

an individual, or to issue a certificate of insurance, or that a non-Federal governmental health plan uses as a basis for a decision whether to enroll an individual under the plan.

Certificate of insurance means the document issued to a person or entity covered under an insurance policy issued to a group health plan or an association or trust that summarizes the benefits and principal provisions of the policy.

Complaint means any expression, written or oral, indicating a potential denial of any right or protection contained in HIPAA requirements (whether ultimately justified or not) by an individual, a personal representative or other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

Group health insurance policy or group policy means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

HIPAA requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146 and 148 of this subchapter.

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in §144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of part 148 of this subchapter. The term “individual health insurance policy” includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of part 146 of this subchapter.

Plan document means the legal document that provides the terms of the

plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

State law means all laws, decisions, rules, regulations, or other State action having the effect of law, of any State as defined in §144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce HIPAA Requirements

§ 150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

§ 150.203 Circumstances requiring CMS enforcement.

CMS enforces HIPAA requirements to the extent warranted (as determined by CMS) in any of the following circumstances:

(a) *Notification by State.* A State notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing HIPAA requirements.

(b) *Determination by CMS.* If CMS receives or obtains information that a State may not be substantially enforcing HIPAA requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with §148.128 of this subchapter instead of complying with the guaranteed availability requirements of §148.120, CMS’s determination focuses on the following:

(1) Whether the State’s mechanism meets the requirements for an acceptable alternative mechanism.

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(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§ 148.101 through 148.126 and § 148.170 of this subchapter.

§ 150.205 Sources of information triggering an investigation of State enforcement.

Information that may trigger an investigation of State enforcement includes, but is not limited to, any of the following:

- (a) A complaint received by CMS.
- (b) Information learned during informal contact between CMS and State officials.
- (c) A report in the news media.
- (d) Information from the governors and commissioners of insurance of the various States regarding the status of their enforcement of HIPAA requirements.
- (e) Information obtained during periodic review of State health care legislation. CMS may review State health care and insurance legislation and regulations to determine whether they are:
 - (1) Consistent with HIPAA requirements.
 - (2) Not pre-empted as provided in § 146.143 (relating to group market provisions) and § 148.120 (relating to individual market requirements) on the basis that they prevent the application of a HIPAA requirement.
- (f) Any other information that indicates a possible failure to substantially enforce.

§ 150.207 Procedure for determining that a State fails to substantially enforce HIPAA requirements.

Sections 150.209 through 150.219 describe the procedures CMS follows to determine whether a State is substantially enforcing HIPAA requirements.

§ 150.209 Verification of exhaustion of remedies and contact with State officials.

If CMS receives a complaint or other information indicating that a State is

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failing to enforce HIPAA requirements, CMS assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, CMS may contact State officials regarding the questions raised.

§ 150.211 Notice to the State.

If CMS is satisfied that there is a reasonable question whether there has been a failure to substantially enforce HIPAA requirements, CMS sends, in writing, the notice described in § 150.213 of this part, to the following State officials:

- (a) The governor or chief executive officer of the State.
- (b) The insurance commissioner or chief insurance regulatory official.
- (c) If the alleged failure involves HMOs, the official responsible for regulating HMOs if different from the official listed in paragraph (b) of this section.

§ 150.213 Form and content of notice.

The notice provided to the State is in writing and does the following:

- (a) Identifies the HIPAA requirement or requirements that have allegedly not been substantially enforced.
- (b) Describes the factual basis for the allegation of a failure or failures to enforce HIPAA requirements.
- (c) Explains that the consequence of a State's failure to substantially enforce HIPAA requirements is that CMS enforces them.
- (d) Advises the State that it has 30 days from the date of the notice to respond, unless the time for response is extended as described in § 150.215 of this subpart. The State's response should include any information that the State wishes CMS to consider in making the preliminary determination described in § 150.217.

§ 150.215 Extension for good cause.

CMS may extend, for good cause, the time the State has for responding to the notice described in § 150.213 of this subpart. Examples of good cause include an agreement between CMS and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.