

## Final HIPAA Enforcement Rule Clarifies Process for Imposition of Civil Money Penalties

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The U.S. Department of Health and Human Services (“HHS”) in mid-February adopted a final rule (“Final Rule”) governing the imposition of civil money penalties on covered entities that violate the various rules that implement the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).<sup>1</sup> Importantly, the Final Rule clarifies the bases for civil money penalty liability; the related investigation, hearing, and appellate processes; the factors considered by HHS in determining penalty amounts; and the grounds for penalty waivers.

Section 262 of HIPAA required HHS to adopt final rules governing certain standard transactions and code sets, the security of health information, and unique health identifiers.<sup>2</sup> HHS responded by adopting final standard transaction and code sets rules in 2000,<sup>3</sup> a final unique employer identifier in 2002,<sup>4</sup> a final security rule in 2003,<sup>5</sup> and a final unique provider identifier in 2004.<sup>6</sup> A final unique health plan identifier is expected in June 2006.<sup>7</sup> When Congress failed to enact privacy legislation within three years of the date of enactment of HIPAA, Section 264 of HIPAA directed HHS to adopt a final rule governing the privacy of individually identifiable health information.<sup>8</sup> HHS responded by adopting a final privacy rule in 2002 (the “Privacy Rule”).<sup>9</sup> Together, these rules comprise the “Administrative Simplification Rules.”

Although HIPAA identifies the upper limit of the civil and criminal penalties that apply to covered entities that violate the Administrative Simplification Rules,<sup>10</sup> neither HIPAA nor any of the Administrative Simplification Rules establish a specific process for the imposition of civil penalties. In response to the absence of administrative guidance in this area, HHS issued in 2003 an interim final rule (“Interim Final Rule”) promulgating procedural requirements for the

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<sup>1</sup> 71 Fed. Reg. 8389 (Feb. 16, 2006), available at <http://www.hhs.gov/ocr/hipaa/enforcerule06.htm> (last visited May 8, 2006).

<sup>2</sup> 42 U.S.C. § 1320d-2 (2005).

<sup>3</sup> 65 Fed. Reg. 50312 (Aug. 17, 2000).

<sup>4</sup> 67 Fed. Reg. 38009 (May 31, 2002).

<sup>5</sup> 68 Fed. Reg. 8334 (Feb. 20, 2003).

<sup>6</sup> 69 Fed. Reg. 3434 (Jan. 23, 2004).

<sup>7</sup> *HHS Details Regulatory Agenda*, HEALTH DATA MANAGEMENT (Oct. 31, 2005), available at <http://www.healthdatamanagement.com/html/PortalStory.cfm?type=gov&DID=13185> (last visited May 8, 2006).

<sup>8</sup> 42 U.S.C. § 1320d-2 (2005).

<sup>9</sup> 65 Fed. Reg. 82462 (Dec. 28, 2000), as amended by 67 Fed. Reg. 53181 (Aug. 14, 2002).

<sup>10</sup> 42 U.S.C. § 1320d-5 (2005) (establishing a civil money penalty of not more than \$100 per violation with an upper limit of \$25,000 per year of like violations); *id.* § 1320d-6 (establishing a base criminal penalty of not more than \$50,000 and/or imprisonment of not more than one year for covered entities that knowingly violate the Administrative Simplification Rules; an intermediate criminal penalty of not more than \$100,000 and/or imprisonment for not more than five years for covered entities that violate the Administrative Simplification Rules under false pretenses; and a high criminal penalty of not more than \$250,000 and/or imprisonment for not more than 10 years for covered entities that violate the Administrative Simplification Rules with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm).

imposition of civil money penalties.<sup>11</sup> The Interim Final Rule had an initial sunset date of September 16, 2004, which was extended to September 16, 2005,<sup>12</sup> and subsequently to March 16, 2006.<sup>13</sup> In the meantime, HHS in 2005 issued a proposed rule (“Proposed Rule”) that would revise the Interim Final Rule’s provisions relating to enforcement of the Administrative Simplification Rules.<sup>14</sup> The Proposed Rule is now followed by the Final Rule, which is codified at 45 C.F.R. Part 160, Subparts C and E, and carried an effective date of March 16, 2006.

The Final Rule adopts most of the provisions of the Proposed Rule without change. However, the Final Rule does make a few important changes in response to public comments. One such change relates to the imposition of joint and several liability on members of a single affiliated covered entity (“SACE”). A SACE is defined as two or more legally separate covered entities that are commonly owned or operated.<sup>15</sup> The Final Rule clarifies that the members of a SACE share joint and several liability for violations of the Administrative Simplification Rules, unless it is established that a particular covered entity member of the SACE is responsible for the violation.<sup>16</sup> Stated another way, if a violation can be shown to lie with one member of a SACE, that member will be held liable for the violation; however, the inability to assign specific responsibility for a violation to one or more members of a SACE does not shield all of its members from liability.<sup>17</sup>

A second important change relates to the method of determining the number of violations of an identical requirement set forth in the Administrative Simplification Rules. HIPAA establishes a civil money penalty of not more than \$100 per violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed \$25,000.<sup>18</sup> The Proposed Rule would have established “variables” to be used to “count” the number of violations of an identical requirement. The proposed variables were: (1) the number of times the covered entity failed to engage in required conduct or engaged in a prohibited act; (2) the number of persons involved in, or affected by, the violation; and (3) the duration of the violation, counted in days. The Final Rule eliminates the use of such variables, and clarifies that the method for determining the number of such violations is grounded in the substantive requirements of the Administrative Simplification Rules.<sup>19</sup>

Perhaps most importantly, the Final Rule clarifies that its compliance and investigation provisions, which formerly applied only to the Privacy Rule, apply to all of the Administrative Simplification Rules.<sup>20</sup> The Final Rule thus provides covered entities with comprehensive guidance regarding the enforcement procedures that will apply if the covered entity violates any provision of the Administrative Simplification Rules.

May 2006

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<sup>11</sup> 68 Fed. Reg. 18895 (Apr. 17, 2003).

<sup>12</sup> 69 Fed. Reg. 55515 (Sept. 15, 2004).

<sup>13</sup> 70 Fed. Reg. 54293 (Sept. 14, 2005).

<sup>14</sup> 70 Fed. Reg. 20224 (Apr. 18, 2005).

<sup>15</sup> 45 C.F.R. § 164.105 (2005).

<sup>16</sup> *Id.* § 160.402(b)(2).

<sup>17</sup> 71 Fed. Reg. at 8401.

<sup>18</sup> 42 U.S.C. § 1320d-5 (2005).

<sup>19</sup> 71 Fed. Reg. at 8405.

<sup>20</sup> 45 C.F.R. § 160.300 (2005).