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Bill Analysis
Legislative Service Commission

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(As Introduced)

Reps. Hagan, Miller

BILL SUMMARY

- Expands eligibility for the Ohio's Best Rx Program by including (1) persons with family income between 250% and 300% of the federal poverty guidelines, (2) persons discharged from employment due to a business reorganization, (3) persons with drug coverage under Workers' Compensation, and (4) persons with drug coverage under a Medicare prescription drug plan, if responsible for the full cost of the drug being purchased.
- Requires that a person's eligibility be confirmed each time a drug is purchased under the Program.
- Permits the submission of a formula, in lieu of individual information for each drug, with regard to the drug pricing and rebate information that must be submitted to the Program by the Department of Administrative Services and the five state retirement systems.
- Requires a drug manufacturer participating in the Program to make payments that are based on its best estimate of the average rebates that apply under the health benefit plans offered to state employees and retirees, when information is not available to make the computation of the plans' average rebates.
- Requires a manufacturer to make aggregate payments to reconcile any difference between its best estimate payments and the plans' average rebates, if the applicable computations can be made within 12 months.
- Requires the Ohio Department of Job and Family Services (ODJFS) to seek confirmation from the Centers for Medicare and Medicaid Services

that manufacturer payments under the Program are exempt from the federal Medicaid "best price" computation.

- Eliminates provisions pertaining to the placement of a drug on a "prior authorization list" used under the health benefit plans offered to state employees and retirees if a drug manufacturer has not entered into an agreement to make payments to the Program for that drug.
- Permits manufacturer agreements with the Program to include terms establishing a process for referring Program participants to the manufacturer's patient assistance programs.
- Permits ODJFS to accept donations, which are to be included in ODJFS' determination of whether it is necessary to charge fees to cover the Program's administrative costs.
- Specifies the process to be used by ODJFS in delegating its powers and duties through a contract with a Program administrator.
- Provides that statutory references to ODJFS are references to the Program administrator if a particular power or duty has been delegated.
- Specifies that the Program may have only one drug mail order system, clarifies that a professional fee cannot be charged for dispensing a drug through mail order system, and clarifies statutory references to the mail order system.
- Permits applications for participation in the Program to be submitted on paper forms or under any other application method ODJFS makes available, including applications by telephone or through the Internet.

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CONTENT AND OPERATION

Overview of the Ohio's Best Rx Program

Under the Ohio's Best Rx Program, eligible persons who enroll may purchase drugs at discounted prices. To be eligible, a person generally must not have another form of drug coverage and must either (1) be 60 years of age or older or (2) have a family income not exceeding 250% of the federal poverty guidelines.

The Program's discounted drug prices are derived from the average prices that apply under the health care benefits plans offered to state employees and retirees. The Program's price for a drug is further discounted if the drug's manufacturer participates in the Program by agreeing to make rebate payments.

When a drug is purchased under the Program, the amount saved is to be reported to the participant. Professional fees and administrative costs may be included in the amount the participant is charged, but the participant cannot be charged more than the amount that would have been paid without using the Program's benefits.

Drugs may be purchased from any participating "terminal distributor of dangerous drugs."¹ In addition, drugs may be purchased through the Program's drug mail order system. If a rebate applies to the drug that is purchased, the Program reimburses the pharmacy for the amount of the rebate that applied to the transaction.

¹ Under current law, pharmacies and other entities that sell drugs at retail are licensed as "terminal distributors of dangerous drugs." A "dangerous drug" is generally a drug that is available only by prescription. (R.C. 4729.01, not in the bill.)

The Ohio Department of Job and Family Services (ODJFS) must administer the Program, unless it chooses to contract with a person to serve as the Program's administrator. The contract may require the administrator to perform any of ODJFS' functions under the Program, other than the adoption of administrative rules and the employment of an ombudsperson.

