



Bob Bennett

## *Bill Analysis*

*Legislative Service Commission*

### **H.B. 311**

125th General Assembly  
(As Introduced)

**Reps. Hagan, Miller**

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#### **BILL SUMMARY**

##### **Ohio's Best Rx Program created**

- Establishes the Ohio's Best Rx Program in the Ohio Department of Job and Family Services (ODJFS) under which eligible individuals receive discounted prices on covered drugs from participating terminal distributors of dangerous drugs (pharmacies and other entities that provide drugs to consumers).
- Establishes eligibility requirements for the Program, including that an individual must (1) either have family income not exceeding 250% of the federal poverty guidelines or be 60 years of age or older, (2) with one exception, not have other outpatient prescription drug coverage, and (3) with certain exceptions, not have had outpatient prescription drug coverage during any of the four months preceding the month of application for the Program.

##### **Participating manufacturers**

- Provides that a manufacturer of one or more drugs covered by a state health benefit plan may enter into an agreement with ODJFS under which the manufacturer agrees to participate in the Program with respect to one or more of those drugs.
- Requires that a participating drug manufacturer make a rebate payment to ODJFS for each covered drug dispensed to an Ohio's Best Rx Program participant.
- Provides that the amount of the rebate is to be based on the weighted average of the per unit rebates for the drug under the state health benefit plans.

- Requires that ODJFS ask the Department of Administrative Services and each state retirement system to determine whether a drug should be placed on a state health benefit plan's prior authorization list if the drug's manufacturer does not agree to include the drug in the Program.
- Provides that the name of a drug manufacturer that does not agree to have a drug it manufactures included in the Program, and the name of the drug, is a public record and requires that ODJFS distribute the information to physicians, pharmacists, and other health professionals.

**Participating terminal distributors**

- Provides that a terminal distributor of dangerous drugs may enter into an agreement with ODJFS to participate in the Program.
- Requires that a participating terminal distributor charge a Program participant a discounted price for each drug the program covers.
- Permits a participating terminal distributor to add to the discounted price a professional fee in an initial amount not to exceed \$3 for each supply of a covered drug of up to 30 days.
- Requires that ODJFS periodically increase the maximum professional fee.
- Requires that a participating terminal distributor disclose to each participant the amount the participant saves when buying a drug under the Program.
- Permits a participating terminal distributor to submit a claim to ODJFS for a payment for charging the discounted price, unless the distributor has received a payment or rebate from the manufacturer of the drug for that transaction.
- Provides that the amount ODJFS is to pay a participating terminal distributor for a claim is to be based on the weighted average of the per unit rebates for drugs under the state health benefit plans.
- Provides, for the purpose of paying ODJFS's administrative costs, for ODJFS to reduce the payment to a participating terminal distributor by a percentage, not to exceed 5%, of the weighted average of the per unit rebates.

### Prices and savings

- Requires that ODJFS use information submitted by the Department of Administrative Services and state retirement systems about rebates and prices under health benefit plans to compute weighted average prices and rebates and use those weighted averages in determining the discounted price for drugs covered by the Ohio's Best Rx Program and the amount participating terminal distributors are to be paid for their claims.
- Requires that ODJFS determine the average percentage savings in the amount participating terminal distributors charge participants of the Ohio's Best Rx Program for each of the 25 drugs most often dispensed under the program.

### Program fund

- Creates in the state treasury the Ohio's Best Rx Program Fund, consisting of rebate payments that participating drug manufacturers pay to ODJFS and the Fund's investment earnings.
- Permits ODJFS to use up to 5% of the money in the Fund that comes from rebate payments to pay the program's administrative costs.

### Other provisions

- Requires that ODJFS make outreach efforts to publicize the Ohio's Best Rx Program and maximize participation in it.
- Permits ODJFS to coordinate the Ohio's Best Rx Program with state health benefit plans to enhance efficiency, reduce the cost of drugs, and maximize the benefits of the program and plans.
- Provides that certain information regarding the Ohio's Best Rx Program is trade secrets, not public records, and may not be used, released, published, or disclosed in a form that reveals a specific drug or the identity of a drug manufacturer.
- Creates the Ohio's Best Rx Program Council to advise ODJFS on the program.

