Alan Van Dyne *Legislative Service Commission*

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(As Passed by the Senate)

Sens. Spada, Hagan, Armbruster, Dann, Fedor, Goodman, Harris, Kearney, D. Miller, Mumper, Padgett, Roberts, Zurz, Niehaus, Gardner

BILL SUMMARY

Basis for drug pricing and manufacturer payments

- Eliminates all provisions under which the Ohio's Best Rx Program's drug prices and manufacturer rebates are based on the weighted average prices and rebates that apply under the health benefit plans offered to state employees and retirees.

- Eliminates all duties of the Department of Administrative Services and the five state retirement systems relative to the Program.

- Replaces the Program's drug pricing system and manufacturer payment standards with the following provisions:

  (1) The Ohio Department of Job and Family Services (ODJFS) must annually designate formulas for use in establishing the Program's base price for each drug dispensed by participating pharmacies. The prices for drugs dispensed through the Program's mail order system are subject to ODJFS's administrative rules.

  (2) When a drug manufacturer chooses to enter into an agreement to participate in the Program by making payments for a particular drug, the manufacturer must specify a "per unit" payment amount for the drug that the manufacturer believes is greater than or comparable to the payment amount generally payable by the manufacturer for the same drug when dispensed to a person using the health benefits provided to state employees and retirees in Ohio or another state.

Consulting pharmacy benefit manager

- Requires any pharmacy benefit manager (PBM) that provides services relative to the outpatient drug coverage included in a health benefit plan

offered to the employees or retirees of a state agency or political subdivision in Ohio to serve as a "consulting PBM" for the Ohio's Best Rx Program, if the PBM is selected by ODJFS to serve in that capacity.

- Requires the selected PBM to serve as the Program's consulting PBM for one year, permits the PBM to be selected for succeeding years, and requires the PBM to provide its services without charge.

- Allows ODJFS to ask the Attorney General to apply for an injunction if the PBM fails to fulfill its duties as the Program's consulting PBM.

Verification services provided by the consulting PBM

- Identifies the consulting PBM's duties as verification of the Program's drug pricing formulas and manufacturer payments and requires ODJFS to use the information derived from the PBM's verification services when designating the Program's pricing formulas and negotiating for payments from drug manufacturers.

- Establishes the following procedures for the provision of verification services by the consulting PBM:

  --**Brand name drug prices**: The consulting PBM must compare ODJFS's formula to the formula most commonly used by the PBM and verify whether the discount percentage included in ODJFS's formula is more than two percentage points below the discount percentage included in the PBM's formula.

  --**Generic drug prices**: ODJFS must identify the 50 generic drugs most frequently purchased under the Program in the preceding year and the weighted average base price that resulted from its generic drug pricing formula. The consulting PBM must compare ODJFS's weighted average base price for the drugs to the equivalent part of the PBM's weighted average payment rate for the same drugs. The consulting PBM must verify whether the discount percentage reflected in ODJFS's weighted average base price is more than two percentage points below the discount percentage included in the PBM's weighted average payment rate.

--**Manufacturer payment amounts**: Annually, ODJFS must select ten drugs included in manufacturer agreements in the preceding year and submit information on the per unit payment amount for those drugs to the consulting PBM. The consulting PBM must verify whether any of the payment amounts were more than 2% lower than the payment amounts negotiated by the PBM for the same drugs. If so, the PBM must identify which of the drugs were subject to the lower payment amounts. ODJFS may publish aggregate information about the drugs in the sample that had the same or higher payment amounts. ODJFS is no longer authorized to ask that a drug be placed on a prior authorization list used by the health benefit plans offered to state employees and retirees when the plans receive a manufacturer rebate for the drug, but the manufacturer has not entered into an agreement to make payments to the Program for that drug.

Audits of the consulting PBM

- Permits ODJFS to ask the consulting PBM to provide for an audit of its relevant contracts with drug manufacturers and pharmacies to determine whether the PBM has provided valid information when verifying the Program's drug pricing formulas and manufacturer payment amounts.

- Authorizes ODJFS to ask for a regularly occurring audit every three years and to ask for a special audit at any time it believes the consulting PBM is not acting in good faith.

- Requires ODJFS to pay the cost of a special audit if the audit findings demonstrate that the PBM acted in good faith and the Director of ODJFS did not specify in writing the reason for requesting the audit.

