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ACT SUMMARY

Creation and administration of the Ohio's Best Rx Program

- Establishes the Ohio's Best Rx Program under which eligible persons who enroll may purchase drugs at discounted prices derived from rebates provided by drug manufacturers or the average prices established by the health benefit plans offered to state employees and members of the state retirement systems.
- Specifies that by creating the Program, it is not the General Assembly's intention to establish an entitlement program.
- Requires the Program to be administered by the Ohio Department of Job and Family Services (ODJFS), but permits ODJFS to contract with a person to be the Ohio's Best Rx Program administrator.

- Requires a person under contract with ODJFS to be the Program administrator to offer a drug mail order system.

Eligibility

- Limits eligibility for the Program to Ohio residents who do not have other drug benefits and are either age 60 or older or have family incomes not exceeding 250% of the federal poverty guidelines.
- Provides that each determination of eligibility is valid for one year and permits persons to reapply annually for enrollment in the Program.

State health benefit plan information

- Requires the Department of Administrative Services and the state retirement systems to submit to ODJFS specified drug pricing and drug manufacturer rebate information based on the drug benefits provided to state employees through the Ohio Med Preferred Provider Organization and the drug benefits provided through the health benefit plans offered by the state retirement systems.
- Requires ODJFS, based on information submitted by the Department of Administrative Services and the state retirement systems, to make computations to be used to determine the discounts to be applied when a Program participant purchases a drug under the Program.

Rebate agreements with participating drug manufacturers

- Permits a drug manufacturer to participate in the Program by agreeing to provide rebate payments pursuant to a rebate agreement entered into with ODJFS.
- Requires a participating manufacturer to make rebate payments for each unit of a drug in an amount that is equal to or greater than (1) the weighted average rebate for the drug that applies under the state and retirement system health benefit plans or (2) another amount agreed to by the manufacturer.

Participation agreements with terminal distributors of drugs

- Permits a terminal distributor of dangerous drugs to participate in the Program by entering into an agreement with ODJFS for purposes of dispensing drugs.
- Requires a participating terminal distributor to charge a Program participant the lesser of the terminal distributor's usual and customary charge for the quantity of drug dispensed or the amount that must be paid under the Program.

Fees and administrative costs

- Permits a participating terminal distributor to charge a professional fee of not more than \$3 for dispensing a drug under the Program and provides for increases in the maximum fee to be established by ODJFS through the adoption of rules.
- Permits ODJFS, for purposes of covering the administrative costs of the Program, to establish an administrative fee of not more than \$1 per transaction to be charged when drugs are dispensed under the Program.
- Permits ODJFS, for purposes of covering the administrative costs of the Program, to establish a "rebate administration percentage" of not more than 5%, which is a percentage of the per unit rebate that is subtracted from the amount of the rebate that applies when determining the discounted drug price to be paid by a Program participant.

Payment of claims for dispensing drugs

- Establishes a process for ODJFS to pay claims submitted by terminal distributors and the Ohio's Best Rx Program administrator for dispensing drugs under the Program.
- Provides for payments to be made only for drugs that are subject to rebate agreements with drug manufacturers.

Coordination with state and federal programs

- Permits ODJFS to make adjustments to the Program to conform it to or coordinate it with any federally funded prescription drug program created

after October 1, 2003, and to take actions to coordinate the Program with a state health benefit plan.

Ohio's Best Rx Program Council

- Creates the Ohio's Best Rx Program Council, consisting of four legislators and nine members appointed by the Governor, to advise ODJFS on the Program and, with approval of a majority of its appointed members, to initiate studies to determine whether there are more effective ways to administer the Program and to provide ODJFS with suggestions for improvements.

Program records

- Requires ODJFS to compile statistics on the most frequently dispensed drugs under the Program and the average savings received, to maintain lists of all participating drug manufacturers and terminal distributors, and to establish procedures for the use and preservation of Program records.
- Provides that information transmitted for any purpose related to the Ohio's Best Rx Program is confidential to the extent required by state or federal law.
- Specifies that certain types of information related to the Program are trade secrets, are not public records, and cannot be used in a manner that reveals a specific drug or the identity of a drug manufacturer.
- Prohibits a person or government entity from selling, soliciting, disclosing, receiving, or using or knowingly permitting the use of information that identifies or could be used to identify an applicant for or participant in the Ohio's Best Rx Program.

State accounting and appropriations

- Creates the Ohio's Best Rx Program Fund, which is in the custody of the Treasurer of State but not in the state treasury, for use in making payments for claims for dispensing drugs covered by a rebate agreement.
- Creates the Ohio's Best Rx Administration Fund in the state treasury for use in paying the administrative costs of the Program.
- Makes an appropriation.

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CONTENT AND OPERATION

IMPLEMENTATION OF THE OHIO'S BEST RX PROGRAM

Overview

The act creates the Ohio's Best Rx Program, under which eligible persons who enroll may purchase drugs covered by the Program at discounted prices. For a person to be eligible, the person must not have another form of drug coverage and must be 60 years of age or older or have a family income not exceeding 250% of the federal poverty guidelines.

The discounted drug prices are derived from rebates provided by drug manufacturers that choose to participate in the Program or the average prices established as part of the health care benefits offered to state employees and the members of the five state retirement systems. The amount the Program participant saves is to be reported to the participant at the time the drug is purchased. Professional fees and administrative costs may be included in the amount the participant is required to pay, but the participant cannot be required to pay more than the amount that would have been paid without using the Program's benefits.

Program participants may purchase drugs from any participating "terminal distributor of dangerous drugs." Under laws unaffected by the act, pharmacies and other entities that sell drugs at retail are licensed as terminal distributors of dangerous drugs.¹ A "dangerous drug," under those laws, is generally a drug that is available only by prescription.²

¹ R.C. 4729.01 (not in the act) describes a "terminal distributor of dangerous drugs" as a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption. The term includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.

