



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 206

128th General Assembly
(As Reported by H. Health)

Reps. Boyd and Oelslager, Combs, Domenick, Wachtmann, Ujvagi, Letson, Yuko, Okey, Chandler

BILL SUMMARY

- Eliminates restrictions on the authority of an advance practice nurse (APN) to prescribe schedule II controlled substances if certain conditions are met.
- Prohibits an APN from prescribing any schedule II controlled substance to a patient in a convenience care clinic.
- Specifies that an APN who holds a certificate to prescribe on the bill's effective date is subject to the restrictions in current law governing an APN's authority to prescribe schedule II controlled substances until the APN renews the certificate or receives a new certificate to prescribe.
- Requires an APN applying for a certificate to prescribe to complete a course of study that consists of at least 45 contact hours in pharmacology and related topics, of which at least 36 (instead of 30) must be contact hours of advanced pharmacology training.
- Requires that the course of study in pharmacology and related topics include training in schedule II controlled substances that meets certain requirements.
- Requires an APN who received a certificate to prescribe prior to the bill's effective date to complete at least six contact hours of training on schedule II controlled substances.
- Requires the Committee on Prescriptive Governance's APN prescriptive authority recommendations to include provisions that apply specifically to schedule II controlled substances.

- Eliminates the prohibition on an APN prescribing schedule II controlled substances in collaboration with a podiatrist.
- Requires the Board of Nursing to adopt rules as necessary to implement the authority of APNs to prescribe schedule II controlled substances.

CONTENT AND OPERATION

Background--schedule II controlled substances

(R.C. 3719.43 and 21 U.S.C. 811 and 812 (not in the bill))

The federal Controlled Substances Act¹ created five schedules (classifications) for substances regulated under federal law. The U.S. Attorney General, after receiving recommendations from the U.S. Secretary of Health and Human Services, determines which drugs are added or removed from the schedules² according to certain criteria.

Before classifying a substance as a schedule II drug, the U.S. Attorney General must find that (1) the drug or other substance has a high potential for abuse, (2) the drug or other substance has a currently accepted medical use in treatment in the U.S. or a currently accepted medical use with severe restrictions, and (3) the abuse of the drug or substance may lead to severe psychological or physical dependence.

Ohio law also creates five schedules of controlled substances. In general, Ohio's controlled substance schedules are the same as the federal schedules. Ohio law specifies that when the U.S. Attorney General adds a substance to a schedule or removes or transfers a substance, the addition, transfer, or removal is automatically effectuated in the corresponding schedules in Ohio law.³

Current law--prescriptive authority of advanced practice nurses

(R.C. 4723.481 and 4723.482; R.C. 4723.431, 4723.48, and 4723.484 (not in the bill))

Existing law authorizes certain advanced practice nurses (APNs), specifically a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner, to prescribe drugs and therapeutic devices in collaboration with a physician or podiatrist if the APN holds the appropriate certificate issued by the Ohio Board of Nursing. An

¹ Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, codified at 21 U.S.C. §§ 801 *et seq.*

² Congress created the initial listing in the Controlled Substances Act.

³ *State v. Klinck* (1989), 44 Ohio St.3d 108, 108.

APN seeking this authority must, generally, demonstrate evidence of successfully completing instruction in advanced pharmacology, pay a fee, and provide any information required by the Board pursuant to administrative rules. The Board is to issue a certificate to prescribe, designated as an "externship certificate," to a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who meets these requirements.

An externship certificate authorizes the holder to prescribe under the supervision of a physician (not a podiatrist). Upon successful completion of the externship and payment of a fee, the APN may apply for and receive a certificate to prescribe that authorizes the APN to prescribe certain drugs and therapeutic devices in collaboration with one or more physicians or podiatrists. To practice collaboratively, the APN must have entered into a "standard care arrangement" with the collaborating physician or podiatrist. This arrangement is generally required to set forth the terms of the collaborative practice.

