

---

# HIPAA Enforcement Rule Overview

**Marc D. Goldstone, Esq.**

Hoagland, Longo, Moran, Dunst & Doukas, LLP

40 Paterson Street, P.O. Box 480

New Brunswick, NJ 08903

732-545-4717

732-545-4579 (fax)

[MGOLDSTONE@HOAGLANDLONGO.COM](mailto:MGOLDSTONE@HOAGLANDLONGO.COM)

[WWW.HOAGLANDLONGO.COM](http://WWW.HOAGLANDLONGO.COM)

[WWW.HEALTHLAWNJ.COM](http://WWW.HEALTHLAWNJ.COM)

# HIPAA Enforcement Rule Overview

- The Old Rule: 68 *FR* 18895, published April 17, 2003, effective on May 19, 2003.
  - Old Expiration Date: September 16, 2003 (Milk didn't expire that quickly!)
  - New Expiration Date: September 16, 2005
- The New Rule Proposal: 70 *FR* 20223.
  - Comments Due June 17, 2005
  - Don't Forget the Complaint Rule: 70 *FR* 15329, effective April 25, 2005

# The Old Rule

- The former rule sunsets in September of 2005
- Until the new rule is published for final adoption, the old rule is still good law
- The new rule proposal contains multiple references to procedural inadequacies and “quirks” that may be of use in arguing matters heard under the “old” rule, until the new rule is finalized
  - Example: “In Sec. 160.502 of the April 17, 2003 interim final rule, we defined a “person” as “a natural or legal person” to clarify, in the context of administrative subpoenas, the distinction between an entity (defined as a “legal person”) and natural persons who would testify on the entity's behalf. The proposed rule would revise and expand this definition.”

# Definitions

- “Persons” are subject to the enforcement rule
- “Persons” are: “a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private”
  - 70 FR 20228

---

# Definitions-Con't

- Who is subject to HIPAA criminal penalties?
- June 1, 2005 DOJ Memorandum to DHHS
- [http://www.worldprivacyforum.org/pdf/hipaa\\_opinion\\_06\\_01\\_2005.pdf](http://www.worldprivacyforum.org/pdf/hipaa_opinion_06_01_2005.pdf)

For the foregoing reasons, we conclude that covered entities and those persons rendered accountable by general principles of corporate criminal liability may be prosecuted directly under 42 U.S.C. § 1320d-6 and that the “knowingly” element of the offense set forth in that provision requires only proof of knowledge of the facts that constitute the offense.

# Definitions-Con't

- Violation? New rule clarifies that the Enforcement Rule applies to “Acts” AND “Omissions”
- “a violation occurs when a covered entity fails to take an action required by a HIPAA rule, as well as when a covered entity takes an action prohibited by a HIPAA rule”
  - 70 FR 20229

# Voluntary Compliance?

- “Voluntary Compliance Enforcement” originally applicable ONLY to privacy rules, now proposed applicable to ALL HIPAA rules: subpart C applies only to the Privacy Rule.
  - 70 FR 20228
- “Technical Assistance” is available (“we’re from the Government and we’re here to help”?)
- Still, a “Kinder and Gentler” OCR ...

# Enforcement Scope

- New rule BROADENS scope
- We propose to define the term "administrative simplification provision" in Sec. 160.302 to mean any requirement or prohibition established by the HIPAA provisions or HIPAA rules: " \* \* \* any requirement or prohibition established by: (1) 42 U.S.C. 1320d-1320d-4, 1320d-7, and 1320d-8; (2) Section 264 of Pub. L. 104-191; or (3) This subchapter"
- 70 FR 20228.



# What's On The Record?

- New rule “clarifies” transcript procedures
- A witness's right to retain a copy of the transcript of his or her testimony may be limited for good cause (5 U.S.C. 555(c)).
- If so limited, the witness may inspect the transcript and propose corrections. If provided a copy of the transcript, the witness may propose corrections. The Secretary may attach corrections to the transcript of a witness's testimonial interview if the record transcribing the interview is incorrect. The Secretary may not propose substantive changes to the witness's testimony.
- 70 FR 20230

# How Can the Record Be Used?

- Testimony and other evidence obtained in an investigational inquiry may be used by HHS in any of its activities and may be used or offered into evidence in ANY administrative or judicial proceeding
- Except to the extent evidence constitutes protected health information. PHI may be disclosed only "if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, or if otherwise required by law"
  - 70 FR 20230