² R.C. 4729.01 (not in the act) describes a "dangerous drug" as a drug in one of the following three categories: (1) any drug to which either of the following applies: (a)



Establishment and administration

(R.C. 5110.02, 5110.35(Q), and 5110.37; Section 5)

The act establishes the Ohio's Best Rx Program. The Program is to be administered by Ohio Department of Job and Family Services (ODJFS), unless ODJFS contracts with a person to be the Ohio's Best Rx Program administrator. ODJFS is required by the act to undertake outreach efforts to publicize the Program and to maximize participation.

The act requires ODJFS to adopt rules to implement the Program, including any rules it determines are necessary for efficient administration of the Program. All rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.), which requires public hearings.

Entitlement not intended

(Section 3)

The act specifies that it is not the intention of the General Assembly to establish an entitlement program through the enactment of the laws governing the Ohio's Best Rx Program.

Contracting for an administrator

(R.C. 5110.01(F), 5110.10, and 5110.11)

The act permits ODJFS to contract with a person to be the Ohio's Best Rx Program administrator. The administrator is required to perform any of ODJFS's duties under the act that ODJFS specifies in the contract. The act specifies, however, that the adoption of rules for the Program cannot be included in the duties to be performed by the administrator.

Before entering into a contract with a person to be the Ohio's Best Rx Program administrator, ODJFS must issue a request for proposals from persons

under the Federal Food, Drug, and Cosmetic Act, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without a prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only on a prescription, or (b) under Ohio's laws regarding pure food and drugs or controlled substances, the drug may be dispensed only on a prescription, (2) any drug that contains a Schedule V controlled substance and that is exempt from Ohio's controlled substances laws or to which those laws do not apply, or (3) any drug intended for administration by injection into the human body other than through a natural orifice.



seeking to be considered. ODJFS must develop a process which it is required to use in issuing the request for proposals, receiving responses to the request, and evaluating the responses on a competitive basis. In accordance with that process, ODJFS must select the person to be awarded the contract.

Mail order system offered through the administrator

(R.C. 5110.01(F), 5110.10(B) and (C), and 5110.35(P))

The act requires the person under contract to be the Ohio's Best Rx Program administrator to offer a mail order system through which Program participants may obtain drugs. ODJFS is required by the act to adopt rules that provide for the standards and procedures governing the operation of the mail order system by the Ohio's Best Rx Program administrator. The Ohio's Best Rx Program administrator is required to charge a participant for each drug included in the Program an amount not exceeding the Program price for the drug plus any administrative fee that is charged under the Program.³

Drugs included

(R.C. 5110.03)

The act requires a drug to be included in the Ohio's Best Rx Program if either of the following applies:

- (1) The drug is covered by a state health benefit plan or state retirement system health benefit plan;
- (2) The drug is covered by a rebate agreement that a drug manufacturer enters into for purposes of participating in the Program.

The act permits ODJFS to exclude from the Program a drug covered by a state health benefit plan or state retirement system health benefit plan if the plan receives a rebate for the drug from the manufacturer but the drug is not covered by a rebate agreement under the Program.

³ Other provisions of the act refer to the administrator's authority to charge a professional fee.

ELIGIBILITY AND APPLICATION REQUIREMENTS

Eligibility to participate

(R.C. 5110.01(B), (C), (D), and (T), 5110.05(A), and 5110.35(A))

To be eligible for the Ohio's Best Rx Program, an individual must meet all of the following requirements at the time of application or reapplication for the Program:

Residency--The individual must be a resident of Ohio.

Age or income--The individual must be either (1) 60 years of age or older or (2) have family income that does not exceed 250% of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services. For eligibility based on income, the family income is to be determined under rules the act requires ODJFS to adopt.

Absence of coverage for drugs--The individual must not have outpatient prescription drug coverage paid for in whole or in part by a third-party payer or publicly funded health program. For purposes of this provision, a third-party payer is (1) an insurance company, (2) a health insuring corporation, (3) a labor organization, (4) an employer, (5) an intermediary organization that is not a health delivery network contracting solely with self-insured employers, (6) a third-party administrator, (7) a health delivery network, or (8) any other person obligated pursuant to a benefits contract to reimburse for covered health care services rendered to beneficiaries under the contract. The publicly funded health programs that cause an individual to be ineligible for the Ohio's Best Rx Program are Medicaid, the Children's Health Insurance Program, the Disability Medical Assistance Program, and any other health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs, other than a prescription drug discount card program offered through the Golden Buckeye Card Program.⁴

Waiting period--The individual must not have had outpatient prescription drug coverage from a third-party payer or publicly funded health program during any of the four months preceding the month in which the application or reapplication is made for the Ohio's Best Rx Program. This restriction, however, does not apply when an individual becomes age 60 or when any of the following occurs with respect to the outpatient prescription drug coverage: (1) the third-party payer that paid all or part of the coverage filed for bankruptcy under federal bankruptcy laws, (2) the individual is no longer eligible for coverage provided

⁴ See "Conformance or coordination with federal programs," discussed below.

through a retirement plan subject to protection under the federal Employee Retirement Income and Security Act (ERISA), or (3) the individual is no longer eligible for the Medicaid Program, the Children's Health Insurance Program, or the Disability Medical Assistance Program.

Application procedures

(R.C. 5110.01(G), 5110.05(B), 5110.35(B) and (C), and 5110.351)

Application and annual reapplication for the Ohio's Best Rx Program must be made in accordance with rules that the act requires ODJFS to adopt and on a form prescribed in those rules. The act specifies that an individual may apply or reapply on behalf of the individual and the individual's spouse and children. It also authorizes the guardian or custodian of an individual to apply or reapply on behalf of the individual. The individual who signs the application and submits it to ODJFS or the Ohio's Best Rx Program administrator for a determination of eligibility is considered the Program applicant.

The rules ODJFS is to adopt under the act must provide for the application and reapplication process, as well as the documentation to be submitted for the purpose of verifying eligibility. In adopting a rule prescribing the application form, the act requires ODJFS to do all of the following:

(1) Specify the information that an applicant must include in the application about the applicant and the applicant's family members included in the application;

(2) Require that the applicant attest that the information provided in the application and the documentation submitted with the application is accurate to the best knowledge and belief of the applicant;

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement on the form is falsification, a first degree misdemeanor.

