Ohio Legislative Service Commission

Final Analysis

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(As Passed by the General Assembly)

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

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Effective date: August 31, 2016

ACT 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 to facilitate medication synchronization.

Controlled substances and dangerous drugs

- Expands the circumstances under which a licensing board may suspend a license, certificate, or 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 when exercising authority 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 but not authorized to exercise physician-delegated prescriptive authority to become so authorized without obtaining a master's 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 to establish, develop, and construct a new nursing home containing up to 20 beds, if certain conditions are met.

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CONTENT AND OPERATION

MEDICATION SYNCHRONIZATION

Coverage for medication synchronization

The act requires certain health insurers and the Medicaid program, including Medicaid managed care organizations, to provide coverage for medication synchronization, if specified conditions are met. It defines "medication synchronization" 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."[1]

Implementation

The act applies to 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 act governs policies, contracts, agreements, arrangements, or plans issued, created, delivered, renewed, established, or modified in Ohio on or after January 1, 2017. The act applies to the Medicaid program, including Medicaid managed care organizations, also beginning January 1, 2017.[2]

The act 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).

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[1] R.C. 1739.05, 1751.68, 3923.602, 4729.20, 5164.7511, and 5167.12.

[2] Section 3.

Conditions

Under the act, health insurance that provides prescription drug coverage, and the Medicaid program, including Medicaid managed care organizations, must provide for medication synchronization if the following conditions are met:[3]

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

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

(3) The prescription drug is eligible for synchronization.

To be eligible for synchronization, a prescription drug must meet the following requirements:[4]

(1) Be covered by the health insurer 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 health insurer, that require a single, designated pharmacy to fill or refill the prescription;

(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 the initial synchronization of an insured or Medicaid recipient's prescriptions, the health insurer and the Medicaid program must provide coverage of a prescription drug that is subject to synchronization when the drug is dispensed in a

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

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

quantity or amount that is less than a 30-day supply. The act limits this requirement to a single occurrence for each drug subject to synchronization, unless either:[5]

(1) The prescriber changes the drug's dosage or frequency; or

(2) The prescriber prescribes a different drug.

The act similarly authorizes a pharmacist to dispense a drug in a manner that varies from the drug's prescription by dispensing less than a 30-day supply, if the action is taken solely to synchronize the patient's prescriptions.[6]

Cost-sharing

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

The act further specifies that it does not require a health insurer or Medicaid to waive any cost-sharing requirements in its entirety.[9]

Dispensing fees

Under the act, health insurers and the Medicaid program cannot use payment structures that incorporate dispensing fees based on the days' supply of drugs dispensed. Dispensing fees must be determined exclusively on the total number of prescriptions that are filled or refilled.[10]

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

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

[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).

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

Incentives not required

The act specifies that a private health insurer, public employee benefit plan, or the Medicaid program is not required to give a pharmacy or pharmacist a financial incentive to recommend medication synchronization to an insured or recipient.[11]

Exemption from mandated benefits review

The act exempts its requirements regarding health insurer coverage of medication synchronization from the existing law that could prevent them from being applied until a review by the Superintendent of Insurance.[12] Under continuing 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 by the state or its political subdivisions.[13] Under the act, coverage for medication synchronization applies and the Superintendent's hearing and determination are not required even if the act's provisions are considered mandated benefits.

CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

Disciplinary action

Licensed professionals

The act 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 continuing law, if a licensing board determines there is clear and convincing evidence that continuing 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 act permits a board to also take this action based on the professional's method of "administering or dispensing" (in addition to "prescribing or personally furnishing") controlled substances. This makes the provision apply to professionals such as nurses who administer controlled substances and pharmacists who dispense them. The act further permits a licensing

[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, not in the act.

board to take action based on the method of prescribing, administering, dispensing, or personally furnishing dangerous drugs that are not controlled substances.[14]

Terminal distributors of dangerous drugs

The act modifies the circumstances under which the State Board of Pharmacy may suspend the license of a terminal distributor of dangerous drugs without a hearing. Under continuing 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 act 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 by including cases involving distributing or prescribing any dangerous drug, rather than only controlled substances.[15]

Terminal distributors are persons and entities engaged in the retail sale of dangerous drugs. They include pharmacies, nursing homes, hospitals, and health care professionals who are authorized to prescribe drugs.[16]

Wholesale distributors of dangerous drugs

The act authorizes the Board 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 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 remains 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 90 days, the suspension becomes void on the 91st day.[17]

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[14] R.C. 3719.121.