Confidentiality regarding the consulting PBM

- Provides for the confidentiality of the information provided by a consulting PBM through its verification services, as well as the information contained in or derived from the audits of the PBM.

- Requires all records received from the consulting PBM to be destroyed promptly after ODJFS has completed the purpose for which the information in the records was obtained.

- Prohibits ODJFS from delegating its functions related to the receipt of information from the consulting PBM or an audit of the PBM to any person serving under contract with ODJFS as the Program's administrator.

Eligibility expansion

- Expands eligibility for participation in the Program as follows:

  --**Income level**: Increases the Program's family income limitation to 300% (from 250%) of the federal poverty guidelines.[1]

  --**Loss of coverage from business reorganization**: Exempts a person from the Program's four-month waiting period after drug coverage ends if the coverage ended due to being temporarily or permanently discharged from employment as the result of a business reorganization.

  --**Workers' Compensation**: Provides that drug coverage under the Workers' Compensation Program does not cause a person to be ineligible for the Ohio's Best Rx Program.

  --**Medicare Part D**: Provides that drug coverage under a Medicare prescription drug plan does not make a person ineligible, but only if all of the following are the case for the particular drug being purchased: (1) the person is responsible for the full cost, (2) the drug is not subject to a rebate from the manufacturer under the person's Medicare plan, and (3) the manufacturer has agreed to the Program's inclusion of persons with Medicare drug coverage.

Application process

- Specifies that the Program's application process may include procedures for submitting applications by telephone or through the Internet.

Annual reapplication

- Eliminates the requirement that Program participants reapply each year for enrollment in the Program.

- Eliminates all provisions related to the annual expiration of a person's enrollment in the Program.

Confirming enrollment

- Requires the entity dispensing a drug under the Program to confirm a person's enrollment.

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[1] *Persons age 60 or older are not subject to an income limitation under the Ohio's Best Rx Program.*

- Specifies that a person's enrollment may be confirmed by telephone, through the Internet, or by any other electronic means when the person's enrollment card or Program identification number is unavailable at the time a drug is being purchased.

Referrals to patient assistance programs

- Provides that a drug manufacturer's payment agreement with the Program may include terms under which Program participants are referred to patient assistance programs operated by the drug manufacturer, if the manufacturer also agrees to make referrals to the Program.

Medicaid best price

- Requires ODJFS to seek confirmation from the Centers for Medicare and Medicaid Services that a drug manufacturer's payments under the Ohio's Best Rx Program are exempt from the manufacturer's "best price" computations that are used to establish the amount of the manufacturer's rebate payments under Medicaid.

Donations

- Permits ODJFS to accept donations to the Program, which are to be included in ODJFS's determination of whether it is necessary to charge fees to cover the Program's administrative costs.

Subsidies for drug costs

- Permits ODJFS to provide Program participants with subsidies, if funds are available, to assist them with the cost of purchasing drugs through the Program, including the cost of any dispensing fees charged.

Delegation of duties to a Program administrator

- Specifies the process to be used by ODJFS in delegating powers and duties under its authority to contract with a person to serve as the Program's administrator.

- Provides that statutory references to ODJFS are references to the Program administrator if a particular power or duty has been delegated.

Mail order system

- Specifies that the Program may have only one drug mail order system.

- Clarifies that the mail order system is not permitted to charge a professional fee for dispensing a drug under the Program.

- Prohibits ODJFS and the drug mail order system from promoting the purchase of drugs through the system by using information collected under the Program regarding the drugs purchased by participants from other participating pharmacies.

Covered drugs

- Requires the Program to include discounted prices for all drugs that require a prescription.

Program purpose

- Specifies that the purpose of the Program is to provide outpatient prescription drug discounts to Ohio residents enrolled in the Program by meeting its eligibility requirements, including eligible persons who are age 60 or older, eligible persons who have low incomes but are not eligible for Medicaid, and other eligible individuals who do not have health benefits that cover outpatient drugs.

Transfer to the Department of Aging

- Requires the Department of Aging, rather than ODJFS to administer the Program beginning July 1, 2007.

- Transfers to the Department of Aging all of the Program's functions, obligations, administrative rules, orders, determinations, employees, and unexpended funds.

- Permits the Department of Aging, in anticipation of the Program's transfer, to enter into a contract with a person to serve as the Program's administrator beginning on or after July 1, 2007.