- Permits the Council to initiate studies to determine whether there are more effective ways to administer the Ohio's Best Rx Program and provide ODJFS with suggestions for improvements.
- Permits ODJFS to adopt rules to make adjustments to the Ohio's Best Rx Program that ODJFS considers appropriate to conform the program to, or coordinate it with, any federally funded prescription drug program created after the bill's effective date.

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## CONTENT AND OPERATION

### *Ohio's Best Rx Program created*

(R.C. 5110.01 and 5110.02)

The bill establishes the Ohio's Best Rx Program in the Ohio Department of Job and Family Services (ODJFS). Individuals eligible for the program are to receive an enrollment card to present to a participating terminal distributor of dangerous drugs (pharmacies and similar entities) to receive discounted prices on drugs covered by the program.<sup>1</sup>

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<sup>1</sup> A "terminal distributor of dangerous drugs" is 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. This 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

## Eligibility

(R.C. 2921.13, 5110.04, 5110.05, 5110.06, 5110.07, and 5110.35)

To qualify for the Ohio's Best Rx Program, an individual must submit a completed application to ODJFS and meet eligibility requirements.<sup>2</sup> The individual must reside in Ohio and either have family income not exceeding 250% of the federal poverty guidelines or be 60 years of age or older. The individual may not have outpatient prescription drug coverage paid for in whole or in part by a third-party payer, Medicaid, or another 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 established by the Ohio Department of Aging.<sup>3</sup> And, the individual must satisfy a "look-back" requirement that provides that an individual may not have had such outpatient prescription drug coverage during any of the four months preceding the month in which the application for the program is made. However, no individual is to be denied eligibility for the program because of the look-back requirement if the individual, at the time application for the program is made, is 60 years of age or older or no longer eligible for outpatient prescription drug coverage for any of the following reasons: the third-party payer that paid all or part of the coverage filed for bankruptcy under federal bankruptcy laws, the individual is no longer eligible for coverage provided through a retirement plan subject to protection under the federal Employee Retirement Income Security Act (ERISA), or the individual is no longer eligible for transitional Medicaid benefits.

The bill requires that an individual applying for the program include with the application documentation to provide verification of the information provided in the application. ODJFS must adopt rules specifying the documentation to be included and rules establishing the application process.

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*licensed health professional authorized to prescribe drugs. (R.C. 4729.01, not in the bill.)*

<sup>2</sup> *An individual's parent, guardian, or custodian may submit the application to ODJFS for the individual.*

<sup>3</sup> *A "third-party payer" is (1) an insurance company, (2) health insuring corporation, (3) labor organization, (4) employer, (5) intermediary organization that is not a health delivery network contracting solely with self-insured employers, (6) third-party administrator, (7) 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. (R.C. 3901.38, not in the bill.)*

The application form must include a space for the applicant to attest that the information provided in the application and the documentation included with the application is, to the best knowledge and belief of the applicant, accurate. The application form must also include (1) a statement printed in bold letters indicating that knowingly making a false statement on the form is the offense of falsification, a misdemeanor of the first degree and (2) information about the Medicaid program, including general eligibility requirements, application procedures, and benefits.<sup>4</sup>

ODJFS is required to make eligibility determinations in accordance with procedures to be established in rules. Individuals determined eligible are to receive an enrollment card that is valid for one year.

**Participating manufacturers and covered drugs**

(R.C. 5110.01, 5110.20, 5110.21, 5110.22, 5110.23, and 5110.35)

The bill provides that a drug manufacturer that manufactures one or more drugs covered by a state health benefit plan may enter into an agreement with ODJFS under which the manufacturer agrees to participate in the Ohio's Best Rx Program with respect to one or more of those drugs. A "state health benefit plan" is a policy or contract of health care benefits that is provided by a collective bargaining agreement between state or local public employees and their public employer, offered by the Department of Administrative Services to state employees, or offered by a state retirement system to persons receiving a pension, allowance, or other cash benefit based on age and service retirement.

