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HHS Office of Civil Rights Levies First Civil Money Penalty for Violations of the HIPAA Privacy Rule - \$4.3 Million

By: [James B. Wieland](#) and [Joshua J. Freemire](#)

Cignet Health Center (Cignet), a provider of physician, imaging, and laboratory services, was recently ordered to pay \$4.3 million as a Civil Money Penalty (CMP) for its failure to comply with the HIPAA privacy rule and its failure to cooperate with the HHS Office of Civil Rights (OCR) in the OCR's investigation of the underlying HIPAA complaint. This is the first CMP levied by the OCR for a failure to comply with Privacy Rule requirements and reflects an increased focus by OCR on Privacy Rule compliance, an assumption supported by the language of the [OCR's Press Release](#). Providers can take some solace, however, in the facts that led to the OCR's imposition of the substantial CMP – Cignet's seemingly inexplicable failure to cooperate with (or even respond to) the OCR's repeated requests for information, cooperation, or explanations led to the imposition of such a substantial CMP. So far as can be determined from the public record, Cignet has not told its side of the story.

The final CMP was levied by the OCR in the [Final Determination issued to Cignet \[PDF\]](#) on February 4, 2011. The facts underlying the CMP, however, are described in greater detail in the [Proposed Determination \[PDF\]](#). In short, Cignet refused to respond to 41 patients' requests for their own medical records (at least some of whom were reportedly requesting their records to seek care elsewhere). Thirty-eight of these refusals to respond resulted in complaints filed with the OCR.

The 38 complaints caused the OCR to initiate an investigation of Cignet. According to the Proposed Determination, Cignet failed to respond to the OCR's March 1, 2010 request for the patient medical records at issue in the complaints. Similarly, Cignet failed to respond to a subpoena duces tecum issued by OCR, demanding the medical records. Finally, Cignet did not appear to defend itself when the OCR sought a petition to enforce its subpoena in the federal District Court for the District

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of Maryland. On March 30, 2010, the District Court granted a default judgment to the OCR in accordance with the petition and directed Cignet to produce the requested records.

On April 7, 2010, Cignet responded. Rather than simply producing the requested records, however, Cignet delivered 59 boxes of medical records to the Department of Justice. According to the Proposed Determination, the 59 boxes did contain the requested records, but they also contained the medical records for approximately 4,500 other individuals which were not requested by the government and which Cignet had no apparent cause or authority to disclose.

The OCR, however, still did not act to immediately penalize Cignet. Rather, on August 19, 2010, the OCR again wrote to Cignet explaining its preliminary findings of Privacy Rule violations and requesting that Cignet provide any affirmative defenses, mitigating factors, or explanations to support that the violations occurred as a result of a reasonable cause rather than willful neglect. Cignet, again, apparently failed to provide any response to the OCR. The OCR determined, on September 27, 2010, that Cignet's failure to respond indicated that no mitigating factors or affirmative defenses should apply to its determination of an appropriate CMP. The OCR also determined the violations at issue were due to Cignet's "willful neglect" of its obligations under the law, a mens rea that prohibits the OCR from waiving any portion of the applicable CMP, even where "the penalty would be excessive relative to the violation."

The Notice of a Proposed Determination was sent to Cignet on October 25, 2010, and provided Cignet 90 days to request a hearing to contest the decision. That time expired in January of 2011, and Cignet failed to request a hearing. Accordingly, the total final CMP, \$4,351,600, was due upon delivery of the February 4, 2011 Final Determination, and Cignet has waived its rights to appeal. Of the \$4.3 million dollar CMP, only \$1,351,600, however, was due to Cignet's failure to allow the 38 patients access to their medical records. The remaining \$3,000,000 was levied as a result of Cignet's repeated refusal to cooperate with the OCR's investigation.

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Ober|Kaler's Comments

There are several lessons to be learned from this first Privacy Rule CMP. First and foremost, providers should take note that, under the new penalty structure, the Privacy Rule has teeth. Penalties can quickly become substantial. Privacy Rule compliance should be high on every provider's list of compliance concerns.

Second, providers should note that, in the event of a complaint, cooperation with OCR is essential. Cignet was provided multiple chances to explain or defend itself, but consistently failed to do so. The OCR's enforcement web site explains that it has investigated and resolved over 12,000 Privacy Rule complaints by requiring changes in privacy practices and "other corrective actions." This is the first CMP issued as a result of Privacy Rule violations, and, as detailed above, it is substantially a result of Cignet's refusal to cooperate.

Finally, providers should note the time frames involved in the OCR's actions and remember that the receipt of a letter from the OCR is no time to panic. The time from investigation to the imposition of penalties, in this case, took nearly a year, but the time provided to Cignet to respond at each stage of the investigation was much less – usually around 30 days. Providers should have policies in place to ensure important mail is quickly routed to the correct compliance or legal personnel. Those personnel, in turn, should know who to contact regarding the receipt of important notices such as corporate officers and in-house or outside legal counsel.

These lessons came too late for Cignet, but with proper compliance training, procedures, and preparations other providers need not find themselves in a similar situation.