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Bill Analysis

Version: As Introduced

Primary Sponsor: Sen. Maharath

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SUMMARY

- Requires the Ohio Department of Health to develop a nonopioid directive form for use by a patient who does not want to be offered, prescribed, furnished, administered, or otherwise provided an opioid analgesic.
- Specifies that a nonopioid directive becomes effective when signed and placed in the patient's medical record and that it can be revoked at any time.
- Specifies that a pharmacist is not required to inquire about a nonopioid directive's existence before dispensing an opioid analgesic.
- Requires that a prescriber give the patient or the patient's representative information about evidence-based nonopioid therapies before initiating treatment for acute or chronic pain, and authorizes the imposition of sanctions for violations.
- Requires certain health care insurers to cover such evidence-based nonopioid therapies, including the services of chiropractors, Oriental medicine practitioners, acupuncturists, and osteopathic physicians.

DETAILED ANALYSIS

Nonopioid directives

The bill establishes procedures for the use of nonopioid directives. A nonopioid directive allows a patient to indicate that the patient does not want to be offered, prescribed, administered, furnished, or otherwise provided with an opioid analgesic.[1]

Under existing law not modified by the bill, an opioid analgesic is a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system.

[1] R.C. 3702.41 to 3702.416.

Examples include the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.[2]

Form

The bill requires the Ohio Department of Health (ODH) to develop a nonopioid directive form. ODH must develop the form not later than one year after the bill's effective date.

When developing the form, ODH must seek input on its contents from organizations representing prescribers, emergency medical services personnel, nursing homes, hospitals, ambulatory surgical facilities, and any other group ODH considers appropriate.[3]

ODH must make the form available on its website and in a format that can be downloaded free of charge and reproduced. ODH must notify each local board of health, as well as prescribers, community addiction services providers, hospitals, and other health care providers and facilities when the form initially becomes available and, if applicable, when updates become available.[4]

Completion of the form

The bill permits any individual or the individual's representative to complete a nonopioid directive form. In the case of a minor, the patient's parent, guardian, or legal custodian is the patient's representative.[5]

The bill specifies that the decision to complete a nonopioid directive form is voluntary.[6]

Activation and revocation of the directive

A nonopioid directive does not become effective until (1) the form is signed by the patient, or by that patient's representative, in the presence of the recipient and (2) the patient or representative submits the form to the recipient, the recipient signs and dates the form in the presenter's presence, and the recipient makes a photocopy of the signed form for the patient's records.[7] The recipient must file the signed form in the patient's medical record.[8]

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[2] R.C. 3719.01(JJ), not in the bill.

[3] R.C. 3702.41(B).

[4] R.C. 3702.41(C).

[5] R.C. 3702.41(A)(3) and 3702.411(A)(1).

[6] R.C. 3702.411(A)(1).

[7] R.C. 3702.411(A)(2).

[8] R.C. 3702.411(B).

"Recipient" is defined by the bill as the prescriber, other person or government entity specified by ODH, or delegate of the foregoing that may receive and file a nonopioid directive.[9]

Compliance

A recipient, prescriber to whom a copy of an effective nonopioid directive form has been transmitted, and any delegate of the foregoing must comply with the nonopioid directive.[10] A professional licensing board may impose a disciplinary sanction for a prescriber's failure to comply with this requirement.[11] In the case of a dentist, physician, podiatrist, or physician assistant, the State Dental Board or State Medical Board may impose a fine in addition, or as an alternative, to another sanction.[12]

Rules

The bill requires the ODH Director to adopt rules in accordance with the Administrative Procedure Act[13] governing the use of nonopioid directives. The rules must do all of the following:[14]

--Specify the persons who are not prescribers and the government entities that may receive an individual's nonopioid directive form and file it in the individual's medical record;

--Establish a standard cover sheet that a recipient may use to transmit, in accordance with applicable state and federal laws governing patient confidentiality, a copy of a nonopioid directive form to a prescriber or other specified person or government entity;

--Establish a procedure for filing a nonopioid directive form in the medical record of the individual to whom it pertains;

--Establish a procedure for an individual to appoint a proxy to override a previously filed nonopioid directive form; and

--Establish a procedure to ensure that any recording, sharing, or distributing of information associated with a nonopioid directive form complies with applicable federal and state laws governing patient confidentiality.

[9] R.C. 3702.41(A)(6).

[10] R.C. 3702.411(C).

[11] R.C. 4715.30(A)(18) (dentists), 4723.28(B)(37) (advanced practice registered nurses), 4730.25(B)(29) (physician assistants), and 4731.22(B)(59) (physicians and podiatrists).

[12] R.C. 4715.30(K), 4730.25(N), and 4731.22(P).

[13] *See* R.C. Chapter 119.

[14] R.C. 3702.413.

