2019 UPDATE (5/14/19) WVHA Implementation Guide for the Opioid Reduction Act

Introduction

During the 2019 Regular Session, the Opioid Reduction Act, originally established during the 2018 Regular Session in **SB 273**, was amended to clarify certain provisions. The changes made to the Act were enacted by the Legislature in **HB 2768** and include the following sections of *West Virginia Code*:

- <u>§16-54-1</u>;
- <u>§16-54-3;</u>
- <u>§16-54-4;</u>
- <u>§16-54-5;</u>
- <u>§16-54-6;</u>
- <u>§16-54-7</u>; and
- <u>§16-54-8</u>,

The major changes in **HB 2768**:

- Replace vague language throughout the Act with "Schedule II Opioid Drug" to specify that the Opioid Reduction Act is only applicable to Schedule II Opioid Drugs.
- Clarify that a prescription for a Schedule II Opioid Drug issued to an adult patient in an emergency room for outpatient use is not considered to be an initial Schedule II opioid prescription.
- Specify that the provisions of the Opioid Reduction Act do not apply to a patient being prescribed, or ordered, any medication in an inpatient setting at a hospital.

These and other changes resulting from the passage of **HB 2768** from the 2019 Regular Session are **HIGHLIGHTED BELOW** in this revised version of the *WVHA Implementation Guide for the Opioid Reduction Act.*

Generally, the Act itself is comprised of **<u>Three Main Parts</u>**:

- **Part 1:** Amendments to the definition of "chronic pain clinics" and changes to the registration process for office-based medication assisted treatment programs (*Pages 2-19 of the final Enrolled version of SB 273 passed during the 2018 Regular Session*);
- **Part 2:** Limitations to prescribing opioids by healthcare practitioners and the steps necessary for prescribing subsequent prescriptions. This section also includes language pertaining to the development of a *Narcotics Contract* executed by the prescribing practitioner. This section of the bill is the most substantial and is the primary focus of this *Implementation Guide*. (*Pages 20-27 of the final Enrolled version of SB 273 passed during the 2018 Regular Session*); and

• **Part 3**: Changes to various Chapter 30 Health Boards and their required activities resulting from the passage of the bill, including the WV Board of Medicine. (*Pages 27-73 of the final Enrolled version of SB 273 passed during the 2018 Regular Session*);

Recommendation

Hospitals and physicians should continue to familiarize themselves with the Opioid Reduction Act in its entirety. This includes changes made to the Act in **HB 2768** during the 2019 Regular Session. We recommend hospitals continue to meet with their *Medical Executive Committees* and other physician groups and senior management teams to discuss all provisions of the Act.

Applicability/Scope

There are specific sections of the Act that directly affect hospitals and healthcare practitioners that practice in hospitals. For purposes of this *Implementation Guide*, the WVHA Legislative Team is focusing on **Part 2** of the Act since they are the most significant. This is the "heart" of the Act which **applies to all physicians regardless of specialty.**

The changes involve:

- The treatment of pain;
- The issuing of opioids;
- Prescribing limitations;
- A Narcotics Contract;
- Requirements for subsequent prescriptions;
- Limitations on all Schedule II controlled substances; and
- Exceptions to the law.

One key term that applies throughout the Act is the definition of "healthcare practitioner." <mark>This section</mark> was amended in HB 2768 to include additional practitioners which are highlighted below:

- A **physician** authorized pursuant to the provisions of <u>§30-3-1</u> *et seq.* and <u>§30-14-1</u> *et seq.* of this code (WV Board of Medicine; and WV Board of Osteopathic Medicine);
- A **podiatrist** licensed pursuant to the provisions of <u>§30-3-1</u> *et seq.* of this code (WV Board of Medicine);
- A physician assistant with prescriptive authority as set forth in <u>§30-3E-3</u> of this code (WV Board of Medicine; and WV Board of Osteopathic Medicine);
- An **advanced practice registered nurse with prescriptive authority** as set forth in <u>§30-7-15a</u> of this code (*WV Board of Registered Nurses*);
- A **dentist** licensed pursuant to the provisions of <u>§30-4-1</u> *et seq.* of this code (*WV Dental Board*); and

- An **optometrist** licensed pursuant to the provisions of <u>§30-8-1</u> *et seq.* of this code (WV Board of Optometry);
- A physical therapist licensed pursuant to the provisions of <u>\$30-20-1</u> et seq. of this code (WV Board of Physical Therapy);
- An occupational therapist licensed pursuant to the provisions of <u>§ 30-28-1</u> et seq. of this code (WV Board of Occupational Therapy);
- An osteopathic physician licensed pursuant to the provisions of <u>\$30-14-1</u> et seq. of this code (WV Board of Osteopathic Medicine); and
- A chiropractor licensed pursuant to the provisions of <u>\$30-16-1</u> et seq. of this code (WV Board of Chiropractic).

