Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 116

131st General Assembly
(As Reported by S. Medicaid)

Reps. Brown and Ginter, Becker, Kuhns, Kraus, Lepore-Hagan, Huffman, Barnes, Bishoff, Duffey, Ramos, Anielski, Antonio, Baker, Blessing, Boyce, Boyd, Buchy, Burkley, Celebrezze, Clyde, Conditt, Craig, Derickson, Dever, Dovilla, Driehaus, Fedor, Green, Hackett, Hall, Hambley, Hayes, Henne, Hill, Howse, G. Johnson, Kunze, Landis, Leland, Maag, Manning, McClain, M. O'Brien, Patterson, Pelanda, Reece, Rogers, Romanchuk, Ruhl, Ryan, Schaffer, Scherer, Schuring, Sears, Sheehy, Slaby, Slesnick, K. Smith, R. Smith, Sprague, Stinziano, Strahorn, Sweeney, Sykes, Terhar, Young, Rosenberger

Sens. Tavares, Williams

BILL SUMMARY

MEDICATION SYNCHRONIZATION

- Requires that certain health insurers and the Medicaid program provide coverage for medication synchronization, which allows drugs that are dispensed for chronic diseases or conditions to be obtained on the same date each month.

- Authorizes a pharmacist to dispense a drug in a manner that varies from the drug's prescription for the purpose of medication synchronization.

CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

- Expands the circumstances under which a licensing board may suspend a license, certificate, or evidence of registration without a hearing for actions related to controlled substances and extends this authority to actions related to other dangerous drugs.

- Extends to three years (from two) the time that certain records related to controlled substances must be preserved or kept.

PHARMACISTS

- Requires a pharmacist to exercise professional judgment in determining the amount of a drug to dispense or sell under an existing provision that authorizes a pharmacist to dispense or sell up to a 30-day supply of a drug without a prescription for a patient on a consistent therapy with a drug that is not a controlled substance.

- Specifies certain information that must be included in a written consult agreement between a physician and a pharmacist for management of a patient's drug therapy.

- Clarifies that, with regard to certain immunities in existing law for pharmacists and physicians practicing under consult agreements, the pharmacist or physician must be acting in accordance with the consult agreement regarding the change in a drug for the immunity to apply.

PHYSICIAN ASSISTANTS

- Permits certain physician assistants who are licensed by the State Medical Board but not authorized to exercise physician-delegated prescriptive authority to become so authorized without obtaining a master's or higher degree.

- Modifies continuing pharmacology education requirements for physician assistants.

CERTIFICATE OF NEED

- Requires the Director of Health to accept for review one certificate of need application for the establishment, development, and construction of a new nursing home if certain conditions are met.

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CONTENT AND OPERATION

MEDICATION SYNCHRONIZATION

Coverage for medication synchronization

The bill requires certain health insurers and the Medicaid program, including Medicaid managed care organizations, to provide coverage for medication synchronization, if specified conditions are met.[1] "Medication synchronization" is defined by the bill as "a pharmacy service that synchronizes the filling or refilling of prescriptions in a manner that allows the dispensed drugs to be obtained on the same date each month."[2]

Implementation of coverage

The bill applies to all of the following types of health insurers: health insuring corporations, sickness and accident insurers, multiple employer welfare arrangements, and public employee benefit plans. In the case of these insurers, the bill governs policies, contracts, agreements, arrangements, or plans issued, created, delivered, renewed, established, or modified in Ohio on or after January 1, 2017. The bill applies to the Medicaid program, including Medicaid managed care organizations, also beginning January 1, 2017.[3]

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[1] R.C. 1739.05, 1751.68, 3923.602, 5164.7511, and 5167.12.

[2] R.C. 1751.68(A), 3923.602(A), 4729.20, and 5164.7511(A).

[3] Section 3.

The bill does not apply to health insurance that is part of employee benefits offered by private employers that self-insure their benefit programs. These programs are generally precluded from state regulation by the federal Employee Retirement Income Security Act (ERISA) (see "**ERISA**," below).

Conditions

Under the bill, an insurance policy, contract, agreement, arrangement, or plan and the Medicaid program, including Medicaid managed care organizations, must provide for medication synchronization if all of the following conditions are met:[4]

(1) In the case of private health insurers, the policy, contract, agreement, arrangement, or plan provides prescription drug coverage;

(2) The individual who is insured (the "insured") or is a Medicaid recipient elects to participate in medication synchronization;

(3) The insured or Medicaid recipient, the prescriber, and a pharmacist at a network pharmacy or pharmacy participating in the Medicaid program agree that medication synchronization would be in the best interest of the insured or the Medicaid recipient;

(4) The prescription drug is eligible for synchronization.