Interaction with the Golden Buckeye Card Program

- Eliminates on July 1, 2007, the prescription drug discount component of the Golden Buckeye Card Program.

- Adds persons with disabilities who qualify for the Golden Buckeye Card Program as a category of persons who are eligible for the Ohio's Best Rx Program.

- Permits the Department of Aging to coordinate the Ohio's Best Rx Program with the basic Golden Buckeye Card Program.

- Authorizes the establishment of a card that serves as both a Golden Buckeye Card and an Ohio's Best Rx Program enrollment card, identified by including the names of both programs on the card or a combined name selected by the Department of Aging.

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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."[2] 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.

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's functions under the Program, other than the adoption of administrative rules and the employment of an ombudsperson.

Basis for drug prices and manufacturer payments under the Program

(R.C. 5110.26 (repealed), 5110.27 (repealed), and 5110.28 (repealed); Section 3)

Current law requires the Department of Administrative Services (DAS) and the five state retirement systems to submit to ODJFS information regarding the drug prices that apply under the health benefit plans offered to state employees and retirees. The information submitted must include the formula used to determine the drug prices, the per unit price for each drug, or both. Using the submitted information, ODJFS must compute the weighted average per unit price for each drug. The weighted average per unit price is used as the basis for the discounted drug price that applies under the Ohio's Best Rx Program.

Current law also requires DAS and the five retirement systems to submit to ODJFS information regarding the rebates received from drug manufacturers. The per unit rebate amount for each drug must be submitted to ODJFS, which is then required to compute a weighted average per unit rebate. The weighted average per unit rebate is used as the minimum rebate that may be offered by a drug manufacturer to the Ohio's Best Rx Program.

The bill eliminates all provisions under which the Ohio's Best Rx Program's drug prices and manufacturer rebates are based on the weighted average prices and

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[2] *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.)*

rebates that apply under the health benefit plans offered to state employees and retirees. All references to the duties of DAS and five retirement systems relative to the Program are removed. The bill specifies that it eliminates all duties and any other obligations of DAS and retirement systems pertaining to the Program.

Replacement system for drug prices and manufacturer payments

(R.C. 5110.04, 5110.07, and 5110.27)

In place of the Ohio's Best Rx Program's existing drug pricing system and drug manufacturer payment standards, the bill provides the following:

(1) ODJFS must annually establish a base price for each drug included in the Program. In the case of drugs dispensed by participating pharmacies, the bill requires that the base price be established by using one or more formulas designated by ODJFS. For the Program's drug mail order system, the bill requires that the base price be established in accordance with ODJFS's rules governing the system.

(2) When a drug manufacturer chooses to enter into an agreement to participate in the Program by making payments for a particular drug it manufactures, the manufacturer must specify a "per unit" payment amount for the drug. The manufacturer must specify a payment amount that the manufacturer believes is greater than or comparable to the payment amount generally payable by the manufacturer for the same drug when dispensed to a person using the health benefits provided to state employees and retirees in Ohio or another state.

(3) ODJFS is required to select a consulting pharmacy benefit manager (PBM) to provide verification services regarding its drug pricing formulas and receipt of drug manufacturer payments.

Duty to serve as the Program's consulting pharmacy benefit manager

(R.C. 5110.01(H) and (I) and 5110.03)

Under the bill, any entity that provides services as PBM relative to the outpatient drug coverage included in a health benefit plan offered to the employees or retirees of a state agency or political subdivision and their eligible dependents is required to provide drug pricing verification services and drug manufacturer payment verification services for the Ohio's Best Rx Program, if the PBM is selected by ODJFS to serve as the Program's consulting PBM. If selected as the consulting PBM, both of the following apply:

(1) The consulting PBM must provide the verification services without charge, either to the Program or to the state agency or political subdivision for which it provides services as a PBM;

(2) The consulting PBM must provide the verification services for the entire year for which it is selected to serve as the consulting PBM, regardless of the duration or termination of its responsibility to the state agency or political subdivision for which it provides services as a PBM.

The bill specifies that its provisions requiring a PBM to serve as the Program's consulting PBM do not impose any duty on the state agency or political subdivision for which it provides services as a PBM. For purposes of these provisions, "state agency" is defined as any organized body, office, agency, institution, or other entity established by the laws of Ohio for the exercise of any function of state government. "Political subdivision" is defined as a county, township, municipal corporation, or any other body corporate or politic that is responsible for government activities in a geographic area smaller than that of the state.

