

173-71-06

**Participating drug manufacturer agreement.**

(A) For purposes of participating in the best Rx program, any drug manufacturer may enter into an agreement with ODA under which the drug manufacturer agrees to make manufacturer payments to ODA with respect to one or more of the manufacturer's drugs when the one or more drugs are dispensed under the best Rx program. The terms of the manufacturer agreement shall comply with section 173.811 of the Revised Code and paragraph (B) of this rule.

(B) A manufacturer agreement shall include terms that do all of the following:

- (1) Specify the time the agreement is to be in effect, which shall be not less than one year from the date the agreement is entered into;
- (2) Specify which of the participating drug manufacturer's drugs are included in the agreement;
- (3) Permit ODA to remove a drug from the manufacturer agreement in the event of a dispute over the drug's utilization;
- (4) Permit the participating drug manufacturer to make additions to the list of drugs covered by the agreement;
- (5) Require that the drug manufacturer specify a per unit amount that will be paid to ODA for each drug included in the agreement that is dispensed to a participant;
- (6) Require that the per unit amount specified by the drug manufacturer be an amount that the manufacturer believes is greater than or comparable to the per unit amount generally payable by the manufacturer for the same drug when the drug is dispensed to an individual using the outpatient drug coverage included in a health benefit plan offered in this state or another state to public employees or retirees and the eligible dependents of those employees or retirees;
- (7) Require the drug manufacturer to make payments in accordance with the amounts computed under division (A) of section 173.812 of the Revised Code and paragraph (C) of this rule;
- (8) Require the drug manufacturer to make manufacturer payments to ODA on a quarterly basis and within thirty days after receipt of an invoice; or, if the amount of the manufacturer payment due for any given quarter is less than fifty dollars, require the drug manufacturer to make the manufacturer

payment once the total manufacturer payments due have accrued to fifty dollars, but for no longer than twelve months. ODA may withhold submitting a quarterly invoice to the drug manufacturer to request a manufacturer payment if no payment is due; or, if the amount of the manufacturer payment due for any given quarter is less than fifty dollars, ODA may withhold submitting a quarterly invoice to the drug manufacturer until the total manufacturer payments due have accrued to fifty dollars, but for no longer than twelve months;

- (9) Require that the manufacturer payments are accompanied by a detailed list identifying the drugs, affirming the manufacturer payments being paid, and identifying, with explanation, any manufacturer payments not being paid as invoiced; and,
  - (10) Permit the drug manufacturer to refer best Rx program applicants and participants to a PAP operated or sponsored by the manufacturer for any drug included in the manufacturer agreement, only so long as the drug manufacturer refers residents of this state to the best Rx program if they apply for the PAP and are found to be ineligible for the PAP.
- (C) When a drug included in a manufacturer agreement is dispensed under the best Rx program, ~~the manufacturer payment amount that applies to the transaction is established in accordance with the following:~~ODA shall compute the manufacturer payment amount by multiplying the per unit amount specified for the drug in the manufacturer agreement by the number of units dispensed.
- ~~(1) ODA shall compute the manufacturer payment amount by multiplying the per unit amount specified for the drug in the manufacturer agreement by the number of units dispensed;~~
  - ~~(2) For purposes of determining the amount to charge a participant under section 173.75 of the Revised Code and the amount that ODA shall pay for a claim in accordance with section 173.801 of the Revised Code, the manufacturer payment amount is computed as follows:~~
    - ~~(a) Multiply the per unit amount specified for the drug in the manufacturer agreement by the program administration percentage;~~
    - ~~(b) Subtract the product determined under paragraph (C)(2)(a) of this rule from the per unit amount specified for the drug in the manufacturer agreement; and,~~
    - ~~(c) Multiply the per unit amount resulting from the computation under paragraph (C)(2)(a) of this rule by the number of units dispensed.~~

- (D) ODA shall update the manufacturer payment amounts or formulas calculated under this rule at least annually.
- (E) In its negotiations with a drug manufacturer proposing to enter into a manufacturer agreement, ODA shall use the best information on manufacturer payments that is available to ODA, including information obtained from the verifications made under section 173.814 of the Revised Code by the consulting PBM. ODA shall use the information in an attempt to obtain manufacturer payments that maximize the benefits provided to participants.
- (F) Annually, ODA shall select a sample of not more than ten of the drugs that were included in the manufacturer agreements in the immediately preceding year. ODA shall submit to the consulting PBM information that identifies the per unit amount of the manufacturer payments that applied to each of the drugs in the sample.

The consulting PBM shall review the submitted information. After the review, the consulting PBM shall provide information to ODA verifying whether any of the per unit payment amounts that applied to the selected drugs were more than two per cent lower than the per unit payment amounts negotiated by the consulting PBM for the same drugs in connection with health benefit plans that generally do not use formularies to restrict the outpatient drug coverage included in the plans. The consulting PBM shall specify which, if any, of the drugs in the sample were subject to the lower per unit payment amounts. An officer of the consulting PBM shall certify the information by signature before providing it to ODA.

- (G) ODA shall seek from the centers for medicare and medicaid services of the United States department of health and human services written confirmation that manufacturer payments are exempt from the medicaid best price computation applicable under Title XIX of the "Social Security Act," 79 Stat. 286 (1965), 42 U.S.C. 1396r-8, as amended.

Entering into a manufacturer agreement does not require a drug manufacturer to make a manufacturer payment that would establish the manufacturer's medicaid best price for a drug.

- (H) Pursuant to section 173.82 of the Revised Code, a drug manufacturer that enters into a manufacturer agreement may submit a request to ODA to audit claims submitted under section 173.80 of the Revised Code. On submission of a request that ODA considers reasonable, ODA shall permit the participating drug manufacturer to audit the claims.

- ~~(I) Once a year or, at the discretion of ODA, at more frequent intervals, ODA shall determine the amount of each manufacturer payment that ODA shall retain for use~~

~~in paying the administrative costs of the best Rx program.~~

- ~~(1) ODA shall retain five per cent of each manufacturer payment as the administrative percentage.~~
- ~~(2) ODA shall pay the participating pharmacies ninety-five per cent of the manufacturer payments received from participating drug manufacturers.~~
- ~~(3) ODA shall deposit the administrative percentage that it retains into the best Rx program fund.~~

Effective: 01/01/2009

R.C. 119.032 review dates: 08/31/2011

CERTIFIED ELECTRONICALLY

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Certification

12/22/2008

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Date

Promulgated Under: 119.03  
Statutory Authority: 173.02, 173.83  
Rule Amplifies: 173.81, 173.811, 173.812, 173.813, 173.814, 173.815,  
173.82, 173.833  
Prior Effective Dates: 11/1/2004, 4/4/2007 (Emer.), 7/5/2007 (Emer.),  
10/4/2007