Medicaid information provided

(R.C. 5110.07 and 5110.35(D))

The act requires ODJFS to provide each applicant for the Ohio's Best Rx Program information about the Medicaid Program. The information must be provided in accordance with the method specified in rules the act requires ODJFS to adopt. The information must include general eligibility requirements, application procedures, and benefits. The information also must explain the ways in which Medicaid's drug benefits are better than the Ohio's Best Rx Program.

Eligibility determination procedures and validity periods

(R.C. 5110.08 and 5110.35(E))

The act requires ODJFS, on receipt of applications and annual reapplications, to make eligibility determinations for the Ohio's Best Rx Program. The determinations must be made in accordance with procedures established in rules the act requires ODJFS to adopt.

Each determination that an individual is eligible is valid for one year, beginning on a date determined in accordance with ODJFS's eligibility determination procedures. The act specifies that the beginning date cannot precede the date on which the individual's eligibility is determined. Annual reapplication may be made if the individual seeks to continue to participate in the Program after the date eligibility would otherwise end.

The act provides that an eligibility determination cannot be appealed under the Administrative Procedure Act, through ODJFS's administrative appeals process for other public assistance programs, or any other provision of the Revised Code.

Enrollment cards

(R.C. 5110.01(H) and 5110.09)

The act requires ODJFS to issue Ohio's Best Rx Program enrollment cards to or on behalf of individuals determined eligible to participate in the Program. The act allows one enrollment card to cover each member of an eligible family. Each individual determined eligible for the Program and included under a valid enrollment card is considered an Ohio's Best Rx Program participant.

An enrollment card is valid only during the period each individual covered by the card is eligible to participate. The card must be presented to a participating terminal distributor each time a drug is purchased through the Program.

Prohibition against providing false statements

(R.C. 2921.13)

The act prohibits a person from knowingly making a false statement, or knowingly swearing or affirming the truth of a false statement previously made, when the statement is made with purpose to obtain an Ohio's Best Rx Program enrollment card. The act includes the prohibition among the actions that constitute the preexisting criminal offense of falsification, a first degree misdemeanor.

INFORMATION ON STATE EMPLOYEE DRUG BENEFITS

Submission of information to ODJFS

(R.C. 5110.01(P), (Q), and (R) and 5110.25)

The act requires specified information to be submitted to ODJFS with respect to a state health benefit plan and each state retirement system health benefit plan. The information is to be used by ODJFS in making computations to determine discounts to be applied when a drug is purchased under the Ohio's Best Rx Program.

The information pertaining to a state health benefit plan must be submitted by the Department of Administrative Services. For purposes of the act, a state health benefit plan is the program of health care benefits offered through the Ohio Med Preferred Provider Organization, or a successor entity selected by the state, to which either of the following apply: (1) it is provided by a collective bargaining agreement or (2) it is offered by the Department to state employees who are paid directly by warrant of the Auditor of State.

The information pertaining to state retirement system health benefit plans must be submitted by each of the five state retirement systems for the plans of health care benefits they are permitted to offer under continuing law. The act identifies the five retirement systems as the Public Employees Retirement System, State Teachers Retirement System, School Employees Retirement System, Ohio Police and Fire Pension Fund, and State Highway Patrol Retirement System.

Information included in the submission

(R.C. 5110.01(L) and (M) and 5110.25(A))

Under the requirement to submit health benefit plan information to ODJFS, all of the following information must be submitted:

- (1) The name of the plan.
- (2) The number of individuals eligible for benefits under the plan.
- (3) The formula used to determine the per unit price for each drug covered by the plan and dispensed through means other than a mail order system, the per unit price for those drugs, or, if the formula and per unit price are available for submission to ODJFS, both the formula and per unit price. For purposes of this provision, the per unit price is the total amount paid to a terminal distributor of dangerous drugs under the plan for one unit of a drug covered by the plan, after the plan discounts or otherwise reduces the amount to be paid to the terminal



distributor. The per unit price includes both (a) the amount that the plan, or other government entity or person authorized to make the payment on the plan's behalf, pays to the terminal distributor, and (b) the amount that the plan beneficiary pays to the terminal distributor in the form of a copayment, coinsurance, or other cost-sharing charge.

(4) The per unit rebate for each drug covered by the plan and dispensed through a mail order system or means other than a mail order system. For purposes of this provision, the per unit rebate means all rebates, discounts, formulary fees, administrative fees, and other allowances a drug manufacturer pays to the plan, or other government entity or person authorized to receive all or part of such payments, for a drug during a calendar year, divided by the total number of units of that drug dispensed under the plan during the same calendar year.

Compliance

(R.C. 5110.01(E), 5110.25(B), 5110.26, and 5110.35(M))

The act requires the Department of Administrative Services and each state retirement system to ensure in all of their relationships with other persons that they are able to submit to ODJFS the required health plan information. The information is to be submitted in accordance with rules the act requires ODJFS to adopt. The rules must provide for a process for calculation and submission of the information.

In submitting information about a drug, the act requires the Department of Administrative Services and each state retirement system to do all of the following:

(1) The Department and retirement systems must compute and submit information separately for each of the drug's national drug code numbers. The act identifies the "national drug code number" as the number registered for a drug pursuant to the listing system established by the United States Food and Drug Administration (FDA) under the federal Drug Listing Act of 1972.⁵

(2) The Department and retirement systems must submit the formula, per unit price, or formula and per unit price information after each change to the formula or per unit price, unless the formula or per unit price changes more than

⁵ *The FDA administers the National Drug Code, which, according to information from the FDA, "serves as a universal product identifier for human drugs" (<http://www.fda.gov/cder/ndc>).*

once a week, in which case they must submit the formula or per unit price information at least once each week.

(3) The Department and retirement systems must provide for the formula or per unit price information to reflect the formula or per unit price as most recently changed.

(4) The Department and retirement systems must submit the information regarding the per unit rebate once a year and provide for the information to reflect the per unit rebate for the previous calendar year.

