

(1) If the 30th calendar day described in paragraph (a) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(2) [Reserved]

(b) The provider has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 of this title, unless the provider can show good cause, as determined at §150.405(b) of this title, for failing to timely exercise its right to a hearing.

PARTS 183 [RESERVED]

PART 184—PHARMACY BENEFIT MANAGER STANDARDS UNDER THE AFFORDABLE CARE ACT

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AUTHORITY: 42 U.S.C. 1302, 1320b-23.

SOURCE: 86 FR 24295, May 5, 2021, unless otherwise noted.

§ 184.10 Basis and scope.

(a) *Basis.* (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.

(2) [Reserved]

(b) *Scope.* This part establishes standards for Pharmacy Benefit Managers that administer prescription drug benefits for health insurance issuers that offer Qualified Health Plans with respect to the offering of such plans.

§ 184.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Health insurance issuer has the meaning given to the term in §144.103 of this subtitle.

Plan year has the meaning given to the term in §156.20 of this subchapter.

Qualified health plan has the meaning given to the term in §156.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in §156.20 of this subchapter.

§ 184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, any entity that provides pharmacy benefits management services on behalf of a qualified health plan (QHP) issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding *bona fide* service fees) that the pharmacy benefits manager (PBM) negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) *Bona fide* service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Limitations on disclosure.* Information disclosed by a PBM under this section shall not be disclosed by HHS or by a QHP receiving the information,

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except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

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(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A PBM that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of section 1927(b)(3)(C) of the Act.

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