§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager 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 QHP issuer 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]

(b) *Limitation on disclosure.* Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific 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

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

(c) *Penalties.* A QHP issuer 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 subsection (b)(3)(C) of section 1927 of the Act.

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