WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

House Bill 4480

BY DELEGATES WALTERS, PERDUE, J. NELSON,
ROHRBACH, STANSBURY, PHILLIPS, BATES, ELLINGTON,
HANSHAW, FRICH AND CAMPBELL

[Introduced February 10, 2016; Referred
to the Committee on Select Committee on Prevention
and Treatment of Substance Abuse then Health and
Human Resources.]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-51-1, §16-51-2 and §16-51-3, all relating to enacting the Addiction Treatment Act of 2016; and placing limitations on prescribing products containing buprenorphine, whether with or without naloxone.

Be it enacted by the Legislature of West Virginia:

That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new article, designated §16-51-1, §16-51-2 and §16-51-3, all to read as follows:

ARTICLE 51. ADDICTION TREATMENT ACT.

§16-51-1. Short title.

This article may be known and cited as the Addiction Treatment Act of 2016.

§16-51-2. Definitions.

As used in this article:

(1) "Addictions specialist" means a licensed allopathic or osteopathic physician who meets the criteria established by the Board of Osteopathic Medicine or the West Virginia Board of Medicine or has a current certification as an addictions specialist by the American Board of Addiction Medicine or a psychiatrist certified by the American Board of Psychiatry and Neurology.

(2) "Controlled substance" means a drug, substance or immediate precursor as defined by section one hundred one, article one, chapter sixty-a of this code.

(3) "Sublingual" refers to the pharmacological route of administration by which drugs diffuse into the blood through tissues under the tongue.

(4) "Therapeutic equivalent" means for the purposes of this article a drug that has essentially the same effect in the treatment of opioid dependence as one or more other drugs. A drug that is a therapeutic equivalent may or may not be chemically equivalent, bioequivalent, or generically equivalent but has the same active ingredient or ingredients, but due to ingredient composition or delivery process may have differing amounts of active ingredient or ingredients.

§16-51-3. Limitations on prescribing.

(a) Any product containing buprenorphine, whether with or without naloxone, may only be prescribed for a use recognized by the federal Food and Drug Administration. This subsection applies to a person:

(1) Who has a documented diagnosis of opiate addiction as shown in their medical record;

(2) Who receives treatment from a provider practicing under 21 U.S.C. § 823(g)(2); and

(3) Who is counted against the total number of patients allowed to the provider as set forth in 21 U.S.C. § 823(g)(2), or any future amendments to federal law.

(b) (1) Any prescription for buprenorphine mono or for buprenorphine without use of naloxone for the treatment of substance use disorder is only permitted to a patient who is:

(A) Pregnant;

(B) A nursing mother; or

(C) Has a documented history of an adverse reaction or hypersensitivity to naloxone.

(2) If the prescriber of buprenorphine mono or buprenorphine without use of naloxone for a patient under subparagraphs (A) or (B), subdivision (1) of this subsection, is not the patient's obstetrical or gynecological provider, the prescriber shall consult with the patient's obstetrical or gynecological provider to the extent possible to determine whether the prescription is appropriate for the patient.

(c) (1) Notwithstanding any other provision to the contrary a physician for purposes of this article is defined as a person with an license to practice allopathic medicine pursuant to article three of chapter thirty of this code or osteopathic medicine pursuant to article fourteen, chapter thirty of this code and are the only healthcare providers authorized to prescribe any buprenorphine product for any federal food and drug administration approved use in recovery or medication-assisted opioid treatment.

(2) Healthcare providers not licensed pursuant to article three, chapter thirty of this code or article fourteen, chapter thirty of this code and who are otherwise permitted to prescribe Schedule II or III drugs under this title, are prohibited from prescribing any buprenorphine product

for treatment of opioid dependence. However, the providers may participate in the assessment and management of patients with an opiate addiction.

(d) (1) A prescriber who treats a patient with more than sixteen milligrams per day of buprenorphine in the sublingual or pill form for more than thirty days for treatment of opioid dependence shall clearly document in the patient's medical record the reason that requires the patient to receive a higher dosage amounts of buprenorphine. For buprenorphine medications that use a different delivery methodology those dosages must be at a level that is therapeutically equivalent to the buprenorphine sublingual film or the pill form. All patients within six months of the start of treatment must be titrated down to a dosage of twelve milligrams of buprenorphine in the sublingual or pill form. For buprenorphine medications that use a different delivery methodology those dosages must be at a level that is therapeutically equivalent to the buprenorphine sublingual film or the pill form.

(2) Treatment with the use of products containing buprenorphine at twelve milligrams or the therapeutic equivalents' approved by the Food and Drug Administration may be no longer than five consecutive years. At the end of five years of treatment the patient may receive up to four milligrams per day or equivalent dosing of buprenorphine/naloxone, or bupenorphine during pregnancy, nursing or documented allergic reaction.

(3) A prescriber who exceeds the dosage requirements of this subsection and treats a patient with more than sixteen milligrams per day of buprenorphine in the sublingual or pill form for more than thirty consecutive days for treatment of opioid dependence shall consult with an addiction specialist or refer the patient to an addiction specialist for management of the patient's treatment plan, except that for buprenorphine medications that use a different delivery methodology those dosages must be at a level that is therapeutically equivalent to the buprenorphine sublingual film or the pill form.

(4) If there is a higher dosage used then clear medical notes shall be placed in the patient's medical file indicating the clinical reason or reasons for the higher level of dosage, not to exceed

the higher dose for more than two years.

(e) When an abuse deterrent form of buprenorphine or buprenorphine/naloxone is approved by the Food and Drug Administration and enters the market or is already on the market and receives the indication of abuse deterrent, the Board of Pharmacy shall notify all physicians prescribing buprenorphine or buprenorphine/naloxone for the indication of maintenance therapy for opioid dependency within sixty days of the availability of the abuse deterrent product or products. Upon receipt of the notice the physicians shall migrate their patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the pharmaceutical, if the patient is: (1) Pregnant; (2) a nursing mother; or (3) has a documented history of an adverse reaction or hypersensitivity and is being treated for opioid addiction.

(f) The West Virginia Board of Medicine and the West Virginia Board of Osteopathic Medicine shall propose rules for legislative promulgation establishing the requirements for physicians who use the term addiction specialist to describe their practice area. A physician who is current in his or her certification as an addictions specialist by the American Board of Addiction Medicine or a psychiatrist certified by the American Board of Psychiatry and Neurology is considered for purposes of this article to be an addictions specialist.

NOTE: The purpose of this bill is to enact the Addiction Treatment Act of 2016. The bill would place limitations on prescribing products containing buprenorphine, whether with or without naloxone.

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