Other terms used throughout the Act are clarified in HB 2768 and may be found in **§16-54-1**.

- 1. "Insurance Provider"
- 2. "Prescribe";
- 3. Referral;
- 4. Schedule II Opioid Drug; and
- 5. Surgical Procedure

The pages that follow summarize **Part 2** of the Act (*Pages 20-27 of the final Enrolled version of SB 273 passed during the 2018 Regular Session*). Part 2 also incorporates the primary changes made in HB 2768 during the 2019 Regular Session.

This summary is organized according to the sequence of events beginning when a patient seeks treatment for pain and continuing through the issuance and prescribing of initial and subsequent opioids.

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I. HOSPITAL EMERGENCY DEPARTMENTS

A. Treatment of Pain

When a patient seeks treatment, a health care practitioner shall refer or prescribe to a patient any of the following treatment alternatives, based on the practitioner's clinical judgement and the availability of the treatment, before starting a patient on an opioid:

- Physical therapy;
- Occupational therapy;
- Acupuncture;
- Massage therapy;
- Osteopathic manipulation;
- Chronic pain management program; and
- Chiropractic services.

All the treatment alternatives listed above are not required to be exhausted prior to the patient being issued a prescription for an opioid.

Nothing precludes a practitioner from simultaneously prescribing an opioid and prescribing or recommending any of the treatments listed above.

Please note: the Act does not differentiate between acute and chronic pain.

B. Prior to issuing a prescription for an opioid

A practitioner shall:

- 1) Advise the patient regarding the quantity of the Schedule II Opioid Drug and a patient's option to fill the prescription in a lesser quantity; and
- 2) Inform the patient of the risks associated with the Schedule II Opioid Drug prescribed.

C. Opioid prescription limitations

An adult patient seeking treatment in an *Emergency Department* being issued a prescription for a Schedule II Opioid Drug for outpatient use - not more than a four-day supply. **HB 2768** passed during the 2019 Regular Session clarified that the prescription for a Schedule II Opioid Drug issued to an adult patient in an emergency room for outpatient use is not considered an initial Schedule II Opioid prescription.

An opioid prescription being issued to a minor may not be for more than a three-day supply. The practitioner is required to discuss with the parent or guardian of the minor the risks associated with opioid use and the reason(s) why the prescription is necessary.

D. General Limitations (applicable to all healthcare practitioners)

i. Schedule II Controlled Substances

No Schedule II controlled substances may be prescribed by a practitioner for greater than a 30-day supply.

However, two additional prescriptions, each for a 30-day supply for a total of a 90-day supply, may be prescribed if the practitioner accesses the West Virginia Controlled Substances Monitoring Program Database. A practitioner is required to conduct and document the results of a physical examination every 90 days for any patient for whom he or she continues to treat with *any* Schedule II Opioid Drug. The physical exam should be relevant to the specific diagnosis and course of treatment and should assess whether continuing the course of treatment would be safe and effective for the patient.

ii. Exceptions

These limitations do not apply to a prescription for a patient:

- Who is currently in active treatment for cancer;
- Receiving hospice care from a licensed hospice provider or palliative care provider;
- A resident of a long-term care facility, or;
- To any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.
- Further, HB 2768 clarified that the provisions of the Opioid Reduction Act do not apply to a patient being prescribed, or ordered, any medication in an inpatient setting at a hospital.

A practitioner who acquires a patient after January 1, 2018, who is currently being prescribed an opioid from another practitioner shall be required to access the Controlled Substances Monitoring Program Database. Any prescription would not be deemed an initial prescription. The practitioner shall otherwise treat the patients as set forth above.

These limitations do not apply to an existing practitioner-patient relationship established before January 1, 2018, where there is an established and current opioid treatment plan which is reflected in the patient's medical record.

II. URGENT CARE FACILITIES

A. Treatment of Pain

When a patient seeks treatment, a health care practitioner shall refer or prescribe to a patient any of the following treatment alternatives, based on the practitioner's clinical judgement and the availability of the treatment, before starting a patient on an opioid:

- Physical therapy;
- Occupational therapy;
- Acupuncture;
- Massage therapy;
- Osteopathic manipulation;
- Chronic pain management program; and
- Chiropractic services.

All the treatment alternatives listed above are not required to be exhausted prior to the patient being issued a prescription for an opioid. Nothing precludes a practitioner from simultaneously prescribing an opioid and prescribing or recommending any of the treatments listed above.