Eligibility expansion

(R.C. 5110.05)

To be eligible for the Ohio's Best Rx Program, current law requires that an individual meet the following requirements at the time of application for the Program:

(1) The individual must be a resident of Ohio.

(2) The individual must either (a) be 60 years of age or older or (b) have family income that does not exceed 250% of the federal poverty guidelines.

(3) The individual must not have outpatient drug coverage paid for by a third-party payer, such as an insurance company or employer, or by a publicly funded health program, such as Medicaid, the Children's Health Insurance Program (CHIP), or Disability Medical Assistance (DMA).

(4) If under age 60, the individual must not have had outpatient drug coverage during any of the four months preceding the month in which the individual applies for the Program. This four-month waiting period, however, does not apply when any of the following occurs: (a) the third-party payer that paid for the coverage filed for bankruptcy under federal law, (b) the individual is no longer eligible for coverage provided through a retirement plan subject to protection under the federal Employee Retirement Income and Security Act (ERISA), or (c) the individual is no longer eligible for Medicaid, CHIP, or DMA.

The bill expands eligibility for participation in the Ohio's Best Rx Program by making the following changes:

--Family income: The bill increases the Program's family income limitation to 300% (from 250%) of the federal poverty guidelines.

--Loss of coverage from business reorganizations: The bill exempts an individual from the Program's four-month waiting period after drug coverage ends if the coverage ended because the individual is temporarily or permanently discharged from employment due to a business reorganization.

--Workers' Compensation: The bill provides that drug coverage under the Workers' Compensation Program does not render a person ineligible for the Ohio's Best Rx Program.

--Medicare Part D: The bill provides that drug coverage under a Medicare prescription drug plan does not render a person ineligible, but only if all of the following are the case with respect to the particular drug being purchased through the Ohio's Best Rx Program:

- (1) The person is responsible for the full cost of the drug;
- (2) The drug is not subject to a rebate from the manufacturer under the person's Medicare prescription drug plan;
- (3) The manufacturer has agreed to the Program's inclusion of persons who have coverage through a Medicare prescription drug plan.

Employer-funded drug coverage

(R.C. 3901.38 (not in the bill), 5110.01, and 5110.05)

The bill includes provisions that refer to having employer-funded drug coverage as a reason that renders a person ineligible to participate in the Program. The bill also includes provisions specifying that the Program's four-month waiting period after employer-funded drug coverage ends is not applicable when the coverage ends because the employer filed for bankruptcy under federal law. These provisions may be duplicative, however, because current law applies the same provisions to a "third-party payer," which is defined as including an employer.

Verifying eligibility at the time of purchase

(R.C. 5110.09)

Under the bill, each time a drug is purchased under the Program, the eligibility of the participant for whom the drug is purchased must be confirmed through ODJFS. If the Program enrollment card that was issued to the participant is available for presentation at the time of purchase, the purchaser must present the enrollment card to the participating terminal distributor dispensing the drug.²

² As a result of the bill's provisions distinguishing "participating terminal distributors" from the Program's drug mail order system, the requirement that the enrollment card be presented does not apply when the mail order system is used to purchase a drug.

Average drug prices and rebates under state health benefit plans

(R.C. 5110.01 and 5110.26)

Current law requires the Department of Administrative Services (DAS) and the five state retirement systems to submit to ODJFS information regarding the drug prices and rebates that apply under the health benefit plans offered to state employees and retirees. For each drug, DAS and the retirement systems must compute and submit information separately for each of the drug's national code numbers.

The bill authorizes DAS and the retirement systems to submit the information by either (1) computing individual information for each of the drug's national drug code numbers or (2) submitting a formula that would permit the determination of individual information. The bill also specifies that the per unit price information for the drugs is not to include any amount paid as an administrative fee for dispensing the drugs.