PARTICIPATING DRUG MANUFACTURERS

Rebate agreements

(R.C. 5110.01(J) and (O), 5110.21(A), (B)(1) to (3) and (6), and 5110.35(L))

A drug manufacturer is permitted by the act to enter into a rebate agreement with ODJFS regarding drugs it manufactures. By entering into a rebate agreement, the manufacturer becomes a participating manufacturer in the Ohio's Best Rx Program.

Under a rebate agreement, a participating manufacturer is required to make a rebate payment to ODJFS for each drug included in the agreement that is dispensed to an Ohio's Best Rx Program participant. The payments must be made on a quarterly basis, unless ODJFS determines that it is best that participating manufacturers make rebate payments on a basis other than quarterly, in which case ODJFS must adopt rules providing for a schedule for payment of the rebates.

The act requires the rebate agreement to specify which of the manufacturer's drugs are included in the agreement. The agreement must permit ODJFS to remove a drug from the agreement in the event of a dispute over the drug's utilization.

The act requires the rebate agreement to specify the time it is to be in effect. The act specifies that the time cannot be less than one year from the date the agreement is entered into.

Rebate amounts for each drug

(R.C. 5110.21(B)(4) and (5))

Rebate amount for each drug unit--Pursuant to the rebate agreement, the act requires that the amount of the rebate payment made for each unit of a drug



dispensed to an Ohio's Best Rx Program participant equal the greater of the following:

(1) The weighted average of the per unit rebates for the drug as computed by ODJFS according to information submitted with respect to the state health benefit plan and state retirement system health benefit plans;

(2) A per unit amount specified by the drug manufacturer. If this amount is used for making the rebate payments, the rebate agreement must specify the intervals at which the manufacturer will report the amounts to ODJFS.

Rebate payment for the quantity of drug dispensed--Pursuant to the rebate agreement, the act requires that the rebate payment for a quantity of a drug dispensed to an Ohio's Best Rx Program participant be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

Weighted average per unit rebates under benefit plans for state employees

(R.C. 5110.21(C) and 5110.35(N))

For purposes of the act's provisions specifying the rebate amount that must be agreed to under a rebate agreement, the act requires ODJFS to compute, once each year, the weighted average of the per unit rebates for each drug using the information available to ODJFS from submissions of per unit rebate information regarding the state health benefit plan and state retirement system health benefit plans. The computation must be made by using the number of individuals eligible for benefits under a state health benefit plan or state retirement system health benefit plan. It also must be made in accordance with rules ODJFS is to adopt that provide for procedures for making the computation.

The act specifies that if no computation can be made, the rebate for the drug is to be the amount specified by the drug manufacturer in the rebate agreement.

**DETERMINATION OF THE AMOUNT TO BE PAID WHEN
PURCHASING DRUGS UNDER THE PROGRAM**

Computations by ODJFS regarding drug prices

(R.C. 5110.27(A) and (C) and 5110.35(N))

The act requires ODJFS to make other computations for each drug included in the Ohio's Best Rx Program. The computations, which are used in establishing the Program's drug prices, must be made by using the number of individuals eligible for benefits under a state health benefit plan or state retirement system

health benefit plan. They also must be made in accordance with rules ODJFS is to adopt that provide for procedures for making the computations.

Per unit price for drugs based on weighted average prices--On receipt of each submission of formula or per unit drug price information from the Department of Administrative Services and state retirement systems, or, at ODJFS's discretion, more frequent intervals, the act requires ODJFS to do the following using the information available to ODJFS from those submissions:

(1) If the drug is covered by one or more state health benefit plans or state retirement system health benefit plans, compute the weighted average of the per unit prices under those plans;

(2) If the drug is not covered by any state health benefit plan or state retirement system health benefit plan, compute a weighted average per unit price using the formula information received from the Department of Administrative Services and state retirement systems for comparable drugs covered by one or more state health benefit plans or state retirement system health benefit plans.

Per unit price for drugs based on subtraction of per unit rebates--If the drug is covered by a rebate agreement under the Program, on receipt of each submission of formula or per unit price information from the Department of Administrative Services and each state retirement system, or, at ODJFS's discretion, more frequent intervals, ODJFS must subtract the per unit rebate agreed to by the manufacturer from the applicable weighed average per unit price derived from the computation described above. If ODJFS establishes a rebate administration percentage (see "*Rebate administration percentage*," discussed below), the per unit rebate subtracted must reflect the reduced amount derived by applying the rebate administration percentage.

Program prices for drugs

(R.C. 5110.01(I) and 5110.14)

The act provides that the Ohio's Best Rx Program price is the price that a participating terminal distributor is to charge a Program participant for a drug included in the Program. The price does not include the professional fee that may be charged by the terminal distributor or the amount of the administrative fee that ODJFS may require to be charged.

The Ohio's Best Rx Program price for a drug is to be determined by multiplying the number of units of the drug dispensed to a participant by whichever of the following is applicable:



(1) If the drug is not subject to a rebate agreement, the weighted average per unit price, as computed by ODJFS;

(2) If the drug is subject to a rebate agreement, the amount computed by ODJFS by subtracting the per unit rebate from the weighted average per unit price.

Amount saved and paid by participants

(R.C. 5110.01(V) and 5110.15)

Pursuant to a terminal distributor's agreement to participate in the Ohio's Best Rx Program, the distributor must report to a Program participant the amount that is saved under the Program on a transaction for a drug included in the Program. The amount saved is determined by subtracting the amount that the participant must pay under the Program from the usual and customary charge for the quantity of the drug dispensed.⁶

When a drug is dispensed under the Program, the amount a participant must pay is the sum of the following:

(1) The Ohio's Best Rx Program price (per unit) multiplied by the number of units dispensed;

(2) The professional fee, if any, charged by the terminal distributor or the Ohio's Best Rx Program administrator dispensing the drug;

(3) The administrative fee, if any, ODJFS requires to be charged.

