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Bill Analysis
Legislative Service Commission

Sub. H.B. 253
127th General Assembly
(As Reported by H. Health)

Reps. Oelslager, J. McGregor, Collier, Letson, Chandler, Okey, Wachtmann, Healy, Boyd, DeBose

BILL SUMMARY

- Eliminates restrictions on the authority of an advance practice nurse (APN) to prescribe schedule II controlled substances pursuant to a certificate to prescribe if certain conditions are met.
- Specifies that an APN who holds a certificate to prescribe or externship certificate to prescribe on the bill's effective date is subject to the restrictions in current law governing an APN's ability to prescribe schedule II controlled substances until the APN renews the certificate to prescribe or receives an extension of the externship certificate.
- Requires an APN applying for an initial 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 issued a certificate to prescribe or externship certificate to prescribe prior to the bill's effective date to complete, as a condition of certificate renewal, at least six contact hours of training on schedule II controlled substances not later than August 31, 2009.
- 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 to prescribe schedule II controlled substances pursuant to a certificate to prescribe.

CONTENT AND OPERATION

Background

Prescriptive authority of advanced practice nurses

(R.C. 4723.481 and 3719.06; R.C. 4723.48 (not in the bill))

Existing law authorizes a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner (advanced practice nurse or APN) to prescribe certain drugs and therapeutic devices if the APN has a certificate to prescribe issued by the Ohio Board of Nursing. To obtain a certificate to prescribe, the APN must, generally, demonstrate evidence of successfully completing instruction in advanced pharmacology, pay a fee, and provide any information required by the Board of Nursing pursuant to administrative rules.

Existing law restricts an APN's ability to prescribe by specifying the following:

(1) The APN is prohibited from prescribing a drug or therapeutic device that is not in the formulary established in rules adopted by the Board (the rules adopted must be consistent with the recommendations the Board receives from the Committee on Prescriptive Governance (*see* "Committee on prescriptive governance," below).

(2) The prescriptive authority cannot exceed the prescriptive authority of the APN's collaborating physician or podiatrist;

(3) The APN may prescribe a schedule II controlled substance in collaboration with a physician (but not a podiatrist) only if (a) the patient receiving the substance is in a terminal condition, (b) the APN's collaborating physician initially prescribed the substance to the patient, and (c) the amount prescribed does not exceed that necessary for the patient's use in a single, 24-hour period.

Schedule II controlled substances

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 various schedules² according to certain criteria.³

Before classifying a substance as a schedule II drug, the U.S. Attorney General must find (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.⁴

Ohio law⁵ 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.⁶

APN's authority to prescribe and personally furnish schedule II controlled substances

(R.C. 3719.06)

Current law

As described above, an APN who holds a certificate to prescribe is authorized to prescribe schedule II controlled substances subject to the following restrictions: (1) the patient to whom the controlled substance is prescribed must be in a terminal condition, (2) the APN's collaborating physician must have initially prescribed the substance for the patient, and (3) the amount prescribed

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 21 U.S.C. 811(b) and (c).

⁴ 21 U.S.C. 812(b).

⁵ R.C. 3719.43.

⁶ *State v. Klinck* (1989), 44 Ohio St.3d 108, 108.

does not exceed the amount necessary for the patient's use in a single, 24-hour period.

APNs are prohibited from personally furnishing schedule II controlled substances to patients.

The bill

In general. The bill maintains the prohibition on an APN personally furnishing a schedule II controlled substance to a patient, but eliminates the restrictions on an APN's ability to prescribe schedule II controlled substances. This means that the bill, except as noted below, authorizes an APN to prescribe a schedule II controlled substance in any circumstance as long as the APN is acting in the course of professional practice and in accordance with the laws regulating APN professional practice and State Board of Pharmacy rules.

Exception to unlimited schedule II prescriptive authority. With respect to an APN who holds a certificate to prescribe on the bill's effective date, the bill specifies that the schedule II prescriptive authority is subject to the restrictions described above until the APN renews the certificate in accordance with the procedure discussed below (*see* "**Advanced pharmacology prerequisite, The bill--renewals**").