Drug manufacturer payments

(R.C. 5110.21)

Current law permits a drug manufacturer to enter into an agreement with ODJFS to make rebate payments to the Ohio's Best Rx Program. When a drug included in the agreement is purchased, the Program's discounted price for the drug is further reduced by the amount of the rebate. ODJFS may retain up to 5% of the rebate for administrative costs. The entity that dispenses the drug is reimbursed by the Program for the amount of the rebate provided.

The bill replaces references to "rebate agreements" and "rebate payments" with references to "manufacturer agreements" and "manufacturer payments." It clarifies that any drug manufacturer may enter into a manufacturer agreement for purposes of participating in the Ohio's Best Rx Program.

Payments based on best estimate of state health benefit plan averages

(R.C. 5110.21(D)(3)(b))

For each drug included in a rebate agreement, the amount to be paid by the manufacturer is specified as a "per unit" amount. The manufacturer must agree to pay an amount that is equal to or greater than the weighted average per unit rebate that applies to the drug under the health benefit plans offered to state employees and retirees. If no computation of the plans' weighted average rebate can be made, the manufacturer must specify the per unit amount that will be paid.

If the plans' weighted average rebate for a drug cannot be computed because ODJFS has not received the necessary information from DAS and the state retirement systems, the bill requires the manufacturer to use its best efforts to ensure that it specifies a per unit payment amount for the drug that is equal to or greater than its estimate of the plans' weighted average per unit rebate for the drug. If the computation can be made later, and it is determined that the manufacturer's specified payment amount was less than the plans' weighted average rebate, the bill requires the manufacturer to make aggregate payments to ODJFS to reconcile the difference.

Aggregate payments

(R.C. 5110.21(D)(3)(c))

The bill's aggregate payment provisions apply only if the computations pertaining to rebates under health benefit plans for state employees and retirees can be made within 12 months after the manufacturer enters into a manufacturer agreement. If a manufacturer is subject to the aggregate payment requirement, the amount to be paid is equal to the difference between (1) the total amount of the per unit payments that were made under the agreement and (2) the total amount that would have been paid by using the weighted average per unit rebates applicable under the health benefit plans offered to state employees and retirees.

The bill requires ODJFS to promptly notify the manufacturer of the amount owed. The manufacturer must make the aggregate payment not later than 30 days after receiving the notice. Aggregate payments are to be deposited to the credit of the existing Ohio's Best Rx Program Fund.

Applicability of the best estimate and aggregate payment provisions

The bill specifies that existing manufacturer rebate agreements for participation in the Program are not subject to the bill's provisions requiring a drug manufacturer to use its best estimate of the weighted average rebates applicable under the health benefit plans offered to state employees and retirees. Likewise, existing agreements are not subject to the bill's requirement that aggregate payments be made if the best estimate amount is later determined to be less than the plans' weighted average rebate.

Medicaid best price

(R.C. 5110.21(F))

Under federal law, drug manufacturers are required to enter into rebate agreements with the federal government as a condition of having their outpatient drugs covered by Medicaid. For each drug, the manufacturer must submit

quarterly reports on the "average manufacturer price." If a brand name drug is still under patent protection, the manufacturer also must submit reports on the drug's "best price," which is defined by federal law as lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. The prices are used to determine future Medicaid reimbursement and the amount of the rebate to be paid.³

The bill requires ODJFS to seek written confirmation from the Centers for Medicare and Medicaid Services that manufacturer payments under the Ohio's Best Rx Program are exempt from the federal Medicaid "best price" computation. The bill specifies that its provisions do not require a manufacturer to make a payment that would establish the manufacturer's Medicaid best price for a drug.

Prior authorization lists

(R.C. 5110.22 (repealed))

If a drug manufacturer has not entered into a rebate agreement with the Ohio's Best Rx Program with respect to a drug for which the manufacturer provides a rebate to a state health benefit plan or state retirement system health benefit plan, current law requires ODJFS to ask the Department of Administrative Services and each state retirement system to determine whether the drug should be placed, for the following plan year, on a "prior authorization list." Additions to prior authorization lists must be made in accordance with state law and applicable collectively bargained agreements.