# Imposition of CMPs?

- New rule **REQUIRES** Secretary to impose CMPs if a violation of a rule is found
- “Proposed Sec. 160.402(a) would require the Secretary to impose a civil money penalty on any covered entity which the Secretary determines has violated an administrative simplification provision, unless the covered entity establishes that an affirmative defense, as provided for by Sec. 160.410, exists”
  - 70 FR 20231

# CMPs-Continued

- Broad discussion of factors mitigating the imposition of CMPs
- Seems to “soften the blow”; in fact, the explanatory text is somewhat contradictory
- For example, Secretary **MUST** issue CMP for a finding of guilt, but **MAY** choose to issue CMPs in a reduced amount, or only against certain parties
  - 70 FR 20231-32
  - see also 70 FR 20233-39

# Collection of CMPs

- Penalty is final upon receipt of the penalty notice, to make clear when subsequent actions, such as collection, may commence
  - 70 FR 20240
- All the “usual suspects” concerning penalty collection still apply

# Authority to Settle

- Secretary may settle any case, whether or not a hearing is requested
  - 70 FR 20240
- Old rule can be read to have required a timely request for a hearing as a condition precedent to entry into settlement negotiations
  - **i.e., DHHS can “settle any case or ... compromise any penalty during the process” 68 FR 18898, *referencing* 45 CFR Part 160.510**

# Penalties are PUBLIC!!!

- **When a penalty proposed by the Secretary becomes final, the Secretary notifies certain specified appropriate State or local agencies, New rule proposes to add “the public generally.”**
  - **70 FR 20240**
- **So, in addition to “the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs, the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization, now EVERYONE will know.**
- **Posting to an HHS Web site and/or the periodic publication of a notice in the Federal Register are among the methods which the Secretary is considering using for the efficient dissemination of such information.**
  - **Id.**

# HIPAA Hearings

- New “layer” of review proposed
- ALJ decisions must be reviewed by the HHS Departmental Appeals Board (DAB) before judicial review can be sought
  - 70 FR 20241
- 30-day window for seeking such review
  - 70 FR 20243.
- DAB appearance MAY be by brief only; no right to oral argument
  - Id
- The ALJ decision thus would be the initial decision of the Secretary” subject to the ruling of the DAB; In the “old rule”, the ALJ’s decision WAS HHS’s final position



---

# HIPAA Hearings-Parties

- Who is the Government Party in a appeal?
- Old Rule-CMS or OCR
- New Rule-"it is possible for both CMS and OCR to be the Secretarial party in a particular case"
- 70 FR 20241

---

# HIPAA Hearings-Con't

- New Rule Adopts Federal Collateral Estoppel Doctrine
- § 160.532 Collateral estoppel.

When a final determination that the respondent violated an administrative simplification provision has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

[70 FR 20224, 20256](#)

# HIPAA Hearings-Attorney's Fees?

- New rule clarifies that there is no “mandatory fee cap” on the respondent’s attorney’s fees
  - 70 FR 20241
- Old rule was silent, and some were concerned that the fee cap provisions contained in other federal rules (such as the Federal Worker’s Compensation Court rules) would apply

---

# Other Concerns

- “Collateral Damage”-There is no bar to use of the information adduced at a HIPAA enforcement hearing in any subsequent proceeding; state court or otherwise
- Rules of evidence in the enforcement process are not harmonious with state court rules; respondents may have to limit their case presentations at HHS as a tool to control their risk of state-court liability. This may adversely affect their ability to defend the Federal charges.

---

Thanks!

➤ Thanks for your kind attention!!!!!!!!!!!!!!!!!!!!!!!!!!!!

---

# Marc D. Goldstone, Esq.

Hoagland, Longo, Moran, Dunst & Doukas, LLP  
40 Paterson Street

P.O. Box 480

New Brunswick, NJ 08903

(732) 545-4717

(732) 545-4579 (FAX)

[MGoldstone@Hoaglandlongo.com](mailto:MGoldstone@Hoaglandlongo.com)

[www.hoaglandlongo.com](http://www.hoaglandlongo.com)

[www.healthlawnj.com](http://www.healthlawnj.com)

---