In order to be eligible for synchronization, a prescription drug must meet all of the following requirements:

(1) Be covered by the policy, contract, agreement, arrangement, or plan or the Medicaid program;

(2) Be prescribed for the treatment and management of a chronic disease or condition and be subject to refills;

(3) Satisfy all relevant prior authorization criteria;

(4) Not have quantity limits, dose optimization criteria, or other requirements that would be violated if synchronized;

(5) Not have special handling or sourcing needs, as determined by the policy, contract, agreement, arrangement, or plan, that require a single, designated pharmacy to fill or refill the prescription;

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[4] R.C. 1751.68(B), 3923.602(B), 5164.7511(B), and 5167.12(D).

(6) Be formulated so that the quantity or amount dispensed can be effectively divided in order to achieve synchronization;

(7) Not be a schedule II controlled substance, opiate, or benzodiazepine.

Achieving synchronization

To provide for medication synchronization, a policy, contract, agreement, arrangement, or plan and the Medicaid program must authorize coverage of a prescription drug subject to medication synchronization when the drug is dispensed in a quantity or amount that is less than a 30-day supply.[5] The bill, however, limits the dispensing of less than a 30-day supply to a single occurrence for each drug subject to synchronization, unless any of the following occur:[6]

(1) The prescriber changes the dosage or frequency of administration of the drug subject to synchronization;

(2) The prescriber prescribes a different drug.

Cost-sharing

The bill specifies that a policy, contract, agreement, arrangement, or plan and the Medicaid program must permit and apply a prorated daily cost-sharing rate for a supply of a prescription drug subject to medication synchronization that is dispensed at a network pharmacy or pharmacy participating in the Medicaid program.[7] In the case of private health insurers, the bill defines "cost-sharing" as the cost to an insured under a policy, contract, agreement, arrangement, or plan according to any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirements imposed by the policy, contract, agreement, arrangement, or plan.[8]

The bill further specifies that it does not require a policy, contract, agreement, arrangement, or plan or the Medicaid program to waive any cost-sharing requirements in its entirety.[9]

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[5] R.C. 1751.68(C), 3923.602(C), and 5164.7511(C).

[6] R.C. 1751.68(D), 3923.602(D), and 5164.7511(D).

[7] R.C. 1751.68(E)(1), 3923.602(E)(1), and 5164.7511(E)(1).

[8] R.C. 1751.68(A)(1) and 3923.602(A)(1).

[9] R.C. 1751.68(E)(2), 3923.602(E)(2), and 5164.7511(E)(2).

Dispensing fees

Under the bill, a policy, contract, agreement, arrangement, or plan and the Medicaid program cannot use payment structures that incorporate dispensing fees that are determined by calculating the days' supply of drugs dispensed. Dispensing fees must be determined exclusively on the total number of prescriptions that are filled or refilled.[10]

Incentives not required

The bill specifies that a private health insurer, public employee benefit plan, or the Medicaid program is not required to provide to a network pharmacy or pharmacist or pharmacy or pharmacist participating in the Medicaid program any monetary or other financial incentive for the purpose of encouraging the pharmacy or pharmacist to recommend medication synchronization to an insured.[11]

Applicability of mandated benefits legislation

The bill exempts its requirements regarding health insurer coverage of medication synchronization from an existing law that could prevent the requirements from being applied until a review by the Superintendent of Insurance has been conducted with respect to mandated health benefits.[12] 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 benefits plans that are subject to ERISA and (2) employee benefit plans established or modified by the state or its political subdivisions.[13] Under the bill, the coverage of medication synchronization is applicable and the Superintendent's hearing and determination are not required even if the bill's provisions are considered mandated benefits.

ERISA

ERISA is a comprehensive federal statute governing the administration of employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs. Larger employers

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[10] R.C. 1751.68(F), 3923.602(F), and 5164.7511(F).

[11] R.C. 1751.68(G), 3923.602(G), and 5164.7511(G).

[12] R.C. 1739.05, 1751.68(B), and 3923.602(B).

[13] R.C. 3901.71.

frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from a sickness and accident insurer or health insuring corporation.

Pharmacists

The bill authorizes a pharmacist to dispense a drug in a manner that varies from the drug's prescription by dispensing a quantity or amount that is less than a 30-day supply, if the pharmacist's action is taken solely for the purpose of medication synchronization.[14]

CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

Disciplinary action

Licensed professionals

The bill expands the circumstances under which a board that licenses professionals may suspend a license, certificate, or evidence of registration without a hearing for actions related to drugs. Under current law, if a licensing board determines there is clear and convincing evidence that continuation of a professional's practice or method of prescribing or personally furnishing controlled substances presents a danger of immediate and serious harm to others, the agency may suspend the license, certificate, or registration without a hearing. The bill permits a board to also take this action based on the professional's method of administering or dispensing controlled substances. This makes the provision applicable to professionals such as nurses who administer controlled substances and pharmacists who dispense them. The bill further permits a licensing board to take action based on the method of prescribing, administering, dispensing, or personally furnishing dangerous drugs that are not controlled substances.[15]

Under continuing law, a dangerous drug is essentially any drug that can legally be dispensed only on a prescription. A controlled substance is a dangerous drug that is subject to additional restrictions because of its potential for abuse. Controlled substances include such drugs as narcotics, depressants, and stimulants.