An agreement between a drug manufacturer and ODJFS must specify the amount of time the agreement is to be in effect, which is to be not less than one year from the date the agreement is entered into. The agreement must also specify which of the manufacturer's drugs are included in the agreement. The program is to cover each drug for which an agreement is in effect.

A drug manufacturer that enters into an agreement with ODJFS must make a rebate payment to ODJFS for each drug that is included in the agreement and dispensed to an Ohio's Best Rx Program participant. The rebate is to be in an amount equal to the weighted average of the per unit rebates for the drug multiplied by the number of units dispensed to the participant.<sup>5</sup> Rebates must be

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<sup>4</sup> *The sanction for a misdemeanor of the first degree is a maximum 180-day jail term, maximum \$1,000 fine, or both.*

<sup>5</sup> *See "**Determining discount prices**" below for a discussion of how the weighted average of the per unit rebates for drugs covered by the Ohio's Best Rx Program is determined.*

made on a quarterly basis or in accordance with a schedule established by rules ODJFS is to adopt if ODJFS determines it is best that rebates be made on a basis other than quarterly.

A drug manufacturer that enters into an agreement with ODJFS is permitted to submit a request to ODJFS to audit claims submitted by terminal distributors of dangerous drugs seeking payment from ODJFS for charging the discounted price for a drug covered by the program.<sup>6</sup> ODJFS is to permit the audit if it considers the request reasonable.

If a drug manufacturer does not agree to enter into an agreement with ODJFS with respect to a drug it manufactures, ODJFS is required 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 state health benefit plan's prior authorization list.<sup>7</sup> Additions to prior authorization lists must be made in accordance with state law and applicable collectively bargained agreements.

The bill provides that the name of a drug manufacturer that does not enter into an agreement with ODJFS for a drug it manufactures that is covered by a state health benefit plan, and the name of the drug, is a public record. ODJFS must distribute the information to physicians, pharmacists, and other health professionals.

### **Participating terminal distributors**

(R.C. 5110.01, 5110.10, 5110.11, 5110.12, 5110.13, 5110.14, 5110.15, 5110.16, 5110.35, 5110.351, and 5110.352)

The bill provides that a terminal distributor of dangerous drugs may enter into an agreement with ODJFS to participate in the Ohio's Best Rx Program. The agreement must specify the amount of time it is to be in effect, which is to be at least one year, and require that the terminal distributor charge an individual participating in the program a discounted price for each drug that the program covers. The discounted price is to be determined by multiplying the number of units of the covered drug that the terminal distributor dispenses to a participant by

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<sup>6</sup> See "**Participating terminal distributors**" below.

<sup>7</sup> *Prior authorization means that a particular drug may be provided to a particular patient only if the health plan gives specific approval before the drug is provided.*

a price that ODJFS computes for the drug's applicable National Drug Code number.<sup>8</sup>

A terminal distributor that enters into an agreement to participate in the program is permitted to add to the discounted price a professional fee in an amount not to exceed, except as provided in rules, \$3 for each supply of a covered drug of up to 30 days. ODJFS is required by the bill to adopt rules periodically increasing the maximum professional fee that a terminal distributor may charge an Ohio's Best Rx Program participant. ODJFS is prohibited from increasing the professional fee to an amount exceeding the dispensing fee paid under the Medicaid program. A terminal distributor is permitted to charge a maximum \$3 professional fee for each supply of a covered drug of up to 30 days regardless of whether the Medicaid dispensing fee for that drug is less than that amount.<sup>9</sup> ODJFS, however, may not increase the maximum professional fee for that drug until the Medicaid dispensing fee exceeds that amount.

A participating terminal distributor is required to disclose to each program participant the amount the participant saves when buying a drug under the program. The amount of the savings is to be determined by (1) subtracting from the usual and customary charge for the drug the amount of the discounted price that the distributor charges the participant for the drug and (2) adding to that amount the professional fee, if any, the distributor charges the participant.<sup>10</sup> The distributor may not release proprietary information about the drug when disclosing the savings.

