
42 U.S. Code § 1395w-114c

Manufacturer discount program

(a) Establishment

The Secretary shall establish a manufacturer discount program (in this section referred to as the “program”). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c).

(b) Terms of agreement

(1) In general

(A) Agreement

An agreement under this section shall require the manufacturer to provide, in accordance with this section, discounted prices for applicable drugs of the manufacturer that are dispensed to applicable beneficiaries on or after January 1, 2025.

(B) Clarification

Nothing in this section shall be construed as affecting—

- (i) the application of a coinsurance of 25 percent of the negotiated price, as applied under paragraph (2)(A) of section 1395w-102(b) of this title, for costs described in such paragraph; or
- (ii) the application of the copayment amount described in paragraph (4)(A) of such section, with respect to costs described in such paragraph.

(C) Timing of agreement

(i) Special rule for 2025

In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2025, and ending on December 31, 2025, the manufacturer shall enter into such agreement not later than March 1, 2024.

(ii) 2026 and subsequent years

In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2026 or a subsequent plan year, the manufacturer shall enter into such agreement not later than a calendar quarter or semi-annual deadline established by the Secretary.

(2) Provision of appropriate data

Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

(3) Compliance with requirements for administration of program

Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary, as applicable, for purposes of administering the program, including any determination

under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

(4) Length of agreement

(A) In general

An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary shall provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) By a manufacturer

A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 31 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 31 of a plan year, as of the day after the end of the succeeding plan year.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)