Injunctions

(R.C. 5110.03(C))

If the entity selected to serve as the Program's consulting PBM fails to provide the Program with drug pricing or manufacturer payment verification services, or fails to provide for an audit when requested by ODJFS to do so, ODJFS may ask the Attorney General to bring an action for injunctive relief in any court of competent jurisdiction. On the filing of an appropriate petition, the court must conduct a hearing on the petition. If it is demonstrated in the proceedings that the PBM has failed to provide the verification services or has failed to provide for the audit, the court must grant a temporary or permanent injunction enjoining the PBM from continuing the failure.

Process for selection of the consulting PBM

(R.C. 5110.04)

The selection of a consulting PBM for the Ohio's Best Rx Program must be made annually. From among the PBMs that provide services to state agencies and political subdivisions, ODJFS must select the PBM that it considers to be the most appropriate PBM to provide drug pricing and manufacturer payment verification services for the Program. In making the selection, ODJFS must consider the PBM that provides services relative to the outpatient drug coverage included in the

health benefit plan offered to the greatest number of employees or retirees of a state agency or political subdivision and their eligible dependents.

ODJFS must provide written notice to the PBM that it has been selected to serve as the Program's consulting PBM. The notice must specify the date on which the PBM is to begin serving as the consulting PBM for the ensuing year. Before the end of the one-year period during which the PBM is to serve, ODJFS must make another selection for a consulting PBM. ODJFS may select either the same PBM or another PBM.

Verification of drug pricing formulas by the consulting PBM

(R.C. 5110.08)

Annually, ODJFS must designate one or more formulas for use in establishing the Ohio's Best Rx Program's base price for drugs dispensed by pharmacies other than the Program's mail order system. Each formula must include a drug pricing discount component that is expressed as a percentage discount. The formula used for generic drugs may include the maximum allowable cost limits that apply to generic drugs under Medicaid.

In designating the one or more formulas, ODJFS must use the best information on drug pricing that is available to ODJFS, including information obtained through the drug pricing verification services provided by the Program's consulting PBM. Based on the available information, ODJFS must modify the one or more formulas as it considers appropriate to maximize the benefits provided to Program participants.

Brand name drugs

(R.C. 5110.09(A))

For brand name drugs, excluding generic drugs marketed under brand names, ODJFS must submit to the consulting PBM the formula ODJFS proposes to use to establish the Program's base price during the year. The consulting PBM must review the formula. In conducting the review, the PBM must compare the drug pricing discount percentage included in ODJFS's formula to the drug pricing discount percentage included in the formula most commonly used by the PBM to establish part of its payment rate for brand name drugs dispensed by pharmacies other than drug mail order systems. If the formulas are not expressed in equivalent terms, the PBM must make all accommodations necessary to make the comparison of the discount percentages.

After conducting the review, the consulting PBM must provide information to ODJFS verifying whether the discount percentage included in ODJFS's formula

is more than two percentage points below the discount percentage included in the formula used by the PBM. The information provided to ODJFS must be certified by signature of an officer of the PBM.

Generic drugs

(R.C. 5110.09(B))

For generic drugs, ODJFS must identify the 50 generic drugs most frequently purchased by Program participants in the immediately preceding year from pharmacies other than the Program's drug mail order system. ODJFS must submit to the consulting PBM the names of the 50 drugs, the number of prescriptions filled for each of the drugs, the formula used to compute the base price for the drugs during the year, and the weighted average base price for the drugs that resulted for the year.

The consulting PBM must review the submitted information. In conducting the review, the PBM must compare ODJFS's weighted average base price to the equivalent part of the PBM's weighted average payment rate for the same drugs when dispensed by pharmacies other than drug mail order systems. For purposes of the comparison, ODJFS and the PBM must express the weighted average base price and payment rate in terms of a discount percentage that is taken from the drugs' average wholesale price, as identified by a national drug price reporting service selected by ODJFS and the PBM.

After conducting the review, the PBM must provide information to ODJFS verifying whether the discount percentage reflected in ODJFS's weighted average base price for the drugs is more than two percentage points below the equivalent part of the PBM's weighted average payment rate for the same drugs. The information provided to ODJFS must be certified by signature of an officer of the PBM.