A participating terminal distributor that charges the discounted price to a program participant may submit a claim to ODJFS, unless the distributor has received a payment or rebate from the manufacturer of the drug for that transaction. To receive a payment from ODJFS, the distributor must, not later than 30 days after the sale, submit a claim to ODJFS in accordance with rules ODJFS is to adopt. The claim must specify (1) the prescription number of the

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<sup>8</sup> See "**Determining discount prices**" below for a discussion of how ODJFS is to compute the price. The United States Food and Drug Administration administers the National Drug Code. The Code "serves as a universal product identifier for human drugs." (<http://www.fda.gov/cder/ndc>).

<sup>9</sup> The Medicaid dispensing fee for flu vaccine is 50¢. (Ohio Administrative Code § 5101:3-9-05.)

<sup>10</sup> The "usual and customary charge" is the amount the terminal distributor of dangerous drugs charges for a drug to an individual who does not receive a discounted price under a drug discount program and for whom no third-party payer or program funded in whole or in part with state or federal funds is responsible for the cost of the drug.

participant's prescription under which the drug is dispensed, (2) the name of, and National Drug Code number for, the drug, (3) the number of units of the drug that the distributor dispensed, (4) the amount the distributor charged for the drug, and (5) the date that the distributor dispensed the drug. ODJFS is required to pay the distributor for complete and timely claims in accordance with rules ODJFS is required to adopt. The amount to be paid is to be determined by (1) multiplying the weighted average of the per unit rebates for the drug's National Drug Code number by the number of units dispensed and (2) subtracting from that amount the proportionate administrative cost.<sup>11</sup> ODJFS is permitted to combine claims from a distributor to make aggregate payments but may not impose a transaction charge on the distributor.

### **Determining discount prices**

(R.C. 5110.01, 5110.25, 5110.26, 5110.27, 5110.28, 5110.29, and 5110.35)

The Department of Administrative Services and each state retirement system is required by the bill to submit information regarding each state health benefit plan to ODJFS to be used in computing the discounted price for drugs covered by the Ohio's Best Rx Program.<sup>12</sup> The Department and systems must provide ODJFS the name of each state health benefit plan, the number of individuals enrolled in each plan, the per unit price for each drug covered by each plan and dispensed through means other than a mail order system, and the weighted average of the per unit rebates for each drug that is covered by each plan and dispensed through any means.<sup>13</sup> In submitting information about a drug, the Department and systems must do all of the following:

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<sup>11</sup> See "**Determining discount prices**" below for a discussion of how the weighted average of the per unit rebates for drugs covered by the Ohio's Best Rx Program is determined and a discussion of the proportionate administrative cost.

<sup>12</sup> The Department of Administrative Services and state retirement systems are to submit the information in accordance with rules the bill requires ODJFS to adopt.

<sup>13</sup> The bill defines "per unit price" as the total amount paid to a terminal distributor of dangerous drugs under a state health benefit plan for one unit of a drug covered by the plan, after rebates, discounts, and other reductions are made. "Per unit price" includes (1) the amount that the state health benefit plan, or other government entity or person authorized to make the payment on behalf of the state health benefit plan, pays to the terminal distributor and (2) the amount that the person covered by the state health benefit plan pays to the terminal distributor in the form of a copayment, coinsurance, or other cost-sharing charge. "Per unit rebate" is defined as all rebates, discounts, formulary fees, administrative fees, and other allowances calculated on a drug-by-drug basis that

(1) Compute and submit information separately for each of the drug's National Drug Code numbers;

(2) Submit the per unit price information each month and provide for the information to reflect the per unit price for the previous month;

(3) Use the number of units for which a per unit rebate is paid in determining the weighted average of the per unit rebates;

(4) Submit the information regarding the weighted average of the per unit rebates once a year and provide for the information to reflect the weighted average for the previous calendar year.

Using the information submitted by the Department of Administrative Services and state retirement systems, ODJFS is required to do all of the following for each National Drug Code number of each drug covered by the Ohio's Best Rx Program:

(1) Once each year, compute the total weighted average of the per unit rebates;

(2) Once each year, subtract the proportionate administrative cost, which is a percentage that ODJFS is to specify in rules, from the total weighted average of the per unit rebates;<sup>14</sup>

(3) Once each month, compute the weighted average of the per unit prices;

(4) Once each month, determine the discounted price to be charged under the program by subtracting the amount computed under (2) from the weighted average of the per unit prices.