Pharmacists

No obligation to determine form existence

When a valid prescription for an opioid analgesic is presented to a pharmacist for dispensing, the pharmacist is not required under the bill to inquire about the existence of a nonopioid directive for the patient or determine if the patient is the subject of a directive.[15]

Immunity

The bill generally grants immunity from criminal prosecution, civil liability, and professional discipline to a pharmacist for actions associated with dispensing an opioid analgesic. To be eligible for immunity from criminal prosecution, the pharmacist cannot knowingly fail to comply with a patient's nonopioid directive. To be eligible for immunity from civil liability and professional discipline, a pharmacist cannot fail to comply with a nonopioid directive in a manner that constitutes willful and wanton misconduct.[16]

Prescribers

Dissemination of information on nonopioid therapies

Before initiating a plan of treatment that includes the use of an opioid analgesic for acute pain or chronic pain, the bill requires that a prescriber give the patient or the patient's representative information about evidence-based therapies that do not require the use of an opioid analgesic to treat that condition. At a minimum, the prescriber must provide information on the services of all of the following: a licensed chiropractor (who may practice both chiropractic and acupuncture); a licensed Oriental medicine practitioner or acupuncturist; and, if the prescriber is not an osteopathic physician, the services of an osteopath that do not involve opioid analgesics.[17]

"Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient's typical function, and is expected to be time limited.[18] Under existing law not modified by the bill, "chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.[19]

[15] R.C. 3702.414(A).

[16] R.C. 3702.414(B).

[17] R.C. 3719.065(B).

[18] R.C. 3719.065(A)(1).

[19] R.C. 3719.065(A)(2).

A prescriber who is a clinical nurse specialist, certified nurse-midwife, certified nurse practitioner, physician assistant, physician, or podiatrist must comply with this requirement, as applicable, and may be disciplined for failure to do so.[20]

Immunity

The bill generally grants recipients, as well as their delegates, employees, or contractors, immunity from criminal prosecution, civil liability, and professional discipline for actions associated with offering, prescribing, administering, furnishing, or otherwise providing an opioid analgesic to a patient who has an effective nonopioid directive. To be eligible for immunity from criminal prosecution, the recipient or the recipient's delegate, employee, or contractor cannot knowingly fail to comply with a signed directive. To be eligible for immunity from civil liability and professional discipline, the prescriber or prescriber's delegate, employee, or contractor cannot fail to comply with a directive in a manner that constitutes willful or wanton misconduct.[21]

Insurance

Impact of nonopioid directives

The bill specifies that the existence or absence of a nonopioid directive for an individual does not do any of the following:[22]

--Affect in any manner the sale, procurement, issuance, or renewal of a policy of life insurance or annuity, notwithstanding any term of a policy or annuity to the contrary;

--Modify in any manner or invalidate the terms of a policy of life insurance or annuity that is in effect on the bill's effective date; or

--Impair or invalidate a policy of life insurance or annuity or any health benefit plan.

Coverage of nonopioid therapies

The bill requires certain health care insurers to provide coverage for evidence-based therapies that do not require the use of opioid analgesics in the treatment of pain. Of the services covered, all of the following must be included, which correspond with the information on services that must be provided by prescribers under the bill (see "**Dissemination of information on nonopioid therapies**," above):

1. Services of a chiropractor, including a chiropractor authorized to perform acupuncture;
2. Services of an Oriental medicine practitioner or acupuncturist;
3. Services of an osteopathic physician that do not involve the use of opioid analgesics.

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[20] R.C. 4723.28(B)(38), 4723.481(E)(2), 4723.53(B), 4730.25(B)(30), 4730.41(B)(5)(b), 4730.57(B), 4731.052(E), 4731.22(B)(33), and 4731.84(B).

[21] R.C. 3702.415.

[22] R.C. 3702.416.

The insurers subject to this requirement are sickness and accidence insurers, health insuring corporations, multiple employer welfare arrangements (MEWAs), and public employee benefit plans.[23] The requirement applies only to policies, contracts, agreements, arrangements, and plans issued, delivered, renewed, established, or modified in Ohio on or after July 1, 2020.[24]

ERISA preclusion

The bill's coverage requirements do not apply to employee benefits offered by private employers that self-insure their benefit programs. The programs are generally precluded from state regulation by the federal Employee Retirement Income Security Act (ERISA), which is a comprehensive federal statute governing the administration of employee benefit plans. Larger employers frequently choose to establish their own health benefit plans in lieu of purchasing coverage from a health insuring corporation or sickness and accident insurer.

Review of mandated benefits legislation

The bill exempts its requirements regarding health insurer coverage of nonopioid therapies from an existing law that could prevent the requirements from being applied until the Superintendent of Insurance has conducted a review with respect to mandated health benefits. Under current law, legislation mandating health benefits cannot be applied to any health benefits arrangement after the legislation is enacted unless the Superintendent holds a public hearing and determines that it can be applied fully and equally in all respects to (1) employee benefit plans that are subject to ERISA and (2) employee benefit plans established or modified by the state or its political subdivisions.[25] Under the bill, the requirements for coverage of nonopioid therapies apply even if the bill's provisions are considered mandated benefits.

History

Action	Date
Introduced	02-12-19

S0051-I-133/ts

[23] R.C. 1739.05(B), 1751.76(B), and 3923.91(B).

[24] Section 3.

[25] R.C. 3901.71.