General restrictions

(R.C. 4723.481 and 4723.50)

Existing law restricts an APN's authority to prescribe. Specifically, an APN may prescribe only drugs and therapeutic devices listed in the formulary established in rules adopted by the Board. Those rules must be consistent with recommendations from the Committee on Prescriptive Governance (see "**Committee on Prescriptive Governance**," below). Also, an APN's prescriptive authority may not exceed the prescriptive authority of the APN's collaborating physician or podiatrist.

Restrictions pertaining to schedule II controlled substances

(R.C. 3719.06 and 4723.481)

An APN who holds a certificate to prescribe may prescribe a schedule II controlled substance in collaboration with a physician (but not a podiatrist) only if (1) the patient to whom the controlled substance is prescribed is in a terminal condition, (2) the collaborating physician initially prescribed the substance for the patient, and (3) the amount prescribed does not exceed the amount necessary for the patient's use in a single, 24-hour period. APNs are prohibited from personally furnishing⁴ schedule II controlled substances to patients.

⁴ "Personally furnishing" is not defined in current law, but it is used in the sense of dispensing a supply of drugs to a patient and is thereby distinguished from the act of administering a drug to a patient.

The bill--APNs' authority to prescribe schedule II controlled substances

Elimination of restrictions on prescribing

(R.C. 3719.06 and 4723.481)

The bill maintains the prohibition on an APN personally furnishing⁵ schedule II controlled substances to patients, but eliminates the restrictions on an APN's ability to prescribe schedule II controlled substances, including the prohibition against prescribing controlled substances in collaboration with a podiatrist. The practical effect of these changes is that the bill, except as discussed below, authorizes an APN with prescriptive authority to prescribe a schedule II controlled substance in any circumstance as long as the APN is acting in the course of professional practice, in collaboration with a physician or podiatrist, and in accordance with other applicable laws.

Convenience care clinics

(R.C. 4723.486)

The bill prohibits an APN from prescribing any schedule II controlled substance to a patient in a convenience care clinic. The bill does not specify the meaning of "convenience care clinic."

Transition for existing APN prescribers

(Section 3)

For an individual who holds a certificate to prescribe issued prior to the bill's effective date, the bill requires, as a condition of obtaining certificate renewal or a new certificate (in the case of an APN holding an externship certificate), that the individual complete a minimum of six contact hours of training pertaining to schedule II controlled substances, as described below (see "**Advanced pharmacology prerequisite**"). For certificate renewals, the six hours are in addition to all other continuing nursing education that must be completed by August 31, 2011.

The bill also specifies that an APN who holds a certificate to prescribe on the bill's effective date is subject to current restrictions governing an APN's ability to prescribe schedule II controlled substances until the APN renews his or her certificate or receives a new certificate after completing an externship.

⁵ *Id.*

Advanced pharmacology prerequisite

(R.C. 4723.482; R.C. 4723.485 (not in the bill))

Current law requires applicants for certificates to prescribe to submit evidence to the Board of successfully completing instruction in advanced pharmacology and related topics in accordance with certain requirements. This instruction must be obtained not longer than three years before the date of application. It must also be obtained through a course of study consisting of planned classroom and clinical study that is approved by the Board in accordance with standards established in rules. The instruction must include (1) a minimum of 30 contact hours of training in advanced pharmacology that includes pharmacokinetic principles and clinical application and the use of drugs and therapeutic devices in illness prevention and maintenance of health, (2) training in the fiscal and ethical implications of prescribing drugs and therapeutic devices, (3) training in the state and federal laws that apply to the authority to prescribe, and (4) any additional training required under Board rules.

As described in the preceding paragraph, current law specifies that the required instruction in advanced pharmacology and related topics must be obtained through a course of study consisting of planned classroom and clinical study. The bill changes the term "instruction" to "a course of study," and accordingly modifies terminology pertaining to requirements of the instruction.

