

# Enforcement Rule Summary

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## **Summary:**

The Enforcement Rule establishes rules of procedure for the imposition of civil money penalties (CMP) on entities that violate HIPAA standards. DHHS intends this as the final installment of the Enforcement Rule. Additionally, the Enforcement Rule sets forth procedural and substantive requirements for imposition of civil money penalties.

**When is the Enforcement Rule effective?** 03/16/2006; there is no implementation period for the Enforcement Rule.

**What does the Enforcement Rule cover?** All Administrative Simplification Provisions (i.e. HIPAA Rules).

## **Generally Speaking:**

- ◆ Privacy Rule: OCR may provide technical assistance to help covered entities voluntarily comply with the Privacy Rule. OCR will seek to resolve matters by informal means before issuing findings of non-compliance, under its authority to investigate and resolve complaints, and to engage in compliance reviews.
- ◆ Other Rules: The enforcement approach of CMS is similar. Enforcement activities will focus on obtaining voluntary compliance through technical assistance. The process will be primarily complaint driven, however there is allowance for compliance checking (audit) and will consist of progressive steps that will provide opportunities to demonstrate compliance or submit a corrective action plan prior to imposing CMP on a covered entity for noncompliance.
- ◆ The Enforcement Rule establishes various procedures for the imposition of CMP, including the procedures for providing notice and a hearing on the Secretary's determination to impose CMP. The Enforcement Rule also addresses a number of substantive issues relating to the imposition of CMP, such as the policies and procedures for determining violations and calculating CMP.

## **When would the Enforcement Rule impact Covered Entities?**

- (1) A person who believes a covered entity is not complying with the administrative simplification provisions may file a complaint with the Secretary, which then initiates an investigation regarding the complaint, or
- (2) The Secretary may conduct compliance reviews (audits) to determine whether covered entities are complying with the applicable administrative simplification provisions.

**What if the violation is considered a criminal act?** DHHS will enforce the civil money penalties while the U.S. Department of Justice will enforce the criminal penalties. A CMP may not be imposed with respect to an act that constitutes an offense punishable under the criminal penalty provision.

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### **What action does the Secretary take when a complaint is received?**

*(a) Resolution when noncompliance is indicated:* (1) If an investigation or compliance review indicates noncompliance, the Secretary will attempt to reach an informal resolution of the matter. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement. (2) If the matter is resolved by informal means, the Secretary will inform the covered entity and, if the matter arose from a complaint, the complainant, in writing. (3) If the matter is not resolved by informal means, the Secretary will follow the necessary steps as outlined in the Rule to initiate assessment of potential civil money penalties (CMP). This includes notification of the covered entity and a 30 day period to provide evidence of mitigating circumstances related to the violation in addition to the notification of a CMP being imposed.

*(b) Resolution when no violation is found:* If, after an investigation, the Secretary determines that further action is not warranted, the Secretary will inform the covered entity and, if the matter arose from a complaint, the complainant, in writing.

### **Who determines the CMP? – The Secretary**

### **How is a Civil Money Penalty (CMP) determined?**

In determination and consideration of civil money penalties, the following is taken into consideration: (1) The nature of the violation; (2) the circumstances under which the violation occurred; (3) degree of culpability; (4) history of prior offenses as they relate to the administrative simplification rule; (5) financial condition of the covered entity; and (6) such other matters as justice may require. These factors are not labeled as aggravating or mitigating, rather they could be considered as either in determining the amount of civil money penalty.

Additionally, a CMP may not be imposed if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision. Also, a CMP may not be imposed if the failure to comply was due to reasonable cause and not to willful neglect and is corrected within a certain time.

**Is there a process for appeal of the decision made by the Secretary?** – Yes, the covered entity has a right to an appeal process, where their case will be reviewed by an ALJ. The decision of the ALJ is considered final, and may be different from the original decision made by the Secretary, including the amount of CMP imposed, if any.