This means that the discounted price to be charged for each unit of a drug dispensed under the Ohio's Best Rx Program is to be an amount determined by subtracting the total weighted average of the per unit rebates under the state health benefit plans for the drug, less the proportionate administrative cost, from the

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*are paid by a drug manufacturer to a state health benefit plan for one unit of a drug dispensed under the plan.*

<sup>14</sup> *The bill requires that the percentage used as the proportionate administrative cost be the same percentage of the money in the Ohio's Best Rx Program Fund coming from rebates made by drug manufacturers that ODJFS uses to pay for the program's administrative costs. That percentage cannot exceed 5%. (See "Ohio's Best Rx Program Fund" below.)*



weighted average of the per unit prices under the state health benefit plans for the drug. The formula for the computation is as follows:

Weighted average per unit prices under state health benefit plans - (weighted average per unit rebates under the state health benefit plans – proportionate administrative cost) = discounted price.<sup>15</sup>

ODJFS is to recompute the discounted price each month as it receives updated information about the weighted average of the per unit prices under the state health benefit plans for the drug and is to make the computations in accordance with procedures established in rules ODJFS is to adopt. In computing the total weighted average of the per unit rebates, ODJFS must use the number of individuals enrolled in each state health benefits plan.

ODJFS is required to report to each terminal distributor of dangerous drugs participating in the program the results of ODJFS's computation of the discounted price to be charged under the program for the National Drug Code numbers of each drug covered by the program. The results must be reported in a manner necessary for the terminal distributors to pay the discounted prices to participants in the program.

**Computation of average percentage savings**

(R.C. 5110.39)

ODJFS is required by the bill to determine the average percentage savings in the amount terminal distributors of dangerous drugs participating in the Ohio's Best Rx Program charge participants of the program for each of the 25 drugs most often dispensed under the program. The determination must be made not later than April 1, 2005. To make the determination, ODJFS is to create a list of those 25 drugs, using data from the most recent six-month period for which the data is available. Next, ODJFS must determine the average amount that participating terminal distributors charge, on a date ODJFS selects, participants for each drug included on the list and then determine, for that date, the average usual and customary charge of the distributors for each of those drugs. ODJFS is to compare those average charges to determine the average percentage savings under the program.

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<sup>15</sup> As discussed above under the heading "**Participating terminal distributors**," a participating terminal distributor is permitted to add a professional fee to the discounted price.

### **Ohio's Best Rx Program Fund**

(R.C. 5110.33 and 5110.34)

The bill creates in the state treasury the Ohio's Best Rx Program Fund. The Fund is to consist of rebate payments that drug manufacturers participating in the program pay to ODJFS and the Fund's investment earnings. ODJFS is required to use money in the Fund to make payments to terminal distributors of dangerous drugs that submit claims in accordance with the bill.<sup>16</sup> ODJFS must also use money in the Fund to pay the program's administrative costs, including costs associated with contracted services, computers, and the Ohio's Best Rx Program Council.<sup>17</sup> The bill provides that ODJFS may use up to 5% of the money in the Fund that comes from rebate payments to pay the program's administrative costs. ODJFS may use all of the money that comes from the Fund's investment earnings to pay the administrative costs.

### **Outreach efforts**

(R.C. 5110.37)

The bill requires that ODJFS make outreach efforts to publicize the Ohio's Best Rx Program and maximize participation in it.

### **Coordination with state health benefit plans**

(R.C. 5110.38)

ODJFS is authorized by the bill to coordinate the Ohio's Best Rx Program with state health benefit plans to enhance efficiency, reduce the cost of drugs, and maximize the benefits of the program and plans.

### **Confidentiality of information regarding the Ohio's Best Rx Program**

(R.C. 5110.55, 5110.56, and 5110.57)

The bill provides that information transmitted by or to any of the following for any purpose related to the Ohio's Best Rx Program is confidential to the extent required by federal and state law:

- (1) Drug manufacturers;

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<sup>16</sup> See "**Participating terminal distributors**" above.

