(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, broken down by pharmacy type, which includes an independent pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public, that is paid by the QHP issuer or the QHP issuer's contracted PBM;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer or its contracted 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) *Confidentiality.* Information disclosed by a QHP issuer or a PBM under this section is confidential and shall not be disclosed by HHS or by a QHP receiving the information, 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

(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.

Subpart D—Federally-Facilitated Exchange Qualified Health Plan Issuer Standards

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.340 Standards for downstream and delegated entities.

(a) *General requirement.* Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, as applicable, with all applicable standards, including—

(1) Standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis;

(2) Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §155.705 of this subchapter;

(3) Standards of §155.220 of this subchapter with respect to assisting with enrollment in QHPs; and

(4) Standards of §§156.705 and 156.715 for maintenance of records and compliance reviews for QHP issuers operating in a Federally-facilitated Exchange or FF–SHOP.

(b) *Delegation agreement specifications.* If any of the QHP issuer's activities or obligations, in accordance with paragraph (a) of this section, are delegated to other parties, the QHP issuer's

agreement with any delegated or downstream entity must—

(1) Specify the delegated activities and reporting responsibilities;

(2) Provide for revocation of the delegated activities and reporting standards or specify other remedies in instances where HHS or the QHP issuer determines that such parties have not performed satisfactorily;

(3) Specify that the delegated or downstream entity must comply with all applicable laws and regulations relating to the standards specified under paragraph (a) of this section;

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period; and

(5) Contain specifications described in paragraph (b) of this section by no later than January 1, 2015, for existing agreements; and no later than the effective date of the agreement for agreements that are newly entered into as of October 1, 2013.

Subpart E—Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

SOURCE: 78 FR 15535, Mar. 11, 2013, unless otherwise noted.

§ 156.400 Definitions.

The following definitions apply to this subpart:

Advance payments of the premium tax credit has the meaning given to the term in § 155.20 of this subchapter.

Affordable Care Act has the meaning given to the term in § 155.20 of this subchapter.

Annual limitation on cost sharing means the annual dollar limit on cost sharing required to be paid by an enrollee that is established by a particular qualified health plan.

De minimis variation means the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan as established in § 156.140(c).

De minimis variation for a silver plan variation means a single percentage point.

Federal poverty level or *FPL* has the meaning given to the term in § 155.300(a) of this subchapter.

Indian has the meaning given to the term in § 155.300(a) of this subchapter.

Limited cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in § 156.420(b)(2).

Maximum annual limitation on cost sharing means the highest annual dollar amount that qualified health plans (other than QHPs with cost-sharing reductions) may require in cost sharing for a particular year, as established for that year under § 156.130.

Most generous or *more generous* means, between a QHP (including a standard silver plan) or plan variation, and one or more other plan variations of the same QHP, the QHP or plan variation designed for the category of individuals last listed in § 155.305(g)(3) of this subchapter.

Plan variation means a zero cost sharing plan variation, a limited cost sharing plan variation, or a silver plan variation.

Reduced maximum annual limitation on cost sharing means the dollar value of the maximum annual limitation on cost sharing for a silver plan variation that remains after applying the reduction, if any, in the maximum annual limitation on cost sharing required by section 1402 of the Affordable Care Act as announced in the annual HHS notice of benefit and payment parameters.

Silver plan variation means, with respect to a standard silver plan, any of the variations of that standard silver plan described in § 156.420(a).

Stand-alone dental plan means a plan offered through an Exchange under § 155.1065 of this subchapter.