

**WEST VIRGINIA LEGISLATURE**

**2024 SECOND EXTRAORDINARY SESSION**

**Introduced**

**Senate Bill 2028**

By Senators Blair (Mr. President) and Woelfel

(By Request of the Executive)

[Introduced September 30, 2024]

1 A BILL to amend and reenact §16-2D-9 of the Code of West Virginia, 1931 as amended; to amend  
2 and reenact §30-7-15a of said code; and to amend and reenact §60A-9-4 of said code, all  
3 relating to permitting research activities; providing that opioid treatment program may be  
4 developed only if part of an approved clinical trial; providing opioid treatment program must  
5 have institutional review board approval; describing opioid treatment program to be  
6 developed; requiring opioid treatment program to be limited to the time frame set forth in  
7 the clinical trial; requiring the opioid treatment program to register with the Board of  
8 Pharmacy; permitting advanced practical registered nurse who is participating in clinical  
9 trial to dispense; requiring clinical trial to be registered with the Board of Pharmacy;  
10 permitting an advanced practice registered nurse who is participating in a clinical trial to  
11 exceed prescription limitations; and requiring clinical trial to be registered with the Board of  
12 Pharmacy.

*Be it enacted by the Legislature of West Virginia:*

## **ARTICLE 2D. CERTIFICATE OF NEED.**

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

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

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

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

9 (3) Add beds in an intermediate care facility for individuals with an intellectual disability,  
10 except that prohibition does not apply to an intermediate care facility for individuals with intellectual  
11 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: ~~and~~ 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 timeframe set forth in the clinical trial, after registering with the Board of Pharmacy;  
and

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

## **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 *et seq.* 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 *et seq.* 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 timeframe of the clinical trial, after registering with the Board of Pharmacy.

(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.**

### **§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 timeframe of the clinical trial, after registering with the Board of Pharmacy.

(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-

- 55 administered form of buprenorphine or buprenorphine/naloxone if approved by the Food and Drug  
56 Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician  
57 may switch his or her patients using buprenorphine or buprenorphine/naloxone to the abuse  
58 deterrent or a practitioner-administered form of the drug.

NOTE: The purpose of this bill is to permit an opioid treatment program to be developed if part of a clinical trial, approved by an institutional review board. The bill sets forth the opioid treatment program services to be developed and provides for a set timeframe. The opioid treatment program is required to register with the Board of Pharmacy. The bill permits an advanced practice registered nurse participating in a clinical trial, approved by an institutional review board, to dispense medication for the timeframe approved in the clinical trial after registering with the Board of Pharmacy. The bill permits the advanced practice registered nurse participating in a clinical trial, approved by an institutional review board, to exceed a 3-day supply for the timeframe of the clinical trial, after registering with the Board of Medicine.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.