<sup>17</sup> See "**Ohio's Best Rx Program Council**" below.

- (2) Terminal distributors of dangerous drugs;
- (3) ODJFS;
- (4) The Department of Administrative Services;
- (5) The state retirement systems;
- (6) The state health benefit plans;
- (7) Ohio's Best Rx Program participants;
- (8) Any other government entity or person.

The bill also provides that certain information regarding the program is trade secrets, not public records, and may not be used, released, published, or disclosed in a form that reveals a specific drug or the identity of a drug manufacturer. This confidentiality provision applies to all of the following:

(1) Information disclosed in an agreement, or in communications related to an agreement, between a terminal distributor of dangerous drugs and ODJFS for the terminal distributor's participation in the program;

(2) Information disclosed in an agreement, or in communications related to an agreement, between a drug manufacturer and ODJFS for the manufacturer's participation in the program;

(3) Information the Department of Administrative Services and state retirement systems submit to ODJFS regarding the per unit price for drugs covered by a state health benefit plan or the weighted average of the per unit rebates for such drugs;

(4) The results of ODJFS's computations of the total weighted average of the per unit rebates for drugs covered by the program and the weighted average of the per unit prices of those drugs;

(5) The results of ODJFS's computations of the average amount that participating terminal distributors charge participants of the program for the 25 most-often dispensed drugs and the average usual and customary charge the distributors charge uninsured persons for those drugs.

All persons and government entities are prohibited from using or revealing the information except as required for the implementation of the program.

The bill provides that its confidentiality provisions do not preclude ODJFS from disclosing information necessary for the implementation of the program.

### *Ohio's Best Rx Program Council*

(R.C. 5110.45, 5110.46, 5110.47, 5110.48, 5110.49, and 5110.50)

The bill creates the Ohio's Best Rx Program Council to advise ODJFS on the program. 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.

The Council is to consist of the President of the Senate, Speaker of the House of Representatives, Senate Minority Leader, House Minority Leader, and a representative of each of the following organizations appointed by the Governor from a list of names submitted by the organizations:

- (1) The Ohio chapter of the American Federation of Labor-Congress of Industrial Organizations;
- (2) The Ohio chapter of the American Association of Retired Persons;
- (3) A disability advocacy organization located in Ohio;
- (4) The Ohio chapter of the United Way;
- (5) The Ohio Alliance of Retired Americans.

The Council is also to include three representatives of research-based drug manufacturers, appointed by the Governor from a list of names submitted by the Pharmaceutical Research and Manufacturers of America.

The Governor is required to make initial appointments to the Council not later than 30 days after the effective date of this provision of the bill. The appointed members are to serve at the Governor's pleasure. If an appointed member's seat becomes vacant, the Governor must fill the vacancy not later than 30 days after the vacancy occurs and in the manner provided for the initial appointment.

The Senate President and House Speaker are to serve as co-chairs of the Council. The Senate President, House Speaker, Senate Minority Leader, and House Minority Leader are not permitted to appoint designees to serve in their places, unless the official becomes incapacitated.

Members of the Council are to serve without compensation and are not to be reimbursed for any expenses associated with their duties on the Council.

None of the Council's findings, recommendations, or studies are to be released to any person or government entity without the approval of at least a majority of the Council's appointed members.

The bill provides that state law regarding the automatic expiration of statutorily created agencies does not apply to the Council. That law provides that an agency created by statute after January 1, 1997, automatically expires four years after its creation, unless the General Assembly takes further action to extend its life (R.C. 101.82-101.87, not in the bill).

### **Rules**

(R.C. 5110.35 and 5110.36)

In addition to the rules the bill specifically requires ODJFS to adopt governing the Ohio's Best Rx Program, the bill provides that ODJFS may adopt other 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 the effective date of this provision of the bill. ODJFS is to adopt all of the rules in accordance with the Administrative Procedure Act (R.C. Chapter 119.), which requires public notice and hearings.

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## **HISTORY**

ACTION	DATE	JOURNAL ENTRY
Introduced	10-23-03	p. 1145

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