Verification of drug manufacturer payments by the consulting PBM

(R.C. 5110.29)

In ODJFS's negotiations with a drug manufacturer proposing to enter into an agreement to make payments under the Ohio's Best Rx Program for one or more of the drugs it manufactures, ODJFS is required by the bill to use the best information on manufacturer payments that is available to ODJFS, including information obtained from the verifications made by the Program's consulting PBM. ODJFS must use the information in an attempt to obtain manufacturer payments that maximize the benefits provided to Program participants.

Manufacturer payment sample

(R.C. 5110.30)

Annually, the bill requires ODJFS to select a sample of not more than ten of the drugs that were included in the manufacturer agreements entered into in the immediately preceding year. ODJFS must submit to the consulting PBM information that identifies the per unit amount of the manufacturer payments that applied to each of the drugs in the sample.

The consulting PBM must review the submitted information. After the review, the PBM must provide information to ODJFS verifying whether any of the per unit payment amounts that applied to the selected drugs were more than two per cent lower than the per unit payment amounts negotiated by the PBM for the same drugs in connection with health benefit plans that generally do not use formularies to restrict the outpatient drug coverage included in the plans. The PBM is required to specify which, if any, of the drugs in the sample were subject to the lower per unit payment amounts. The information provided to ODJFS must be certified by signature of an officer of the PBM.

Aggregate information on manufacturer payments

(R.C. 5110.54)

Current law requires ODJFS to compile a list consisting of the name of each drug manufacturer participating in the Ohio's Best Rx Program.

As part of the list of participating manufacturers, the bill permits ODJFS to include aggregate information regarding the drugs included in ODJFS's sample that were verified by the consulting PBM as having per unit payment amounts that were not more than two per cent lower that the consulting PBM's negotiated per unit payment amounts. The information may not identify a specific drug and must be expressed only as a percentage of the drugs included in ODJFS's sample.

Audits of the consulting PBM

(R.C. 5110.05)

To determine whether the consulting PBM has provided valid information when providing drug pricing or manufacturer payment verification services, ODJFS may request that the PBM provide for an audit of its relevant contracts with drug manufacturers and pharmacies. Under the bill, the audit may be performed only by an auditor that is mutually satisfactory to ODJFS and the PBM and independent of both.

In making audit requests, ODJFS may request an audit on a regularly occurring basis, but not more frequently than once every three years. In addition to regularly occurring audits, the bill permits ODJFS to request an audit at any time it has a reasonable basis to believe that the consulting PBM is not acting in good faith. Notice of the request must be made in writing and signed by the Director of Job and Family Services. The notice may specify the basis for the belief that the PBM is not acting in good faith. If the basis for the belief is not specified and the audit findings demonstrate that the PBM acted in good faith, ODJFS must pay the cost incurred by the PBM in providing for the audit.

If the audit findings demonstrate that the consulting PBM's verification services did not result in valid information, the bill requires ODJFS to use the findings for purposes of confirming the validity of its drug pricing formulas and entering into agreements with drug manufacturers for payments to the Program.

Confidentiality of information provided by the consulting PBM

(R.C. 5110.021(B)(6), 5110.55, 5110.56, and 5110.59)

The bill includes the following provisions establishing the confidentiality of the information obtained from the Program's consulting PBM through its verification services or an audit of the PBM:

(1) The information transmitted by or to the PBM for any purpose related to the Program is confidential to the extent required by federal and state law.

(2) The drug pricing and manufacturer payment information verified by the PBM, and the information contained in or pertaining to an audit of the PBM, are "trade secrets," are not public records, and cannot be used, released, published, or disclosed in a form that reveals a specific drug or the identity of a drug manufacturer.

(3) All records ODJFS receives from the PBM in its provision of verification services must be destroyed promptly after ODJFS has completed the purpose for which the information in the records was obtained.

(4) ODJFS may not delegate to any person serving under contract as the Program's administrator any of ODJFS's powers or duties to do the following: (a) receive verification of drug pricing or manufacturer payment information from the PBM, (b) request that the PBM provide for an audit, or (c) review or use any information contained in or pertaining to an audit of the PBM other than the audit's findings of whether the verification information provided by the PBM was valid.

Eligibility expansion

(R.C. 5110.14)

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.

Application procedures

(R.C. 5110.01, 5110.15, 5110.16, 5110.35, and 5110.351 (repealed))

The bill makes the following changes to the application procedures used to enroll in the Ohio's Best Rx Program:

(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's 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.