PARTICIPATING TERMINAL DISTRIBUTORS

Participation agreements

(R.C. 127.16, 5110.01(K) and (S), and 5110.12)

A terminal distributor of dangerous drugs is permitted by the act to enter into an agreement with ODJFS to participate in the Ohio's Best Rx Program for

⁶ Under the act, the "usual and customary charge" is described as the amount a participating terminal distributor or the Ohio's Best Rx Program administrator charges for a drug included in the Program to an individual who does not receive a discounted price for the drug pursuant to any drug discount program, including the Ohio's Best Rx Program, a prescription drug discount card program established under the Golden Buckeye Card Program, or a pharmacy assistance program established by any person or government entity, and for whom no third-party payer or program funded in whole or part with state or federal funds is responsible for all or part of the cost of the drug the distributor dispenses to the individual.

purposes of dispensing drugs. The act specifies that the agreement is not subject to continuing laws that generally prohibit a state agency from making a \$50,000 purchase from a particular supplier unless the purchase is made by competitive selection or with the approval of the Controlling Board.

Terms of participation agreements

(R.C. 5110.12)

An agreement entered into with a terminal distributor of dangerous drugs to participate in the Ohio's Best Rx Program must do all of the following:

- (1) Be in effect for not less than one year;
- (2) Specify the dates the agreement is to begin and end;
- (3) Permit the participating terminal distributor to terminate the agreement before the date the agreement would otherwise end by providing the ODJFS notice of early termination at least 30 days before the effective date of the early termination;
- (4) Require that the participating terminal distributor charge a Program participant for each drug included in the Program the lesser of (a) the sum of the Program's price for the drug, any professional fee, and any administrative fee, or (b) the terminal distributor's usual and customary charge;
- (5) Permit the participating terminal distributor to charge a professional fee of not more than \$3, except as provided in rules adopted under the act allowing for an increased amount to be charged;
- (6) Require the participating terminal distributor to charge an administrative fee, in an amount determined in accordance with rules adopted under the act, for each transaction in which a quantity of the drug is dispensed, if an administrative fee is required by those rules;
- (7) Require the participating terminal distributor to disclose to each participant the amount the participant saves under the Program;
- (8) Require the participating terminal distributor to submit a claim to ODJFS for each sale of a drug to a participant;
- (9) Permit the participating terminal distributor to deliver drugs to participants by mail.



Pricing information provided prior to participation agreement

(R.C. 5110.12)

Before entering into an agreement with a terminal distributor to participate in the Ohio's Best Rx Program, the act requires ODJFS to provide the terminal distributor with (1) a formula that allows the terminal distributor to calculate the price of each drug included in the Program, (2) a statistically valid sampling of drug prices that includes the prices of not less than two branded and two generic drugs from each category of drugs included in the Program, or (3) the current Program price for each drug included in the Program.

Pricing information provided after participation agreement

(R.C. 5110.29)

The act requires ODJFS to report all of the following to each participating terminal distributor and the Ohio's Best Rx Program administrator in a manner enabling the distributor and administrator to comply with the act's provisions establishing the Ohio's Best Rx Program price for a drug included in the Program:

- (1) For a drug not covered by a rebate agreement, the weighted average per unit price, as computed by ODJFS;
- (2) For a drug covered by a rebate agreement, the amount computed by ODJFS by subtracting the per unit rebate from the weighted average per unit price;
- (3) The amount of the administrative fee, if any, that is to be charged.

Nonparticipating terminal distributors

(R.C. 5110.13)

Under the act, ODJFS cannot prohibit a terminal distributor of dangerous drugs from participating in any other program ODJFS administers on the basis that the terminal distributor has not entered into an agreement to participate in the Ohio's Best Rx Program. Similarly, the act prohibits an entity under contract with ODJFS to serve as the Ohio's Best Rx Program administrator from prohibiting a terminal distributor of dangerous drugs from participating in a program or network the entity administers or operates on the basis that the terminal distributor has not entered into an agreement to participate in the Program.

Ombudsperson

(R.C. 5110.10(A) and 5110.40)

The act requires ODJFS to employ an ombudsperson to assist terminal distributors of dangerous drugs with grievances regarding the Ohio's Best Rx Program. The act excludes employment of the ombudsperson from the duties that may be performed by a person under contract with ODJFS to be the Ohio's Best Rx Program administrator.

PAYMENT FOR DISPENSING DRUGS COVERED BY REBATE AGREEMENTS

Submission of claims

(R.C. 5110.16, 5110.18, and 5110.35(H) and (I))

The act requires a participating terminal distributor or the Ohio's Best Rx Program administrator to submit a claim to ODJFS for each drug dispensed to a Program participant. Neither ODJFS nor the Program administrator is permitted to charge a participating terminal distributor for the submission or processing of a claim.

The act requires a claim for dispensing a drug to be submitted not later than 30 days after the drug is dispensed. The claim must be submitted in accordance with an electronic method provided for in rules the act requires ODJFS to adopt. The claim must specify all of the following:

- (1) The prescription number under which the drug was dispensed to the Program participant;
- (2) The name of, and national drug code number for, the drug dispensed;
- (3) The number of units of the drug dispensed;
- (4) The amount the participant was charged for the drug;
- (5) The date the drug was dispensed;
- (6) Any additional information, as provided for in ODJFS's rules, that ODJFS determines is necessary for it to make payments for claims.



Prohibition against providing false statements

(R.C. 2921.13)

The act prohibits a person from knowingly making a false statement, or knowingly swearing or affirming the truth of a false statement previously made, when the statement is made with purpose to obtain a payment for dispensing a drug under the Ohio's Best Rx Program. The act includes the prohibition among the actions that constitute the preexisting criminal offense of falsification, a first degree misdemeanor.

Payment for claims

(R.C. 5110.17(A) and 5110.35(J))

The act requires ODJFS to pay a participating terminal distributor or the Ohio's Best Rx Program administrator for complete and timely claims for drugs included in the Program. Payment, however, is made only for drugs covered by a rebate agreement between a drug manufacturer and ODJFS.

The payment must be made not later than two weeks after the claim is received by ODJFS. ODJFS is to adopt rules providing for the method of making payments for claims.

