

HIPAA Enforcement Q's and A's

Q: What action will be taken against HIPAA covered entities that have not submitted extension requests by October 15, 2002?

A: A covered entity that has not implemented the HIPAA transaction and code set standards AND has not submitted an extension request is noncompliant, and could be subject to enforcement actions.

Q: Who will enforce the HIPAA standards?

A: HHS has determined that CMS will have responsibility for enforcing the transactions and code set standards, as well as security and identifiers standards when those are published. CMS will also continue to enforce the insurance portability requirements under Title I of HIPAA. The Office for Civil Rights in HHS will enforce the privacy standards.

Q: Doesn't the HIPAA law envision HHS providing technical assistance to the industry to help them become compliant?

A: Yes. Our enforcement strategy will concentrate on achieving voluntary compliance through technical assistance. Penalties would be imposed as a last resort.

Q: What will the enforcement process look like?

A: The enforcement process for HIPAA transactions and code sets (and for security and standard identifiers when those are adopted) will be primarily complaint-driven. Upon receipt of a complaint, CMS would notify the provider of the complaint, and the provider would have the opportunity to demonstrate compliance, or to submit a corrective action plan. If the provider does neither, CMS will have the discretion to impose penalties.

Q: What kinds of penalties could be imposed?

A: The Administrative Simplification Compliance Act (ASCA) permits the Secretary of HHS to exclude noncompliant covered entities from the Medicare program between October 16, 2002 and October 16, 2003 if they have not submitted an extension request.

In addition, the original HIPAA legislation permits civil monetary penalties of not more than \$100 for each violation, with a cap of \$25,000 per calendar year. (Much larger penalties are provided for certain wrongful disclosure of individually identifiable health information).

Thus, the ASCA penalty is for failure to submit an extension request, and it applies only to Medicare providers, while the HIPAA penalty is for noncompliance, and

is generally applicable. Medicare providers could be both excluded and fined, while non-Medicare covered entities would be subject only to the civil monetary penalties.

Q: Will these penalties be imposed on all covered entities that did not submit requests?

A: No. The process leading to these penalties would be initiated primarily in response to an external complaint filed against a covered entity. Once a complaint is received, the entity will have opportunities to avoid penalties by demonstrating compliance, showing how they will achieve compliance by submitting a corrective action plan, or, for ASCA purposes, showing that they had submitted an extension request. Only when an entity does none of these things would consideration be given to invoking civil monetary penalties or excluding a provider from Medicare.

Q: How would someone file a complaint against a covered entity?

A: CMS will develop a web-based complaint management process, and will provide information on this process as part of our HIPAA outreach activities.

Q: How will CMS publish details about how this process will work?

A: CMS intends to develop guidelines that would set out how the enforcement process will operate and how penalties will be imposed.

Q: What should a covered entity that did not submit an extension request do now?

A: They should come into compliance as soon as possible, and should be prepared to submit a corrective action plan in the event a complaint is filed against them.

Q: Will a covered entity that was not in existence prior to October 15, 2002 be subject to these penalties?

A: A newly formed covered entity could utilize a clearinghouse or compliant vendor to become compliant at the time it comes into existence. If the entity is not able to achieve compliance immediately, good faith efforts could be taken into account in the event a complaint is filed. Also, in the event of a complaint, the entity could submit a corrective action plan.