WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Committee Substitute

for

House Bill 4480

(BY DELEGATES WALTERS, PERDUE, J. NELSON,

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HANSHAW, FRICH AND CAMPBELL)

[Originating in the House Committee on Health and

Human Resources on February 24, 2016.]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-51-1 and §16-51-2, all relating to prescribing certain controlled substances; defining terms; limiting to whom certain drugs may be prescribed; requiring notification; requiring a physician to prescribe certain drugs; limiting the prescription of drugs containing buprenorphine; setting a titration procedure; providing exemption to the titration procedure; and requiring chart notations.

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 and §16-51-2, all to read as follows:

ARTICLE 51. ADDICTION TREATMENT.

§16-51-1. Definitions.

As used in this article:

(1) "Addictions specialist" means a licensed allopathic or osteopathic physician who is certified as an addictions specialist by the American Board of Addiction Medicine or the American Osteopathic Association.

(2) "Buccal" means a drug that is absorbed across buccal mucosa directly into the venous circulation.

(3) "Controlled substance" means a drug, substance or immediate precursor in Schedules I through V of article two, chapter sixty-a of this code.

(4) "Drug" means as that term is defined in article five, chapter thirty.

(5) "Physician" means a person licensed 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.

(6) "Sublingual" means a pharmacological route of administration by which drugs diffuse into the blood through tissues under the tongue.

(7) “Tablet” means sublingual flat tablet intended to be inserted beneath the tongue, where the active ingredient is absorbed directly through the oral mucosa.

(8) “Therapeutic equivalent” means a drug that has essentially the same effect in the maintenance treatment of opioid dependence as one or more other drugs that 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.

§16-51-2. Limitations on prescribing.

(a) A physician may only prescribe a drug that has been approved by the Food and Drug Administration for use in maintenance or detoxification of opioid dependence to a person:

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

(2) Who receives treatment from a physician 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).

(b) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within sixty days of the availability of the an abuse deterrent form of buprenorphine or buprenorphine/naloxone is approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician shall switch their patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the drug.

(c) (1) A prescription for buprenorphine mono or buprenorphine without use of naloxone for the maintenance treatment of opioid dependence 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 paragraphs (A) or (B), is not the patient’s obstetrical or gynecological provider,

the physician shall consult with the patient's obstetrical or gynecological provider to the extent possible to determine whether the prescription is appropriate for the patient.

(d) (1) A physician, who treats a patient with more than sixteen milligrams per day of buprenorphine in the sublingual, buccal or oral solid dosage 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 amount of buprenorphine. For buprenorphine drugs that use a different delivery methodology those dosages, such as a buccal administration or future delivery systems, must be at a level that is therapeutically equivalent to the buprenorphine sublingual film or the oral solid dosage form.

(2) A patient within six months of the start of treatment must be titrated down to a dosage of twelve milligrams of buprenorphine in the sublingual, buccal, or oral solid dosage form. For buprenorphine drugs that use a different delivery methodology those dosages must be at a level that is therapeutically equivalent to the buprenorphine sublingual film, buccal, or the oral solid dosage form.

(3) Treatment with the use of drugs containing buprenorphine at twelve milligrams or its therapeutic equivalents may be no longer than five consecutive years. At the end of five years of treatment, a physician may prescribe a patient up to four milligrams per day or therapeutic equivalent of buprenorphine/naloxone, or bupenorphine if the patient is pregnant, nursing or a documented allergic reaction.

(4) A physician who exceeds the dosage requirements of this subsection and treats a patient with more than sixteen milligrams per day of buprenorphine in the sublingual, buccal, or oral solid dosage 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.

(5) If physician treats a patient with more than sixteen milligrams per day of buprenorphine in the sublingual, buccal or oral solid dosage 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. This dosage may not exceed more than two years.

(e) The Bureau for Medical Services shall place at least two buprenorphine/naloxone drugs on the Medicaid preferred drug list with at least with one having a buccal film delivery system.

(f) The titration schedule provided in subdivisions two and three of subsection (d) may not be implemented retroactively to effect a patient currently being prescribed a buprenorphine product.