Computation of payment amounts

(R.C. 5110.17(B))

Under the act, the amount to be paid for a claim is to be determined as follows:

(1) Multiply the appropriate per unit rebate amount for the drug for which the claim is made by the number of units of the drug dispensed;

(2) If an administrative fee was charged, subtract the administrative fee from the product obtained under (1), above, for each transaction in which a quantity of the drug is dispensed. If the drug dispensed is not subject to a rebate agreement between a drug manufacturer and ODJFS, the result of this computation will be a negative number.

Aggregate payments

(R.C. 5110.18(C))

The act permits ODJFS to combine claims from a participating terminal distributor or the Ohio's Best Rx Program administrator to make aggregate payments to the distributor or administrator for the claims submitted.

Overpayments

(R.C. 5110.17(D))

If a negative number results from the total of the amounts computed by ODJFS for payment of claims to a participating terminal distributor or the Ohio's Best Rx Program administrator for any period for which payments are due, the act specifies that the terminal distributor or administrator has been overpaid for the claims submitted. When there is an overpayment, the act requires ODJFS to reduce future payments to the terminal distributor or administrator or collect an amount from the terminal distributor or administrator sufficient to reimburse ODJFS for the overpayment.

Claims not to be paid

(R.C. 5110.19)

Under the act, ODJFS cannot make an Ohio's Best Rx Program payment for a claim for dispensing drugs if any of the following are the case:

- (1) The claim is submitted by a terminal distributor of dangerous drugs that is neither a terminal distributor participating in the Program nor the Ohio's Best Rx Program administrator.
- (2) The claim is for a drug that is not included in the Program.
- (3) The claim is for a drug included in the Program but the drug is dispensed to an individual who is not covered by a valid Program enrollment card.
- (4) A person or government entity has paid the participating terminal distributor or the Program administrator through any other prescription drug coverage program or prescription drug discount program for dispensing the drug, unless the payment is reimbursement for redeeming a coupon or is an amount directly paid by a drug manufacturer to the terminal distributor for dispensing drugs to residents of a long-term care facility.

Drug manufacturer audits of claims

(R.C. 5110.21(D))

Under the act, if a drug manufacturer participating in the Ohio's Best Rx Program submits a request that ODJFS considers reasonable, ODJFS is required on submission of the request to permit the manufacturer to audit claims for payment submitted by terminal distributors participating in the Program.

**DETERMINATION OF PROFESSIONAL FEES AND
ADMINISTRATIVE CHARGES**

Professional fee for dispensing drugs

(R.C. 5110.12(E), 5110.35(F), and 5110.352)

Among the provisions that must be included in an agreement with a terminal distributor to participate in the Ohio's Best Rx Program, the act provides that the professional fee charged to Program participants cannot exceed \$3. The act requires ODJFS to adopt rules periodically increasing the maximum professional fee that participating terminal distributors and the Ohio's Best Rx Program administrator may charge.

In adopting a rule under this provision, ODJFS is required to review the amount of the professional fee once a year or, at ODJFS's discretion, at more frequent intervals. The act prohibits ODJFS from increasing the professional fee to an amount exceeding the dispensing fee paid under Medicaid.

The act specifies that a participating terminal distributor and the Ohio's Best Rx Program administrator may charge a maximum \$3 professional fee regardless of whether the Medicaid dispensing fee for that drug is less than that amount. ODJFS, however, cannot adopt a rule increasing the maximum professional fee for that drug until the Medicaid dispensing fee for that drug exceeds that amount.

Administrative fee

(R.C. 5110.01(A), 5110.12(F), 5110.35(G), and 5110.353)

Once a year, or at more frequent intervals in ODJFS's discretion, ODJFS must determine the amount of the administrative fee, if any, that participating terminal distributors or the Ohio's Best Rx Program administrator are to charge each time a drug is dispensed under the Ohio's Best Rx Program. If the fee is to be charged, ODJFS must adopt rules providing for the fee.

In determining the amount of any administrative fee, ODJFS must determine an amount, not exceeding \$1 per transaction, that equals or is less than the amount needed to cover the administrative costs of the Ohio's Best Rx Program when added to other funds available under the act for administrative costs and the investment earnings of the moneys in the Ohio's Best Rx Program Fund created by the act. Once a year, or at more frequent intervals in ODJFS's discretion, ODJFS must report to the Ohio's Best Rx Program the methodology underlying the determination of the administrative fee.

Rebate administration percentage

(R.C. 5110.01(N), 5110.35(K), and 5110.354)

At least once a year, or at more frequent intervals in ODJFS's discretion, ODJFS must determine the percentage, if any, to be specified in rules adopted under the act as the rebate administration percentage. The percentage, which the act specifies cannot exceed 5%, is to result in an amount that equals or is less than the amount needed to cover the administrative costs of the Ohio's Best Rx Program when added to the sum of the administrative fee, if any, that ODJFS requires to be charged each time a drug is dispensed under the Program and the investment earnings of the Ohio's Best Rx Program Fund created by the act. Once a year, or at more frequent intervals in ODJFS's discretion, ODJFS must report to the Ohio's Best Rx Program Council the methodology underlying the determination of the rebate administration percentage.

Computations regarding the rebate administration percentage

(R.C. 5110.14(B), 5110.17(B)(1), and 5110.27(B))

If a rebate administration percentage is established, the act requires ODJFS, at intervals specified by the ODJFS, to make the following computation for each drug covered by a rebate agreement:

- (1) Multiply the per unit rebate amount agreed to by the drug manufacturer under a rebate agreement with ODJFS by the rebate administration percentage;
- (2) Subtract the product obtained under (1), above, from the per unit rebate amount agreed to under the rebate agreement.

The result of the computation is the per unit rebate amount to be used by ODJFS in establishing the Ohio's Best Rx Program price for a drug subject to a rebate agreement. It is also used to determine the amount a terminal distributor or the Ohio's Best Rx Program administrator is paid for a claim for dispensing a drug subject to a rebate agreement.