[15] R.C. 4729.571.

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

[17] R.C. 4729.561.

Preservation of records

The act 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:[18]

(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.

(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, 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.

(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.

PHARMACISTS

Drugs dispensed without a prescription

The act requires a pharmacist to exercise professional judgment in determining the amount of a drug to dispense or sell under a law otherwise unchanged by the act that authorizes a pharmacist to dispense or sell up to a 30-day supply without a prescription. Under continuing law, in the case of a patient who is on a consistent drug therapy with a drug that is not a controlled substance, a pharmacist may generally dispense up to a 30-day supply without a prescription if: (1) the pharmacy has a record of a prescription for the patient, but the prescription does not provide for a refill or the time for providing refills has elapsed, (2) the pharmacist is unable to obtain

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

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.[19]

Pharmacist consult agreements

Continuing law authorizes one or more pharmacists to enter into a consult agreement with one or more physicians to manage a patient's drug therapy.[20] The act makes changes regarding the contents of a consult agreement and civil immunities.

Contents of a consult agreement

The act requires a written consult agreement to 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. This replaces a more general prior requirement that the agreement include practice protocols and drug therapy management protocols.

The act also requires the agreement to contain a description of how the pharmacist is to comply with recordkeeping and communication requirements in continuing law unchanged by the act.[21]

Immunity from civil liability

Continuing law provides that 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 the pharmacist manages 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 act adds that for the immunity to apply, the pharmacist or physician must be acting in accordance with the consult agreement regarding the change.[22]

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

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

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

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

PHYSICIAN ASSISTANTS

Prescriptive authority

The act 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 the act, a licensed physician assistant may become eligible to exercise physician-delegated prescriptive authority without obtaining a master's or higher degree if the physician assistant meets the conditions described in (1) and (2) below:[23]

(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 throughout the three-year period preceding application for physician-delegated prescriptive authority; or

(b) Hold a degree 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 the U.S. armed forces, the national guard of any state, or the U.S. Public Health Service Commissioned Corps.

(2) The physician assistant must have had prescriptive authority while practicing in the other jurisdiction, the armed forces or national guard, or the Public Health Service Commissioned Corps.

Continuing education in pharmacology

The act modifies the continuing pharmacology education requirements for physician assistants who have been granted physician-delegated prescriptive authority. Under continuing law, every two years, a physician assistant with the authority must complete 12 hours of continuing education in pharmacology. The act repeals a requirement that the institution from which the continuing education is obtained be accredited and have received recognition from the State Medical Board. Instead, the act requires the continuing pharmacology education be obtained through a program or course that has been approved either by the Board or by a person who has been Board-authorized to approve continuing education programs and courses. Under the act, if the Board chooses to authorize persons to approve continuing pharmacology education

[23] R.C. 4730.11.

programs and courses, the Board must do so in accordance with standards that it establishes.[24]

CERTIFICATE OF NEED

Application for new nursing home

The act 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 containing up to 20 beds, if the following conditions are met:[25]

(1) 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.

(2) 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.

(3) The new nursing home will not have more than 20 beds, all of which are (a) transferred from an existing nursing home in a contiguous county that has a 2010 population between 135,000 and 140,000, (b) proposed to be licensed as nursing home beds, (c) proposed to be certified for the Medicare program, and (d) not proposed to be certified for the Medicaid program.

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

(5) The application for the certificate of need is submitted by February 27, 2017 (180 days after the act's effective date).

The act does not name the county in which the new nursing home must be located; however, the only counties that satisfy the act's conditions are Madison County and Champaign County, which have populations of 43,435 and 40,097 people, respectively. Additionally, the nursing home beds must be transferred from an existing nursing home in Clark County, which has a population of 138,333 people. According to the 2010 regular federal census, Madison County and Champaign County are the only

[24] R.C. 4730.49.

[25] Section 4(B).

counties that have a population between 40,000 and 45,000 people and border a county (i.e., Clark County) with a population between 135,000 and 140,000.[26]

The act 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 Director's current 50-bed minimum.[27]

HISTORY

ACTION	DATE
Introduced	03-11-15
Reported, H. Health & Aging	06-24-15
Passed House (92-0)	06-30-15
Reported, S. Medicaid	04-25-16
Passed Senate (33-0)	05-04-16
House concurred in Senate amendments (96-0)	05-11-16

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[26] Ohio Development Services Agency. "Census 2010 Population Counts for Counties," available at https://development.ohio.gov/reports/reports_census2010_map.htm.

[27] Section 4(C).