Please note: the bill does not differentiate between acute and chronic pain.

B. Prior to issuing a prescription for an opioid

A practitioner shall:

- 1) Advise the patient regarding the quantity of the Schedule II Opioid Drug and a patient's option to fill the prescription in a lesser quantity; and
- 2) Inform the patient of the risks associated with the Schedule II Opioid Drug prescribed.

C. Opioid prescribing limitations

An adult patient seeking treatment in an *Urgent Care Facility* being issued a prescription for a Schedule II Opioid Drug for outpatient use – not more than a four-day supply. However, additional dosing for up to no more than a seven-day supply is permitted *if* the medical rational for more than a four-day supply is documented in the medical record. If a seven-day supply is deemed medically necessary, the health care practitioner is required to comply with the "Initial Opioid Prescription" requirements outlined on **Page 8.**

An opioid prescription being issued to a minor may not be for more than a three-day supply. The practitioner is required to discuss with the parent or guardian of the minor the risks associated with opioid use and the reason(s) why the prescription is necessary.

D. General Limitations (applicable to all healthcare practitioners)

i. Schedule II Controlled Substances

No Schedule II controlled substances may be prescribed by a practitioner for greater than a 30-day supply.

However, two additional prescriptions, each for a 30-day supply for a total of a 90-day supply, may be prescribed if the practitioner accesses the West Virginia Controlled Substances Monitoring Program Database. A practitioner is required to conduct and document the results of a physical examination every 90 days for any patient for whom he or she continues to treat with *any* Schedule II Opioid Drug. The physical exam should be relevant to the specific diagnosis and course of treatment and should assess whether continuing the course of treatment would be safe and effective for the patient.

ii. Exceptions

These limitations do not apply to a prescription for a patient:

- Who is currently in active treatment for cancer;
- Receiving hospice care from a licensed hospice provider or palliative care provider;
- A resident of a long-term care facility, or;
- To any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.
- Further, HB 2768 clarified that the provisions of the Opioid Reduction Act do not apply to a patient being prescribed, or ordered, any medication in an inpatient setting at a hospital.

A practitioner who acquires a patient after January 1, 2018, who is currently being prescribed an opioid from another practitioner shall be required to access the Controlled Substances Monitoring Program Database. Any prescription would not be deemed an initial prescription. The practitioner shall otherwise treat the patients as set forth above.

These limitations do not apply to an existing practitioner-patient relationship established before January 1, 2018, where there is an established and current opioid treatment plan which is reflected in the patient's medical record.

III. HEALTH CARE PRACTITIONER OPIOID PRESCRIBING LIMITATIONS

A. Treatment of Pain

When a patient seeks treatment, a health care practitioner shall refer or prescribe to a patient any of the following treatment alternatives, based on the practitioner's clinical judgement and the availability of the treatment, before starting a patient on an opioid:

- Physical therapy;
- Occupational therapy;
- Acupuncture;
- Massage therapy;
- Osteopathic manipulation;
- o Chronic pain management program; and
- Chiropractic services.

All the treatment alternatives listed above are not required to be exhausted prior to the patient being issued a prescription for an opioid.

Nothing precludes a practitioner from simultaneously prescribing an opioid and prescribing or recommending any of the treatments listed above.

Please note: the bill does not differentiate between acute and chronic pain.

B. Opioid prescribing limitations

An opioid prescription being issued to a minor may not be for more than a three-day supply. The practitioner is required to discuss with the parent or guardian of the minor the risks associated with opioid use and the reason(s) why the prescription is necessary.

C. Initial opioid prescription

All practitioners, not otherwise subject to the limitations outlined in the Emergency Department and/or the Urgent Care settings, are limited to prescribing *not more than* a seven-day supply for an *initial opioid prescription*.

D. Practitioner requirements prior to issuing an initial (1st prescription) opioid

Practitioner shall:

1) Take and document the results of a thorough medical history, including the patient's experience with nonopioid medication, nonpharmacological pain management approaches, and substance abuse history;

2) Conduct, as appropriate, and document the results of a physical examination. <mark>The physical exam should be relevant to the specific diagnosis and course of treatment and should assess whether continuing the course of treatment would be safe and effective for the patient;</mark>

3) Advise the patient regarding the quantity of the opioid and a patient's option to fill the prescription in a lesser quantity;

4) Inform the patient of the risks associated with the opioid prescribed;

5) Develop a treatment plan, with particular attention focused on determining the cause of the patient's pain; and

6) Access relevant prescription monitoring information under the Controlled Substances Monitoring Program Database.

For **post-surgery patients**, a practitioner may prescribe an initial seven-day supply of an opioid immediately following a surgical procedure. Subsequent prescriptions are subject to the below provisions.