Annual reapplication and expiration of enrollment

(R.C. 5110.01(E), 5110.14, 5110.17, 5110.18, 5110.25(C), and 5110.35)

Under current law, each determination by ODJFS that an individual is eligible to participate in the Ohio's Best Rx Program is valid for one year. An individual seeking to continue to participate in the Program must reapply annually.

The bill eliminates the Program's annual reapplication requirement. It also eliminates all provisions related to the annual expiration of an individual's enrollment in the Program.

Enrollment cards

(R.C. 5110.18(A))

Current law requires ODJFS to issue Ohio's Best Rx Program enrollment cards to applicants who apply and are found eligible to participate in the Program.

The bill requires ODJFS to determine the information to be included on the enrollment card, including an identification number. ODJFS must also determine the card's size and format. If ODJFS establishes an application method that permits individuals to apply through the Internet, the bill authorizes ODJFS to issue the enrollment card by sending the applicant an electronic version of the card in a printable format.

Confirmation of enrollment

(R.C. 5110.18(B))

Under current law, each time a drug is purchased under the Ohio's Best Rx Program, the participant's enrollment card must be presented to the participating pharmacy.

The bill provides that each time a drug is purchased under the Program, the entity dispensing the drug must confirm whether the individual for whom the drug is dispensed is enrolled in the Program. If the drug is being purchased at a pharmacy rather than by mail, and the individual's enrollment card is available for presentation at the time of the purchase, the purchaser must present the card to the pharmacy as confirmation of the individual's enrollment. If the drug is being purchased through the Program's mail order system and the individual's Program identification number is available, the purchaser must present the identification number as confirmation of enrollment. Otherwise, the pharmacy or mail order system must confirm the individual's enrollment through ODJFS. The bill requires ODJFS to establish the methods to be used in confirming enrollment through ODJFS, including confirmation by telephone, through the Internet, or by any other electronic means.

Attestation of no other drug coverage

(R.C. 5110.18(C))

The bill provides that purchasing a drug under the Program by using an enrollment card or any other method serves as an attestation by the participant for whom the drug is dispensed that the participant meets the Program's eligibility standards that require an individual to have no health benefits or other coverage for outpatient drugs.

Amount to be charged for drugs

(R.C. 5110.10, 5110.11, 5110.12, 5110.14 (repealed), 5110.15 (repealed), 5110.20, 5110.23, and 5110.28)

With respect to the existing laws specifying the amount that an Ohio's Best Rx Program participant is to be charged for a drug, the bill makes numerous changes for purposes of conforming those laws with the bill's pricing system that is no longer based on the health benefit plans offered to state employees and retirees. The bill retains, however, the underlying basis for determining the amount that a participant is to be charged under the Program and savings that result. Specifically, the amount saved under the Program is the difference between the following:

(1) The pharmacy or mail order system's usual and customary charge for the drug.

(2) The drug's base price established by ODJFS, minus any drug manufacturer payment for the drug,[3] plus any professional fee charged for dispensing the drug (up to $3.00), plus any administrative fee established by ODJFS (up to $1.00).

The bill specifies that when a drug is purchased at the usual and customary charge, the transaction is not subject to the Program's statutes pertaining to the purchase or dispensing of a drug under the Program. Under this provision, for example, the dispensing pharmacy is not required to submit a claim to the Program for the transaction and a drug manufacturer is not required to make a payment to the Program for the transaction.

Manufacturer agreements to make payments for drugs purchased

(R.C. 5110.26)

Current law permits a drug manufacturer to enter into an agreement with ODJFS to make rebate payments for a drug it manufactures when the drug is dispensed under the Ohio's Best Rx Program. The pharmacy that dispenses the drug is reimbursed for the amount of the rebate that is provided to the purchaser.

The bill replaces references to "rebate agreements" and "rebate payments" with references to "manufacturer agreements" and "manufacturer payments." It

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[3] *To cover administrative expenses, ODJFS may retain up to five per cent of the manufacturer payment that applies to a drug (R.C. 5110.28(B)).*

clarifies that any drug manufacturer may enter into a manufacturer agreement for purposes of participating in the Program.

Referrals to patient assistance programs

(R.C. 5110.27(B))

For any drug included in a manufacturer agreement, the bill authorizes the terms of the agreement to provide for the establishment of a process for referring Ohio's Best Rx Program applicants and participants to a patient assistance program operated or sponsored by the manufacturer. The bill specifies, however, that the referral process may be included only if the manufacturer agrees to refer to the Program residents of Ohio who apply but are found to be ineligible for the patient assistance program.

