical service provider shall report the full legal name, address, and birth date of the person who is being treated, including any known ancillary evidence of the overdose. The Board of Pharmacy shall coordinate with the Division of Justice and Community Services and the Office of Drug Control Policy regarding the collection of overdose data.

(d) The Board of Pharmacy may prescribe, by rule promulgated pursuant to this article, the form to be used in prescribing a Schedule II, III, IV, and V substance or opioid antagonist if, in the determination of the Board of Pharmacy, the administration of the requirements of this section would be facilitated.

(e) Products regulated by the provisions of §60A-10-1 *et seq.* of this code shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.

(f) Reporting required by this section is not required for a drug administered directly to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a

patient by a practitioner. The quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of 72 hours with no greater than two 72-hour cycles dispensed in any 15-day period of time: *Provided*, That an advanced practice registered nurse who is participating in a clinical trial, with institutional review board approval, for the rural expansion of medication-assisted treatment for opioid use disorder may exceed the 3-day supply for the time frame of the clinical trial, after registering with the Board of Pharmacy: *Provided, further,* That this exemption only permits one program to participate once in CTN-0102-XR, which is also the same program as provided for in §30-7-15a of this code.

(g) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within 60 days of the availability of an abuse deterrent or a practitioner-administered form of buprenorphine or buprenorphine/naloxone if approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch his or her patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent or a practitioner-administered form of the drug.

The Clerk of the Senate and the Clerk of the House of Delegates hereby certify that the foregoing bill is correctly enrolled.

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Clerk of the Senate

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Clerk of the House of Delegates

Originated in the Senate.

In effect from passage.

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President of the Senate

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Speaker of the House of Delegates

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The within is ..... this the.....

Day of ....., 2024.

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Governor