E. Practitioner requirements prior to issuing a subsequent (2nd) prescription opioid

A practitioner shall discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age, the risks associated with the drug being prescribed. This discussion shall be included in a notation in the patient's medical record and shall include:

1) The risks of addiction and overdose associated with opioid drugs (Schedule II opioid drugs) and the dangers of taking opioid drugs with alcohol, benzodiazepines, and other central nervous system depressants;

2) The reasons why the prescription is necessary;

3) Alternative treatments that may be available; and

4) Risks associated with the use of drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled substance, and that the risks of taking more opioids than prescribed, or mixing sedatives, benzodiazepines, or alcohol with opioids, can result in fatal respiratory depression.

F. Requirements when issuing an opioid prescription subsequent to the initial prescription (2nd prescription)

After issuing the initial prescription the practitioner, after consultation with the patient, may issue a subsequent prescription for an opioid to the patient if:

1) It would not be deemed an initial prescription;

2) The practitioner determines a subsequent prescription is necessary and appropriate to the patient's treatment needs and documents the rationale for the issuance of it; and

3) The practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion and documents that determination.

G. Issuance of a 3rd prescription for a prescription opioid

At the time of the issuance of the third prescription for a Schedule II opioid drug the practitioner *shall consider* referring the patient to a pain clinic or a pain specialist. For purposes of this bill:

"Pain management clinic" means all privately-owned pain management clinics, facilities, or offices not otherwise exempted from this article and which meet both of the following criteria:

(1) Where in any month more than 50 percent of patients of the clinic are prescribed or dispensed Schedule II opioids or other Schedule II controlled substances specified in rules promulgated pursuant to this article for chronic pain resulting from conditions that are not terminal; and

(2) The facility meets any other identifying criteria established by the secretary by rule.

"Pain specialist" means a practitioner who is board certified in pain management or a related field.

The practitioner shall discuss the benefits of seeking treatment through a pain clinic or a pain specialist and provide him or her with an understanding of any risks associated with choosing not to pursue that as an option.

If the patient declines to seek treatment from a pain clinic or a pain specialist and opts to remain a patient of the practitioner, and the practitioner continues to prescribe a Schedule II opioid drug, the practitioner shall:

1) Note in the patient's medical records that the patient knowingly declined treatment from a pain clinic or pain specialist;

2) Review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and document the results of that review;

3) Assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment; and

4) Periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence, and document with specificity the efforts undertaken.

H. Narcotics Contract (See Addendum A)

The Act states that in conjunction with the issuance of a third prescription for a Schedule II Opioid Drug, the patient shall execute a **Narcotics Contract** with their prescribing practitioner. The contract shall be made a part of the patient's medical record.

The WVHA Legislative Team has developed a **Template Narcotics Contract** for member hospitals to utilize if necessary based on the requirements of the contract. This template is **Addendum A** of this **Implementation Guide**. The contract is required to provide a minimum that:

(1) The patient agrees only to obtain scheduled medications from this particular prescribing practitioner;

(2) The patient agrees he or she will only fill those prescriptions at a single pharmacy which includes a pharmacy with more than one location;

(3) The patient agrees to notify the prescribing practitioner within 72 hours of any emergency where he or she is prescribed scheduled medication; and

(4) If the patient fails to honor the provisions of the narcotics contract, the prescribing practitioner may either terminate the provider-patient relationship or continue to treat the patient without prescribing a Schedule II opioid drug for the patient. Should the practitioner decide to terminate the relationship, he or she is required to do so pursuant to the provisions of this code and any rules promulgated hereunder. Termination of the relationship for the patient's failure to honor the provisions of the contract is not subject to any disciplinary action by the practitioner's licensing board.

(5) If another physician is approved to prescribe to the patient.

A pharmacist is not responsible for enforcing the provisions of this section and the Board of Pharmacy may not discipline a licensee if he or she fills a prescription in violation of the provisions of this section.

If you currently have a Narcotics Contract in place, please review it to ensure you're in compliance with the requirements now in law.

I. General Limitations (applicable to all healthcare practitioners)

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These limitations do not apply to an existing practitioner-patient relationship established before January 1, 2018, where there is an established and current opioid treatment plan which is reflected in the patient's medical record.

WVHA Contact

For questions regarding the applicability/scope of the new law, or any concerns regarding implementation, please feel free to contact the following WVHA staff: <u>Brandon Hatfield</u>, WVHA General Counsel (304) 353-9720; <u>Tony</u> <u>Gregory</u>, VP Legislative Affairs (304) 353-9719; or <u>Jim Kranz</u>, VP Quality (304) 353-9712.