The bill eliminates the provisions pertaining to the placement of a drug on a state or retirement system health benefit plan's prior authorization list.

Referrals to patient assistance programs

(R.C. 5110.21(C))

For each drug included in a manufacturer agreement, the bill permits the agreement to establish a process for referring Ohio's Best Rx Program applicants to patient assistance programs operated by the manufacturer, if the manufacturer agrees to refer to the Program residents of Ohio who apply but are ineligible for the manufacturer's patient assistance programs.

³ 42 United States Code 1396r-8(c); *Commerce Clearing House, Medicare and Medicaid Guide, paragraph 14,591.*

Donations

(R.C. 5110.32, 5110.33, 5110.353, and 5110.354)

The existing Ohio's Best Rx Program Fund consists of the rebates provided by drug manufacturers, the administrative fees that ODJFS may charge under the Program, and the Fund's investment earnings. Money in the Fund is to be used to make payments to terminal distributors for the amount of the rebates that apply when drugs are purchased under the Program.

In addition to the other amounts in the Fund, the bill provides for the Fund to contain any amounts donated to the Fund and accepted by ODJFS. The donated amounts are to be included in ODJFS' determinations of whether it is necessary to charge fees to cover the Program's administrative costs.⁴

Delegation of program administration by contract

(R.C. 5110.02; 5110.10 and 5110.11 (repealed))

Current law requires ODJFS to administer the Ohio's Best Rx Program, but also authorizes ODJFS to contract with a person to be the Program's administrator. The contract may require the administrator to perform any of ODJFS' duties, other than the adoption of rules and employment of the Program's ombudsperson.

The bill delineates the delegation process to be used by ODJFS when entering into a contract for a Program's administrator and certain effects of the delegation. Specifically, the bill provides the following:

(1) The terms of the contract must specify the extent to which the powers or duties are delegated to the Program administrator.

(2) In exercising powers or performing duties delegated under the contract, the administrator is subject to the same statutes that grant the powers or duties to ODJFS, as well as any limitations or restrictions that are applicable to or associated with those powers or duties.

(3) Wherever ODJFS is referred to in a statute relative to a delegated power or duty, both of the following are the case:

⁴ *The bill also provides for the donated amounts to be included in the Ohio's Best Rx Administration Fund, which is to be used to pay the administrative costs of the Program (R.C. 5110.33). An amendment may be necessary to clarify that the donations made to the Program Fund can be transferred to the Administration Fund.*

--If ODJFS has delegated the power or duty in whole, the reference to ODJFS is, instead, a reference to the administrator.

--If ODJFS retains any part of the delegated power or duty, the reference to ODJFS is a reference to both ODJFS and the administrator.

(4) ODJFS is not permitted to delegate the authority to enter into contracts for a Program administrator.

Statutory references to the Program administrator

(R.C. 5110.01, 5110.02, 5110.13, 5110.18, 5110.55, 5110.58, and 5110.59)

The bill eliminates the statutory definition of "Ohio's Best Rx Program administrator," as well as the use of that term within the statutes governing the Program. Instead, the bill provides that any statutory reference to ODJFS is a reference to the Program administrator if the power or duty described in the statute is delegated in ODJFS' contract with the administrator.

Mail order system

(R.C. 5110.01, 5110.02(B)(4), 5110.10 (repealed), 5110.11, 5110.14(B), 5110.15(B), and 5110.352)

Under current law, the person under contract to be the Ohio's Best Rx Program administrator is required to offer a drug mail order system. ODJFS must adopt rules establishing standards and procedures governing the operation of the system. Existing law is not consistent in specifying whether a professional fee may be charged when a drug is purchased through the system, but ODJFS' rules do not permit the system to charge a professional fee.⁵

The bill specifies that not more than one mail order system may be included within the Program. It also clarifies that a professional fee cannot be charged when a drug is dispensed through the mail order system.