Medicaid best price

(R.C. 5110.31)

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.[4]

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.

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[4] *42 United States Code 1396r-8(c); Commerce Clearing House,* Medicare and Medicaid Guide, *paragraph 14,591.*

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.

Donations

(R.C. 5110.353, 5110.354, 5110.42, and 5110.43)

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's determinations of whether it is necessary to charge fees to cover the Program's administrative costs.

Transfer between the Program Fund and the Administration Fund

(R.C. 5110.42 and 5110.43)

Current law also creates the Ohio's Best Rx Administration Fund. Money in the Administration Fund is to be used to pay the administrative costs of the Program.

The bill clarifies that money in the Ohio's Best Rx Program Fund may be used to make transfers to the Administration Fund.

Subsidies for drug costs

(R.C. 5110.39 and 5110.43)

The bill permits ODJFS to establish a component of the Ohio's Best Rx Program under which subsidies are provided to participants to assist them with the cost of purchasing drugs under the Program, including the cost of any professional fees charged for dispensing the drugs. The subsidies may be provided only when the Ohio's Best Rx Administration Fund includes an amount that exceeds the amount necessary to pay the Program's administrative costs.

Delegation of powers and duties to a Program administrator

(R.C. 5110.021, 5110.10 (repealed), 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's 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:

--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.

(5) ODJFS is not permitted to delegate its authority relative to audits of the Program's consulting PBM.

Statutory references to the Program administrator

(R.C. 5110.01, 5110.21, 5110.24, 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's contract with the administrator.

Mail order system

(R.C. 5110.01, 5110.19, 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's 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.

The bill expressly requires ODJFS to include the mail order system within the Program. The bill specifies, however, 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.

Limits on promoting the mail order system

(R.C. 5110.19(B))

The bill prohibits ODJFS and the Program's mail order system from promoting the purchase of drugs through the system by using information collected under the Program regarding the drugs purchased by participants from other pharmacies participating in the Program. It specifies, however, that the

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

prohibition does not preclude the use of the information for purposes limiting the amount that a Program participant may be charged for a quantity of a drug purchased through the drug mail order system to an amount that is not more than the amount that would be charged if the same quantity of the drug were purchased from another pharmacy.

Statutory references to the mail order system

(R.C. 5110.01, 5110.11, 5110.22, 5110.23, 5110.25, 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. 5110.13, 5110.24, 5110.54, and 5110.58(D)(2))

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's calculation of the average annual percentage savings obtained by Program participants;

(4) Specifies that the mail order system, to the extent required or authorized by ODJFS, may solicit, disclose, receive, or use identifying information regarding Program applicants and participants or knowingly permit the use of identifying information. This authority, however, is subject to the bill's prohibition against using information regarding purchases from other pharmacies to promote the mail order system.

Drugs included in the Program

(R.C. 5110.02 and 5110.03 (repealed))

Current law requires the Ohio's Best Rx Program to include all drugs that are included in a drug manufacturer rebate agreement with the Program and all other drugs that are covered by the health benefit plans offered to state employees and retirees.

The bill requires the Program to include all drugs included in a manufacturer agreement and all other drugs that may be dispensed only pursuant to a prescription issued by a licensed health professional.

Program purpose

(R.C. 5110.02)

The bill specifies that the Ohio's Best Rx Program is established for the purpose of providing outpatient prescription drug discounts to Ohio residents enrolled in the Program by meeting its eligibility requirements, including eligible individuals who are age 60 or older, eligible individuals who have low incomes but are not eligible for Medicaid, and other eligible individuals who do not have health benefits that cover outpatient drugs.

Technical and conforming changes

In addition to the technical and conforming changes included as part of the provisions described above, the bill does all of the following:

--Eliminates statutory definitions of terms that are no longer used in the bill because they are inapplicable under the bill's provisions or because the bill creates statutory cross-references to the operative provisions of law on which the definitions are based (R.C. 5110.01);

--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. 5110.14);

--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. 5110.20);

--Clarifies that existing laws providing for the confidentiality of information regarding manufacturer payments to the Program are applicable when the information is used to compute the payment of claims submitted by participating pharmacies and the Program's mail order system (R.C. 5110.56(A)(5));

--Relocates provisions of existing law authorizing drug manufacturers to audit the claims submitted under the Program (R.C. 5110.32);

--Modifies ODJFS's 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, 2921.13, and 5110.38).

