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§ 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 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.

§ 150.217 Preliminary determination.

If, at the end of the 30-day period (and any extension), the State has not established to CMS's satisfaction that it is substantially enforcing the HIPAA requirements described in the notice, CMS takes the following actions:

(a) Consults with the appropriate State officials identified in § 150.211 (or their designees).