Rather than basing the mail order system's discounted price for a drug on the weighted average price paid under health benefit plans for state employees and retirees, the bill provides that the mail order's system's price is subject to rules adopted by ODJFS. The price, however, cannot exceed the price that would have been charged for the same drug by other terminal distributors participating in the Program.

⁵ *Ohio Administrative Code 5101:13-1-06(E)(13)(c).*

The bill expressly requires ODJFS to include the mail order system within the Program, but specifies that the terms of any contract for a Program administrator must include provisions for offering a system. Under the bill, the contract may permit the administrator to offer the drug mail order system by contracting with another person.

Statutory references to the mail order system

(R.C. 5110.01, 5110.16, 5110.17, 5110.19, 5110.29, 5110.57, and 5110.58)

In addition to defining the term "Ohio's Best Rx Program administrator" to mean the person under contract with ODJFS to perform delegated functions, current law defines the term as meaning the person that offers the Program's drug mail order system.

In the statutes that use the term "Ohio's Best Rx Program administrator" in the context of the drug mail order system, the bill eliminates the use of that term. Instead, the bill refers to the "drug mail order system included in the Program."

Distinguishing the mail order system from other terminal distributors

(R.C. 5110.18, 5110.23, and 5110.39)

In distinguishing the mail order system from other terminal distributors under the Program, the bill does all of the following:

(1) Provides that the mail order system cannot be charged for the submission or processing of a claim under the Program;

(2) Requires ODJFS to include the name of the mail order system in the list it compiles of other terminal distributors participating in the Program;

(3) Provides for the mail order system's drug prices to be included in ODJFS' calculation of the average annual percentage savings obtained by Program participants.

Application procedures

(R.C. 5110.01, 5110.06, 5110.08, 5110.35, and 5110.351 (repealed))

The bill makes the following changes to the application procedures used to obtain an Ohio's Best Rx Program enrollment card:

(1) Eliminates the requirement that ODJFS prescribe the application form in administrative rules;

(2) Allows an individual to apply by submitting a paper form prescribed and supplied by ODJFS or pursuant to any other application method ODJFS makes available, including methods that permit an individual to apply by telephone or through the Internet;

(3) Provides that ODJFS' rules governing the application process must include a process to be used in certifying that an applicant has attested to the accuracy of the information and documentation submitted with the application;

(4) Specifies that an applicant's signature on a paper form must be used to certify the applicant's attestation of accuracy.

Technical and other conforming changes

As part of the provisions described above, the bill makes numerous technical and conforming changes. In addition to those changes, the bill does the following:

--Replaces the definitions of "administrative fee," "rebate administration percentage," and "rebate agreement" with statutory cross-references to the operative provisions of law on which the definitions are based (R.C. 5110.01 and 5110.56);

--Replaces the phrases "covered by a rebate agreement" and "subject to a rebate agreement" with the phrase "included in a manufacturer agreement," in reference to the drugs for which a manufacturer has agreed to make payments to the Program (R.C. 5110.03, 5110.14(A), 5110.27, and 5110.29);

--Replaces the phrase "outpatient prescription drug coverage" with "coverage for outpatient drugs," in reference to the Program's eligibility requirement that an individual not have other forms of drug coverage (R.C. 5110.05);

--Distinguishes "participating terminal distributors" from the Program's mail order system by specifying that ODJFS enters into agreements with participating terminal distributors for purposes of making drugs available through distributors other than the Program's mail order system (R.C. 5110.12);

--Relocates the statutes describing the method to be used in computing weighted averages pertaining to the health benefit plans offered to state employees and retirees (R.C. 5110.21, 5110.27, and 5110.28 (repealed));

--Modifies ODJFS' rule-making authority to conform with the bill's provisions (R.C. 5110.35);

--Makes conforming changes in other statutes that contain references to the Program (R.C. 127.16 and 2921.13).

HISTORY

ACTION	DATE
Introduced	01-11-06

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