Transfer of the Program to the Department of Aging

(R.C. 173.71 to 173.91 and 173.99; Sections 4 to 7)

On July 1, 2007, the bill transfers the Ohio's Best Rx Program from ODJFS to the Department of Aging. After the transfer, the Department must administer the Program in accordance with the same statutes that previously applied to ODJFS.

Advance contracting for a Program administrator

(Section 7)

In anticipation of the Program's transfer, the Department of Aging is permitted by the bill to negotiate or enter into a contract with a person to serve as the Program administrator beginning on or after July 1, 2007. When negotiating or entering into the contract, the Department must comply with the same contracting provisions that apply to ODJFS under existing law and the bill.

Implementation of the transfer

(Section 7)

The bill includes the following provisions specifying the effect of the Program's transfer and the manner in which the transfer is to be implemented:

(1) All of the Program's functions, assets, and liabilities are transferred from ODJFS to the Department of Aging. The transferred Program is successor to, assumes the obligations of, and otherwise constitutes the continuation of the Program as it was operated by ODJFS.

(2) Any Program business commenced but not completed before July 1, 2007, must be completed by the Department of Aging. The business must be completed in the same manner, and with the same effect, as if completed by ODJFS prior to the transfer.

(3) No validation, cure, right, privilege, remedy, obligation, or liability pertaining to the Program is lost or impaired by reason of the transfer. Each such validation, cure, right, privilege, remedy, obligation, or liability must be administered by the Department of Aging.

(4) All rules, orders, and determinations pertaining to the Program as it was operated by ODJFS continue in effect as rules, orders, and determinations of the Program when it is administered by the Department of Aging, until modified or rescinded by the Department. If necessary to ensure the integrity of the numbering of the Administrative Code, the Director of the Legislative Service Commission must renumber the rules to reflect the Program's transfer.

(5) Subject to the lay-off provisions of the laws governing public employees, all of the Program's employees in ODJFS must be transferred to the Department of Aging. The transferred employees are to retain their positions and all of the benefits accruing to those positions.

(6) The Director of Budget and Management must determine the amount of the unexpended balances in the appropriation accounts that pertain to the Program as operated by ODJFS immediately prior to July 1, 2007. The Director must recommend to the Controlling Board the transfer of the balances to the appropriation accounts that pertain to the Department of Aging. ODJFS is required to provide full and timely information to the Controlling Board to facilitate the transfer.

Coordination with the Golden Buckeye Card Program

(R.C. 173.724)

The bill authorizes the Department of Aging to coordinate the Ohio's Best Rx Program with the Department's Golden Buckeye Card Program, which provides retail discounts and other benefits to persons who are age 60 or older and persons who have disabilities.

In coordinating the programs, the Department may establish a card that serves as both a Golden Buckeye Card and an Ohio's Best Rx Program enrollment card. The Department may identify the card by including the names of both programs on the card or by selecting a combined name.

Elimination of the Golden Buckeye Card's prescription drug component

(R.C. 173.061 (repealed), 173.062, 173.07 (repealed), 173.071 (repealed), and 173.072 (repealed); Sections 4, 5, and 6)

On July 1, 2007, the bill eliminates the laws requiring the Director of Aging to establish one or more prescription drug programs that enable cardholders to receive reduced prices on prescription drugs dispensed at participating pharmacies. All statutes related to the prescription drug programs are simultaneously eliminated.

Persons with disabilities added to Ohio's Best Rx Program

(R.C. 173.76)

When the Ohio's Best Rx Program is transferred to the Department of Aging, and the Department's one or more prescription drug discount programs are eliminated, the bill simultaneously adds persons with disabilities who were included in the Department's eliminated programs as a category of persons who are eligible for the Ohio's Best Rx Program. Under this provision, a "disabled person"[6] means a person who has some impairment of body or mind and has been certified as permanently and totally disabled by an agency of Ohio or the United States having the function of so classifying persons.

HISTORY

ACTION	DATE
Introduced	01-11-06
Reported, S. Health, Human Services & Aging	11-30-06
Passed Senate (27-2)	11-30-06

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[6] *Although the bill refers to an existing definition of "disabled person," the statute that is cross-referenced refers to a "person with a disability" (R.C. 173.06(D), not in the bill).*