INTERACTION WITH FEDERAL AND STATE PROGRAMS

Conformance or coordination with federal programs

(R.C. 5110.36)

Regardless of any of the act's provisions for the Ohio's Best Rx Program, the act permits ODJFS to adopt rules to make adjustments to the Program that ODJFS considers appropriate to conform the Program to, or coordinate it with, any federally funded prescription drug program created after October 1, 2003.⁷ The rules must be adopted in accordance with the Administrative Procedure Act.

Coordination with state health benefit plans

(R.C. 5110.38)

The act permits ODJFS to coordinate the Ohio's Best Rx Program with a state health benefit plan to enhance efficiency, reduce the cost of drugs, and maximize the benefits of the Program and state health benefit plans.

Actions when a manufacturer does not enter into a rebate agreement

(R.C. 5110.22)

If a drug manufacturer has not entered into a rebate agreement under the Ohio's Best Rx Program with respect to a drug it manufactures that is covered by a state health benefit plan or state retirement system health benefit plan that receives a rebate for the drug from the manufacturer, the act 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 of the state health benefit plan or state retirement system health benefit plan. The act specifies that any resulting additions made to prior authorization lists must be made in accordance with state law and applicable collectively bargained agreements.

⁷ On December 8, 2003, the federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 was signed by the President and became Public Law No: 108-173.

OHIO'S BEST RX PROGRAM COUNCIL

Creation and duties

(R.C. 5110.45)

The act creates the Ohio's Best Rx Program Council, consisting of four legislators and nine persons appointed by the Governor. The act requires the Council to advise ODJFS on the Program. With the approval of a majority of the Council's appointed members, the Council is permitted to initiate studies to determine whether there are more effective ways to administer the Program and provide ODJFS with suggestions for improvements.

Members

(R.C. 5110.46)

The act provides for the Ohio's Best Rx Program Council to consist of the following 13 members:

- The President of the Senate and Minority Leader of the Senate;
- The Speaker of the House of Representatives and Minority Leader of the House of Representatives;
- A representative of the Ohio Chapter of the American Federation of Labor-Congress of Industrial Organizations, appointed from a list of names submitted to the Governor by that organization;
- A representative of the Ohio Chapter of the American Association of Retired Persons, appointed from a list of names submitted to the Governor by that organization;
- A representative of the Ohio Alliance of Retired Americans, appointed from a list of names submitted to the Governor by that organization;
- A representative of a disability advocacy organization located in Ohio, appointed from a list of names submitted to the Governor by disability advocacy organizations located in Ohio;
- A representative of the Ohio Chapter of the United Way, appointed from a list of names submitted to the Governor by that organization;
- Three representatives of research-based drug manufacturers, appointed from a list of names submitted to the Governor by the Pharmaceutical Research and Manufacturers of America;



--A pharmacist licensed to practice pharmacy in Ohio, appointed from a list of names submitted to the Governor by the Ohio Pharmacists Association.

Governor's appointments

(R.C. 5110.47)

The Governor is required by the act to make initial appointments to the Ohio's Best Rx Program Council not later than 30 days after the act's effective date. The act provides that the appointed members serve at the pleasure of the Governor. If an appointed member's seat becomes vacant, the Governor is required to fill the vacancy not later than 30 days after the vacancy occurs and in the manner provided for the initial appointment.

Legislative members

(R.C. 5110.48)

The President of the Senate and Speaker of the House of Representatives are required by the act to serve as co-chairs of the Ohio's Best Rx Program Council. The President and Speaker, as well as the Minority Leader of the Senate and Minority Leader of the House of Representatives, are authorized by the act to appoint, respectively, an alternate to attend any Council meeting. The alternate must be a member of the General Assembly.

Administrative matters

(R.C. 5110.49 to 5110.51)

The act provides that the members of the Ohio's Best Rx Program Council are to serve without compensation. It further provides that the members are not to be reimbursed for any expenses associated with their duties on the Council.

The act provides that the Council's records are a public record for purposes of Ohio's Public Records Law. The act specifies, however, that this provision does not apply to any part of records that contain a trade secret, as defined in laws unaffected by the act.⁸

The act provides that the Council is not subject to the Sunset Review Committee and the preexisting laws that provide for a newly created agency to be

⁸ For an explanation of the meaning of "trade secrets," see "**Protection of trade secrets.**" discussed below.

terminated by a specific date, generally within four years after its creation, unless the General Assembly takes action to extend the agency's existence.

COMPILATION OF PROGRAM INFORMATION

Statistics on frequently dispensed drugs

(R.C. 5110.39)

Not later than April 1, 2005, ODJFS is required by the act to create a list of the 25 drugs most often dispensed to Ohio's Best Rx Program participants under the Program. In creating the list, ODJFS must use the most recent six-month period for which the information is available.

By the same deadline, the act requires ODJFS to determine the average percentage savings that Ohio's Best Rx Program participants receive for each of the 25 drugs included on the list. This is to be calculated by comparing the average amount that terminal distributors charge Program participants for each of the drugs, on a date selected by ODJFS, to the average of the terminal distributors' usual and customary charge for each of the drugs on that date.

List of participating manufacturers and terminal distributors

(R.C. 5110.23)

The act requires ODJFS to compile a list consisting of the name of each drug manufacturer that enters into a rebate agreement under the Ohio's Best Rx Program and the names of the drugs included in each rebate agreement. ODJFS also must compile a list consisting of the name of each participating terminal distributor. The act provides that the lists are public records and requires ODJFS to "specifically" make the list available to physicians, participating terminal distributors, and other health professionals.

Use and preservation of records

(R.C. 5110.35(O) and 5110.59)

The act requires ODJFS to adopt rules that establish standards and procedures for the use and preservation of records regarding the Ohio's Best Rx Program. It requires ODJFS and the Ohio's Best Rx Program administrator to use and preserve the records in accordance with those rules and specifies that the requirement applies to ODJFS's or the administrator's use and preservation of records received or generated by ODJFS, any other government entity, or any person.