The bill requires that the length of the course of study in advanced pharmacology and related topics be at least 45 contact hours. It also increases, from 30 to 36, the requirement of the minimum number of contact hours of instruction in advanced pharmacology that includes pharmacokinetic principles and clinical application and the use of drugs and therapeutic devices in illness prevention and maintenance of health.⁶

The bill adds the requirement that the content of the course of study in advanced pharmacology include, specific to schedule II controlled substances, all of the following:

(1) Indications for the use of schedule II controlled substances in drug therapies, including pain management therapies;

(2) The most recent guidelines for pain management therapies, as established by state and national organizations such as the Ohio Pain Initiative and the American Pain Society;

⁶ Current rules adopted by the Board require this portion of the instruction to consist of a minimum of 36 hours (Ohio Administrative Code 4723-09-02).

(3) Ethical and fiscal implications of prescribing schedule II controlled substances;

(4) State and federal laws that apply to the authority to prescribe schedule II controlled substances;

(5) Prevention of abuse and diversion of schedule II controlled substances, including identification of the risk of abuse and diversion, recognition of abuse and diversion, types of assistance available for prevention of abuse and diversion, and methods of establishing safeguards against abuse and diversion.

Former APN pilot program participants

(R.C. 4723.482(A)(2); R.C. 4723.56 and 4723.58 (repealed by H.B. 478 of the 119th General Assembly))

Am. Sub. S.B. 154 of the 121st General Assembly permitted certain APNs who participated in one of three APN pilot programs operating in medically underserved areas of Ohio to obtain approval from the Board to prescribe drugs and therapeutic devices. To obtain this approval, the participant had to complete pharmacology courses determined to be acceptable by the Board.

Am. Sub. H.B. 241 of the 123rd General Assembly accelerated the termination of the pilot programs (originally scheduled to terminate in 2010), causing them to be terminated in January, 2004. It also created the current procedures by which APNs may receive authority to prescribe in any area of Ohio by obtaining a certificate to prescribe. Am. Sub. H.B. 241 permitted pilot program participants who had prescriptive authority on May 17, 2000, to be issued a certificate to prescribe without having to complete another pharmacology training program or an externship. The bill repeals the part of the provision that permits an APN who was a pilot program participant to apply for a certificate to prescribe without having to complete another course of study in advanced pharmacology. Therefore, the bill requires an APN who was a pilot program participant, as a condition of renewing a certificate to prescribe, to complete the same pharmacology instruction as any other APN seeking a new certificate to prescribe. Under the bill, this instruction includes instruction pertaining specifically to schedule II controlled substances (see "**Advanced pharmacology prerequisite**," above).

Committee on Prescriptive Governance

(R.C. 4723.492; Section 4; R.C. 4723.49 (not in the bill))

The Committee on Prescriptive Governance, created in May 2000, consists of a clinical nurse specialist, a certified nurse-midwife, a certified nurse practitioner, a Board

member who is at a minimum a registered nurse, four physicians, a pharmacist member of the State Board of Pharmacy, and a pharmacist actively engaged in practice as a clinical pharmacist in Ohio. The Committee is responsible for developing recommendations regarding the authority of APNs to prescribe drugs and therapeutic devices pursuant to a certificate to prescribe.

The bill requires the Committee to develop recommendations regarding the authority of APNs to prescribe schedule II controlled substances. The recommendations must be developed not later than 90 days after the bill's effective date.

Rulemaking

(R.C. 4723.50; Section 5)

The bill requires the Board, not later than 90 days after the bill's effective date, to adopt rules as necessary to implement the bill's provisions pertaining to the authority to prescribe schedule II controlled substances pursuant to a certificate to prescribe. The bill expressly requires the Board's rules establishing criteria for APN standard care arrangements with physicians and podiatrists to include components that apply to the authority to prescribe schedule II controlled substances.

HISTORY

| ACTION | DATE |
|---------------------|----------|
| Introduced | 06-02-09 |
| Reported, H. Health | 10-06-09 |

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