**Who is responsible for the CMP if it is determined to be applicable to the violation?** – The Enforcement Rule provides that only a covered entity is liable for a CMP under section 1176.

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**What is the basis of a CMP in the case of a violation by an agency's business associate?** Section 160.402 addresses this as follows: "A covered entity is liable, in accordance with the federal common law of agency, for a CMP for a violation based on the act of omission of any agent of the covered entity, including a workforce member, acting with in the scope of the agency unless – (1) the agent is a business associate of the covered entity; (2) the covered entity has complied, with respect to such business associate, with the applicable requirements of Section 164.308(b) and 164.502(e) of this subchapter; and (3) the covered entity did not – (i) Know of a pattern of activity or practice of the business associate, and (ii) Fail to act as required by Sections 164.314(a)(1)(ii) and 164.504(e)(1)(ii) of this subchapter, as applicable."

**What are the time limits for imposing a CMP?** The Secretary may not initiate a CMP action later than 6 years after the date of the occurrence of the violation.

**What are the amounts of a CMP?**

The Secretary may not impose CMP – (i) In the amount of more than \$100 for each violation; or (ii) In excess of \$25,000 for identical violations during a calendar year (Jan 1 – Dec 31).

**How are 'identical violations' determined as they relate to the assessment of CMP?**

Section 1176(a)(1) speaks of "violations of an identical requirement or prohibition".

The manner in which the number of identical violations is determined will depend on the nature of the provision violated. The final rule makes clear that the Secretary will determine the number of identical violations based on the nature of the obligation of the covered entity to act (or not act) under the provision violated. Additionally, the Rule specifies that a separate violation occurs each day the covered entity is in violation of the provision.

With respect to the transactions standards, it is anticipated that the definition of a requirement violation will be interpreted as the requirement to conduct a standard transaction. While one could view each required data element in a transaction as separate requirement, because the Implementation Guide (IG) for each transaction is incorporated by reference into the regulations, one could also view the underlying IG's as functioning simply to describe what constitutes compliance in a particular case, rather than establishing separate compliance requirements for each data element within the transaction. While either interpretation is permissible, it is expected that the latter view of the Rule will be taken in order to facilitate predictability of determining violations under that Rule. Thus, each noncompliant transaction would be counted as a violation regardless of the number of missing or noncompliant data elements.

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Additionally, the Rule indicates that the number of violations of a particular provision will be determined in a similar manner each time as case presents a violation of that provision, with due regard to the individual facts and circumstances of the case.

An example given in the Q&A of the Final Rule explained that a health plan found to have conducted 200 eligibility transactions which are missing several required data elements would be found to have committed 200 violations of one identical requirement to conduct a covered transaction as a standard.

### **Are Corrective Action Plans (CAP) and good faith efforts taken into consideration when determining a CMP?**

Yes, where the corrective action is taken in response to a complaint from an individual, the final rule provides the Secretary with authority to consider such corrective action as a factor in determining a CMP. With respect to a covered entity's good faith attempt to comply with the HIPAA provisions and rules, such actions could be mitigating factors depending on the circumstances. A covered entity's history of prior compliance generally may be considered, which could include, as appropriate, prior violations, as well as prior compliance efforts.

### **Can a CMP be waived?**

Yes, (Section 160.412). For violations that are not corrected within the period allowed under the Rule, the Secretary may waive the CMP, in whole or in part, to the extent that payment of the penalty would be excessive relative to the violation.

### **Collection of CMP:**

A hybrid entity is, by definition, a single legal entity. Where a penalty is assessed against a covered entity that has designated itself as a hybrid entity, the legal entity that is the covered entity is responsible for payment of the penalty. How the covered entity allocates the penalty payment as a matter of internal accounting is a business decision of the covered entity.

If an agency with the same structure as a Medicaid agency is assessed a penalty, can federal dollars be withheld in lieu of payment of the penalty? Yes - Section 1128A(f) provides for setoff of penalty amounts against Federal or state agency funds then or later owing to the person penalized.