Certificates to prescribe

Collaboration with podiatrists

(R.C. 4723.481(C); R.C. 4723.431 (not in the bill))

Current law. Under existing law, an APN must, generally, practice in collaboration with one or more physicians or podiatrists. An APN is not permitted to prescribe a schedule II controlled substance in collaboration with a podiatrist.

The bill. The bill eliminates the prohibition on an APN prescribing a schedule II controlled substance in collaboration with a podiatrist.

Advanced pharmacology prerequisite

(R.C. 4723.482 and Section 3; R.C. 4723.485 (not in the bill))

Current law. Current law requires certificate to prescribe applicants to submit evidence to the Board of Nursing of successfully completing instruction in advanced pharmacology and related topics in accordance with certain requirements. The advanced pharmacology instruction must be obtained not later than three years before the application for the certificate is filed and 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 rules.

The bill--new certificate applicants. The bill requires new certificate applicants to *complete* (rather than obtain) the course of study in advanced pharmacology not later than three years before filing an application. The bill adds a requirement that the length of the course of study in advanced pharmacology and related topics be not less than 45 contact hours, with a minimum of 36 (as opposed to 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.

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.

(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.

(6) Any additional training required by rules adopted by the Board of Nursing.

The bill--renewals. The bill requires an individual who holds a certificate to prescribe or externship certificate to prescribe issued prior to the bill's effective date to successfully complete, as a condition of obtaining certificate renewal or extension, a minimum of six contact hours of training pertaining to schedule II controlled substances. The six hours are in addition to all other continuing nursing education that must be completed not later than August 31, 2009, as a condition of obtaining renewal or extension of the certificate.

The bill also specifies that an APN who holds a certificate to prescribe or externship certificate to prescribe on the bill's effective date is subject to the restrictions in current law governing an APN's ability to prescribe schedule II controlled substances until the APN renews the certificate to prescribe or receives an extension of the externship certificate.

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 or sought to participate in one of three APN pilot programs operating in medically underserved areas of Ohio to obtain approval from the Board of Nursing to prescribe drugs and therapeutic devices. To obtain this approval, the pilot program participant had to complete pharmacology courses determined to be acceptable by the Board under rules the Board was required to adopt.

Am. Sub. H.B. 241 of the 123rd General Assembly enacted law to, among other things, accelerate termination of the pilot programs (originally scheduled to terminate in 2010) and create procedures by which APNs could receive authority to prescribe in any area of Ohio by obtaining a "certificate to prescribe." This law also permitted pilot program participants who had prescriptive authority on May 17, 2000, to be given a certificate to prescribe without having to complete another pharmacology training program and without being required to complete an externship.

In January 2004, pursuant to law enacted by Am. Sub. H.B. 241 of the 123rd General Assembly, all of the pilot programs were terminated. The bill repeals a 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.⁷

Committee on prescriptive governance

(R.C. 4723.492; Section 4)

The Committee on Prescriptive Governance, created in May 2000, consists of a clinical nurse specialist, a certified nurse-midwife, a certified nurse practitioner, a Nursing 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 recommendations the Committee must develop to include provisions that apply specifically to the authority of APNs to prescribe schedule II controlled substances. The recommendations regarding the schedule II prescriptive authority must be developed not later than 90 days after the bill's effective date.

Rulemaking on standard care arrangements

(R.C. 4723.50; Section 5)

Current law

Current law requires the Board of Nursing to adopt rules to establish criteria for the components of standard care arrangements that APNs must generally enter into with one or more physicians or podiatrists.

The bill

The bill requires the criteria to include the components that apply to the authority to prescribe schedule II controlled substances.

The bill requires the Board to adopt rules as necessary to implement the authority to prescribe schedule II controlled substances pursuant to a certificate to prescribe not later than 90 days after the bill's effective date.

⁷ An APN who was a pilot program participant and desires to renew a certificate to prescribe must complete the training pertaining to schedule II controlled substances described in Section 3 of the bill in addition to all other continuing nursing education the APN must complete under law unchanged by the bill.

HISTORY

ACTION

DATE

Introduced

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03-18-08

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