Terminal distributors of dangerous drugs

The bill modifies the circumstances under which the State Board of Pharmacy may suspend the license of a terminal distributor of dangerous drugs without a hearing.

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[14] R.C. 4729.20(B).

[15] R.C. 3719.121.

Under continuing law, a terminal distributor of dangerous drugs is generally a person or entity that is engaged in the retail sale of dangerous drugs. Terminal distributors include pharmacies, nursing homes, hospitals, and health care professionals who are authorized to prescribe drugs.[16]

Under current law, if the Board determines that there is clear and convincing evidence that the method used by a terminal distributor to distribute controlled substances presents a danger of immediate and serious harm to others, the Board may suspend the terminal distributor's license without a hearing. The bill expands this authority by permitting the Board to also take this action based on the terminal distributor's method of prescribing controlled substances. Furthermore, it extends the Board's authority to cases involving distributing or prescribing any dangerous drug, rather than only controlled substances[17]

Wholesale distributors of dangerous drugs

The bill grants the Board the authority to suspend the registration certificate of a registered wholesale distributor of dangerous drugs without a hearing if the Board determines there is clear and convincing evidence that the method used by the wholesale distributor to distribute dangerous drugs presents a danger of immediate and serious harm to others. The Board must follow the procedure in Ohio's Administrative Procedure Act (R.C. Chapter 119.). The suspension is to remain in effect until the Board's final adjudication unless the Board either removes the suspension or fails to issue its final adjudication order within 90 days after the hearing. If the final adjudication order is not issued within the 90-day period, the suspension becomes void on the 91st day.[18]

Preservation of records

The bill extends to three years (from two) the time that certain records pertaining to controlled substances must be preserved or kept. Under continuing law, the following records must be preserved or kept:[19]

(1) An official written order for any schedule II controlled substance must be preserved by each party to the transaction, including the person giving the order and the person who sells or dispenses the controlled substance.

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[16] R.C. 4729.01, not in the bill.

[17] R.C. 4729.571.

[18] R.C. 4729.561.

[19] R.C. 3719.04(B) and 3719.07(D).

(2) Every licensed health professional authorized to prescribe drugs must keep a record of all controlled substances received and a record of all controlled substances administered, dispensed, or used other than by prescription.

(3) Every person, other than a pharmacist, manufacturer, or wholesaler, who is authorized to purchase and use controlled substances must keep a record of all controlled substances purchased and used other than by prescription.

(4) Manufacturers and wholesalers must keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared by them, and of all controlled substances received or sold by them.

(5) Every category III terminal distributor of dangerous drugs must keep records of all controlled substances received or sold. Under continuing law, a category III terminal distributor may possess, have custody or control of, and distribute certain intravenous fluids, any dangerous drug, and any controlled substance.[20]

(6) Every person who sells or purchases for resale schedule V controlled substances that are exempt from certain laws pertaining to controlled substances must keep a record showing the quantities and kinds thereof received or sold. Schedule V controlled substances are substances, such as cough syrups, that contain both nonnarcotic materials and limited quantities of narcotic materials.

PHARMACISTS

Drugs dispensed without a prescription

For a patient who is on a consistent drug therapy with a drug that is not a controlled substance, current law authorizes a pharmacist to dispense or sell up to a 30-day supply without a prescription. The pharmacist may do this if all of the following conditions are met: (1) the pharmacy has a record of a prescription for the patient, but the prescription does not provide for a refill or the time permitted by Pharmacy Board rules for providing refills has elapsed, (2) the pharmacist is unable to obtain authorization to refill from the original prescriber or a health care professional responsible for the patient's care, and (3) in the pharmacist's professional judgment, the drug is essential to sustaining the patient's life or continuing drug therapy for a chronic condition and failure to supply the drug could result in harm to the patient's health. The

[20] R.C. 4729.54, not in the bill.

bill requires the pharmacist to exercise professional judgment in determining the amount of the drug to dispense or sell.[21]

Pharmacist consult agreements

Current law authorizes one or more pharmacists to enter into a consult agreement with one or more physicians to manage a patient's drug therapy if certain conditions are met.[22] The bill makes changes regarding the contents of a consult agreement and civil immunities.