CONFIDENTIALITY OF PROGRAM AND CONSUMER INFORMATION

State and federal requirements

(R.C. 5110.55)

The act provides that information transmitted for any purpose related to the Ohio's Best Rx Program is confidential to the extent required by federal and state law. The confidentiality provision applies to the information that is transmitted by or to drug manufacturers, terminal distributors of dangerous drugs, the Ohio's Best Rx Program administrator, ODJFS, the Department of Administrative Services, the five state retirement systems, a state health benefit plan or state retirement system health benefit plan, Program participants, and any other government entity or person.

Protection of trade secrets

(R.C. 5110.01(U) and 5110.56)

The act provides that certain types of information related to the Program are trade secrets, are not public records under state law, and cannot be used, released, published, or disclosed in a form that reveals a specific drug or the identity of a drug manufacturer. Under laws unaffected by the act, a "trade secret" is information, including the whole or any portion or phase of any scientific or technical information, design, process, procedure, formula, pattern, compilation, program, device, method, technique, or improvement, or any business information or plans, financial information, or listing of names, addresses, or telephone numbers, that satisfies both of the following: (1) it derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (2) it is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Specifically, the act's trade secret provision applies to the following: (1) the amounts to be paid under the Program for claims submitted by terminal distributors or the Ohio's Best Rx Program administrator, (2) information disclosed in a rebate agreement or in communications related to a rebate agreement, (3) the drug pricing and rebate information submitted to ODJFS by the Department of Administrative Services and the state retirement systems with respect to a state health benefit plan or state retirement system health benefit plan, and (4) the elements of the computations made by ODJFS for the Program and any results of those computations that reveal or could be used to reveal the drug pricing or rebate information and amounts used to make the computations.

The act prohibits a person or government entity from using or revealing any information it protects as a trade secret. The act provides an exception from this prohibition if using or revealing the information is required for the implementation of the Ohio's Best Rx Program.

Permissible disclosures

(R.C. 5110.57)

The act specifies that its provisions on confidentiality of Program information and trade secrets do not preclude ODJFS from disclosing information necessary for implementation of the Program, including the disclosure of information to a participating terminal distributor or the Ohio's Best Rx Program administrator for purposes of enabling the terminal distributor or administrator to comply with the act's requirement that the appropriate amount be charged when a drug is dispensed to a Program participant.

Confidentiality of consumer information

(R.C. 5110.58 and 5110.99)

The act prohibits a person or government entity from selling, soliciting, disclosing, receiving, or using information that identifies or could be used to identify an Ohio's Best Rx Program applicant or participant. The act specifies that the prohibition does not apply to aggregate information about applicants and participants that does not identify and could not be used to identify an individual applicant or participant. Whoever violates the prohibition is guilty of a first degree misdemeanor.

Notwithstanding its prohibition on the disclosure and other uses of identifying information regarding Program applicants and participants, the act specifies the following:

(1) ODJFS and the Ohio's Best Rx Program administrator are permitted to solicit, disclose, receive, or use identifying information or knowingly permit the use of identifying information for a purpose directly connected to the administration of the Program, including disclosing or knowingly permitting the use of identifying information included in a claim for payment for dispensing drugs under the Program that a participating drug manufacturer audits under the act's provisions permitting such audits, contacting applicants or participants regarding participation in the Program, and notifying applicants and participants regarding participating terminal distributors.

(2) ODJFS and the Program administrator are permitted to solicit, disclose, receive, or use identifying information or knowingly permit the use of identifying information to the extent required by federal or state law.

(3) ODJFS and the Program administrator are permitted to disclose identifying information to the applicant or participant who is the subject of that information or to the parent, spouse, guardian, or custodian of that applicant or participant.

(4) A participating terminal distributor or the Program administrator is permitted to solicit, disclose, receive, or use identifying information or knowingly permit the use of identifying information to the extent required or permitted by an agreement the distributor enters into to participate in the Program or a contract the administrator enters into with ODJFS to administer the Program.

(5) For purposes of auditing a claim for payment for dispensing drugs under the Program, a participating drug manufacturer is permitted to solicit, receive, and use identifying information included in the claim.

STATE ACCOUNTING AND APPROPRIATIONS

Program fund

(R.C. 5110.32)

The act creates the Ohio's Best Rx Program Fund. The Fund is to consist of rebate payments made by drug manufacturers participating in the Program, any administrative fees charged under the Program when a participant purchases a drug, and the Fund's investment earnings.

The Fund is to be in the custody of the Treasurer of State, but is not to be part of the state treasury. ODJFS is to use money in the Fund to make payments to participating terminal distributors and the Ohio's Best Rx Program administrator, if any, pursuant to the claims they submit for dispensing drugs to Program participants.

Administration fund

(R.C. 5110.33)

The act creates in the state treasury the Ohio's Best Rx Administration Fund. ODJFS is required to use money in the Fund to pay the administrative costs of the Ohio's Best Rx Program, including costs associated with contracted services, staff, outreach activities, computers and network services, and the Ohio's Best Rx Program Council.

The Treasurer of State is required to transfer money into the Fund from the Ohio's Best Rx Program Fund. The transfers are to be made in accordance with a schedule developed by the Treasurer of State and ODJFS. The Treasurer must transfer amounts equal to the following:

(1) Amounts resulting from application of the rebate administration percentage;

(2) The amount of the administrative fees charged under the Program when drugs are dispensed to participants;

(3) The amount of investment earnings credited to the Ohio's Best Rx Program.

Appropriations

(Section 4)

The act appropriates funds from the state treasury for purposes of ODJFS's creation and operation of the Ohio's Best Rx Program and establishes a process for obtaining a supplemental appropriation, if needed.⁹ The act provides that the use of state funds for start-up costs does not obligate the state to fund further Program costs, as the Program is a discount program, not an entitlement program.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	10-23-03	p. 1145
Reported, H. Finance & Appropriations	12-09-03	p. 1270
Passed House (93-1)	12-09-03	pp. 1271-1272
Passed Senate (32-1)	12-10-03	pp. 1263-1264
House concurred in Senate amendments (96-1)	12-10-03	pp. 1326-1327

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⁹ For a detailed description of the appropriation and its designated uses, see the Legislative Service Commission's Fiscal Note for H.B. 311.