validation audit or the application of a risk score error rate to its risk adjustment payments and charges.

(e) *Adjustment of payments and charges.* HHS may adjust payments and charges for issuers that do not comply with audit requirements and standards, as specified in paragraphs (b) and (c) of this section.

(f) *Data security and transmission.* (1) An issuer must submit the risk adjustment data and source documentation for the initial and second validation audits specified by HHS to HHS or its designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

[78 FR 15531, Mar. 11, 2013]

Subpart H—Distributed Data Collection for HHS-Operated Programs

SOURCE: 78 FR 15531, Mar. 11, 2013, unless otherwise noted.

§ 153.700 Distributed data environment.

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

§ 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

§ 153.720 Establishment and usage of masked enrollee identification numbers.

(a) *Enrollee identification numbers.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must—

(1) Establish a unique masked enrollee identification number for each enrollee; and

(2) Maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year.

(b) *Prohibition on personally identifiable information.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment

or reinsurance program on behalf of the State, as applicable, may not—

(1) Include enrollee's personally identifiable information in the masked enrollee identification number; or

(2) Use the same masked enrollee identification number for different enrollees enrolled with the issuer.

§ 153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year.

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Disclosure and Review Provisions

Subpart C—Effective Rate Review Programs

AUTHORITY: Section 2794 of the Public Health Service Act (42 USC 300gg–94).

SOURCE: 76 FR 29985, May 23, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 154.101 Basis and scope.

(a) *Basis.* This part implements section 2794 of the Public Health Service (PHS) Act.

(b) *Scope.* This part establishes the requirements for health insurance issuers offering health insurance coverage in the small group or individual markets to report information concerning unreasonable rate increases to the Centers for Medicare & Medicaid Services (CMS). This part further establishes the process by which it will be determined whether the rate increases are unreasonable rate increases as defined in this part.

§ 154.102 Definitions.

As used in this part:

CMS means the Centers for Medicare & Medicaid Services.

Effective Rate Review Program means a State program that CMS has determined meets the requirements set forth in §154.301(a) and (b) for the relevant market segment in the State.

Federal medical loss ratio standard means the applicable medical loss ratio standard for the State and market segment involved, determined under subpart B of 45 CFR part 158.

Health insurance coverage has the meaning given the term in section 2791(b)(1) of the PHS Act.

Health insurance issuer has the meaning given the term in section 2791(b)(2) of the PHS Act.

Individual market has the meaning given the term under the applicable State's rate filing laws, except that:

(1) Where State law does not define the term, it has the meaning given in section 2791(e)(1)(A) of the PHS Act; and

(2) Coverage that would be regulated as individual market coverage (as defined in section 2791(e)(1)(A)) if it were not sold through an association is subject to rate review as individual market coverage.

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies that a health insurance issuer offers in a State.

Rate increase means any increase of the rates for a specific product offered