Contents of a consult agreement

Current law requires a consult agreement to be in writing and to include (1) the diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid, (2) practice protocols, and (3) drug therapy management protocols. Regarding protocols, the bill instead provides that the agreement must contain a description of the (1) drugs or drug categories the agreement involves, and (2) procedures, decision criteria, and plan the pharmacist is to follow in acting under the consult agreement. The bill also requires that the agreement contain a description of how the pharmacist is to comply with recordkeeping and communication requirements in existing law.[23]

Immunity from civil liability

Current law provides certain immunities for pharmacists and physicians with regard to the actions of other parties to a consult agreement. Specifically, a pharmacist is not liable in a civil action for injury or loss to a person or property that arises from a physician's change in a drug for a patient whose drug therapy is being managed by the pharmacist under a consult agreement. A physician similarly is not liable for injury or loss arising from a pharmacist's change in a drug for a patient under a consult agreement, unless the physician authorized the specific change in the drug. The bill adds that for the immunity to apply, the pharmacist or physician must be acting in accordance with the consult agreement regarding the change.[24]

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[21] R.C. 4729.281(A).

[22] R.C. 4729.39(A).

[23] R.C. 4729.39(B)(3).

[24] R.C. 4729.39(D)(1)(a) and (b).

PHYSICIAN ASSISTANTS

Prescriptive authority

The bill permits certain physician assistants who are licensed by the State Medical Board and are not authorized to exercise physician-delegated prescriptive authority to become so authorized without obtaining a master's or higher degree. Under current law, a licensed physician assistant who is not authorized to exercise physician-delegated prescriptive authority must obtain a master's or higher degree to become eligible to exercise physician-delegated prescriptive authority. Under the bill, a licensed physician assistant may also become eligible to exercise physician-delegated prescriptive authority by meeting the conditions described in (1) or (2) below:[25]

(1) The physician assistant must either:

(a) Hold a current, valid license to practice as a physician assistant issued by another jurisdiction and have been in active practice in any jurisdiction throughout the three-year period immediately preceding the date of application for physician-delegated prescriptive authority;

(b) Hold a degree obtained from a program accredited by the Accreditation Review Commission on Education for the Physician Assistant and have at least three years' experience practicing as a physician assistant while on active duty in any of the United States armed forces, the national guard of any state, or the United States Public Health Service Commissioned Corps.

(2) The physician assistant must have had prescriptive authority while practicing as a physician assistant in another jurisdiction, any of the United States armed forces, the national guard of any state, or the United States Public Health Service Commissioned Corps.

Continuing education in pharmacology

The bill modifies the continuing pharmacology education requirements for physician assistants who have been granted physician-delegated prescriptive authority. Under current law, every two years, a physician assistant with physician-delegated prescriptive authority must complete 12 hours of continuing education in pharmacology from an accredited institution recognized by the State Medical Board. Under the bill, the continuing pharmacology education must be obtained through a program or course approved either by the Board or by a person who has been Board-authorized to approve continuing education programs and courses. If the Board

[25] R.C. 4730.11.

chooses to authorize persons to approve continuing pharmacology education programs and courses, the bill requires the Board to establish standards for granting that authority and to grant the authority in accordance with the standards.[26]

CERTIFICATE OF NEED

Application for new nursing home

The bill requires the Director of Health to accept for review one certificate of need application for the establishment, development, and construction of a new nursing home if the following conditions are met:[27]

(1) The application is submitted not later than 180 days after the bill's effective date.

(2) The new nursing home will be located in a county that has a population between 40,000 and 45,000 persons, as shown by the 2010 regular federal census.

(3) The new nursing home will be located in either (a) a distinct part of a building in which an existing residential care facility is operated, including a distinct part that is an addition to the building, or (b) a separate building located on the same property as an existing residential care facility.

(4) The new nursing home will have not more than 20 beds, all of which are (a) transferred from an existing nursing home located in a county that has a population between 135,000 and 140,000 persons and is contiguous to the county in which the new nursing home is to be located, (b) proposed to be licensed as nursing home beds, (c) proposed to be certified for participation in the Medicare program, and (d) not proposed to be certified for participation in the Medicaid program.

(5) After the proposed transfer of the beds, there will be existing nursing home beds remaining in the county from which the beds are transferred.

The bill prohibits the Director from denying the application on the grounds that the new nursing home is to have fewer than 50 beds and from requiring the applicant to obtain a waiver of the current minimum 50-bed requirement established by the Director.[28]

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[26] R.C. 4730.49.

[27] Section 4(B).

[28] Section 4(C).

HISTORY

ACTION	DATE
Introduced	03-11-15
Reported, H. Health & Aging	06-24-15
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