

October 15, 2002

HHS Secretary Tommy G. Thompson announced today that the Centers for Medicare & Medicaid Services (CMS) will be responsible for enforcing the transaction and code set standards that are part of the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

“HIPAA administrative simplification is going to streamline and standardize the electronic filing and processing of health insurance claims, save money and provide better service for providers, insurers and patients,” Thompson said.

“To accomplish this will require an enforcement operation that will assure compliance and provide support for those who file and process health care claims and other transactions,” Thompson said. “CMS is the agency best able to do this.”

CMS will continue to enforce the insurance portability requirements of HIPAA. The HHS Office for Civil Rights (OCR) will enforce the HIPAA privacy standards. CMS and OCR will work together on outreach and enforcement and on issues that touch on the responsibilities of both organizations – such as application of security standards or exception determinations.

Ruben J. King-Shaw Jr., CMS deputy administrator and chief operating officer, said CMS will create a new office to bring together its responsibilities under HIPAA, including enforcement.

“Concentrating these CMS responsibilities in a new office with a single mission will give us the most efficient operation possible, while providing strong support for all our partners in the health care community,” King-Shaw said.

The new CMS office will establish and operate enforcement processes and develop regulations related to the HIPAA standards for which CMS is responsible. These standards include transactions and code sets, security, and identifiers for providers, insurers and employers for use in electronic transactions. The office will report directly to the deputy administrator.

The office also will conduct outreach activities to HIPAA covered entities such as health care providers and insurers to make sure they are aware of the requirements and to help them comply.

Federal law requires most health plans, clearing houses, and those providers that conduct certain transactions electronically to be compliant with the HIPAA transactions standards by Oct. 16, 2002, unless they file on or before Oct. 15 for a one-year extension. Those who are not compliant and have not filed for the extension may be subject to statutory penalties. (The law gives certain small health plans until Oct. 16, 2003 to comply).

Enforcement activities will focus on obtaining voluntary compliance through technical assistance. The process will be primarily complaint driven and will consist of progressive steps that will provide opportunities to demonstrate compliance or submit a corrective action plan.

A fact sheet summarizing the administrative simplification standards required by HIPAA is available at <http://www.hhs.gov/news/press/2002pres/hipaa.html>. More detailed information about the standards is available at <http://www.cms.hhs.gov/hipaa>.

Note: All HHS press releases, fact sheets and other press materials are available at www.hhs.gov/news.

- CMS has been designated by the Secretary of HHS to enforce the HIPAA administrative simplifications provisions, with the exception of the privacy standards. This includes transactions and code sets, security and identifiers. CMS will also continue to enforce the insurance portability provisions under Title I of HIPAA.

- In order to perform these duties CMS will create a new office within the agency to focus on HIPAA activities. This office will establish and operate enforcement processes, develop regulations related to HIPAA standards, and conduct outreach activities to HIPAA covered entities. The office will report directly to the deputy administrator.

- The enforcement process will be primarily complaint-driven. The focus of enforcement activities will be to obtain voluntary compliance through technical assistance. The process will be progressive, affording a covered entity against whom a complaint has been filed opportunities to demonstrate compliance or to develop a corrective action plan.

- Privacy enforcement will be the responsibility of the HHS Office for Civil Rights, and the two agencies will work together to address common issues.

- Penalties:

- Under the Administrative Simplification Compliance Act (ASCA) -- noncompliant covered entities may be excluded from the Medicare program between October 16, 2002, and October 16, 2003, if they have not submitted an extension request.

- Under HIPAA -- 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 disclosure of individually identifiable health information).

- Key HIPAA Dates:

- 10/16/02 -- Original compliance date for transactions and code sets
 - 10/15/02 -- Deadline for filing extension request
 - 10/16/03 -- Extended compliance date for transactions and code sets
 - 04/14/03 -- Initial compliance date for privacy

HIPAA Enforcement Q's and A's External

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.