



HEALTH CARE UPDATE

Brace For New HIPAA Enforcement

Massachusetts General Hospital To Pay \$1 Million To Settle HIPAA Charges *Announcement Made 2 Days After OCR Announces \$4.3 Million HIPAA Civil Penalty Against Cignet*

General Hospital Corporation and Massachusetts General Physicians Organization Inc. (Mass General) has agreed to pay the U.S. government \$1,000,000 to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) announced the Resolution Agreement two days after announcing that its first official assessment of a civil monetary penalty CMP under HIPAA – a \$4.3 million against Cignet Health of Prince George’s County, Md., (Cignet).

HIPAA Privacy Rule restricts the use, access and disclosure by health care providers, health plans, health care clearinghouses and their business associates (covered entities) of individually identifiable health care information (PHI) to those outlined within the Rules. Under HIPAA covered entities also are responsible for establishing and enforcing policies and procedures that safeguard PHI against improper use, access or disclosure by employees, business associates, and other third parties. Noncompliance with the Privacy and Security Rules exposes a covered entity to criminal prosecution and penalties, civil penalties or both. The Privacy Rule requires covered entities to safeguard the privacy of patient information, including such information during its disposal. Under amendments to HIPAA enacted under the HITECH Act, business associates now also are accountable and subject to direct liability for failing to comply with HIPAA’s requirements.

Health care providers and other covered entities would be wise to step up HIPAA compliance efforts and risk management in response to these developments. The Mass General and Cignet announcements demonstrate that OCR is moving forward on its announced plans to hold health plans, health care providers and other covered entities that violate HIPAA accountable. Added to other recent developments, the Mass General and Cignet enforcement actions demonstrate that OCR’s commitment to enforcing HIPAA and illustrate the significant exposures that covered entities and business associates risk by disregarding their HIPAA obligations.

As stated by OCR Director Georgina Verdugo when announcing the Mass General Resolution Agreement, stating, “We hope the health care industry will take a close look at this agreement and recognize that OCR is serious about HIPAA enforcement. It is a covered entity’s responsibility to protect its patients’ health information.”

“To avoid enforcement penalties, covered entities must ensure they are always in compliance with the HIPAA Privacy and Security Rules,” Verdugo added, “A robust compliance program includes employee training, vigilant implementation of policies and procedures, regular internal audits, and a prompt action plan to respond to incidents.”

Covered entities are urged to heed these warning by strengthening their HIPAA compliance and adopting other suitable safeguards to minimize HIPAA exposures. Health plans and other covered entities as well as their business associates should tighten privacy policies, breach and other monitoring, training and other practices to mitigate against exposures in light of recently tightened requirements and new enforcement risks. To minimize the potential that the health plan’s sharing of information with the employer will create or spread HIPAA or other privacy risks to the employer or members of its workforce, employers and other plan sponsors and members of their workforce also should take steps to ensure not only that their health plan documents, policies and procedures, as well as those policies and practices applicable to the employer, its human resources, and benefits advisors when accessing or handling health plan or other medical information on behalf of the employer, rather than the plan, are appropriately designed and administered.

Mass Mutual Resolution Agreement

According to OCR, Mass General, one of the nation’s oldest and largest hospitals, signed a Resolution Agreement with HHS that requires it to pay \$1 million and develop and implement a comprehensive set of policies and procedures to safeguard the privacy of its patients. Like previously announced Resolutions Agreements with Rite-Aid, CVS Pharmacies, Inc. and Provident Health, the Mass General Resolution Agreement follows an extensive investigation by OCR.

The incident giving rise to the agreement involved the loss of protected health information (PHI) of 192 patients of Mass General’s Infectious Disease Associates outpatient practice, including patients with HIV/AIDS. OCR opened its investigation of Mass General after a complaint was filed by a patient whose PHI was lost on March 9, 2009. OCR’s investigation indicated that Mass General failed to implement reasonable, appropriate safeguards to protect the privacy of PHI when removed from Mass General’s premises and impermissibly disclosed PHI potentially violating provisions of the HIPAA Privacy Rule.

The impermissible disclosure of PHI involved the loss of documents consisting of a patient schedule containing names and medical record numbers for a group of 192 patients, and billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis and name of providers for 66 of those patients. These documents were lost on March 9, 2009, when a Mass General employee, while commuting to work, left the documents on the subway train that were never recovered.

Mass General also agreed to enter into a Corrective Action Plan (CAP), which requires the hospital to:

- Develop and implement a comprehensive set of policies and procedures that ensure PHI is protected when removed from Mass General's premises;
- Train workforce members on these policies and procedures; and
- Designate the Director of Internal Audit Services of Partners HealthCare System Inc. to serve as an internal monitor who will conduct assessments of Mass General's compliance with the CAP and render semi-annual reports to HHS for a 3-year period.

\$4.3 Million Cignet CMP Shows OCR Enforcement Resolve

OCR's enforcement resolve is further evidenced by its assessment of a \$4.3 million CMP against Cignet

Announced just two days before the Mass General Resolution Agreement, the Cignet CMP announced February 22, 2011 is the first CMP ever assessed by OCR under the HIPAA Privacy Rule. The assessment resulted after OCR found Cignet violated 41 patients' HIPAA rights and committed other HIPAA violations. The \$4.3 million CMP against Cignet applies the expanded HIPAA violation categories and increased HIPAA civil monetary penalty amounts authorized by HIPAA amendments made by Section 13410(d) of the Health Information Technology for Economic and Clinical Health (HITECH) Act. [Read more details.](#)

Other Signs of Rising Risks

Even before the Mass General Resolution Agreement and Cignet CMP announcements, HIPAA Privacy exposures of covered entities for failing to comply with HIPAA already had risen significantly. As of January 1, 2011, OCR reports that 12,781 of the cases it has investigated have been resolved by requiring changes in privacy practices and other corrective actions by the covered entities and has referred more than 484 Privacy Rule breach investigations to the Department of Justice for consideration for potential criminal prosecution. While OCR had not assessed any civil monetary penalties against any covered entity for violation of HIPAA before Cignet, OCR's collection of \$1 Million from Rite Aid in a 2010 Resolution Agreement, \$2.25 million from CVS Pharmacy, Inc. under a 2009 Resolution Agreement and \$100,000 from Providence Health & Services under a 2008 Resolution Agreement demonstrated that covered entities could face significant civil liability for willful violations of the Privacy Rules. See e.g., [Rite Aid Pays \\$1 Million HIPAA Privacy Settlement As OCR Tightens HIPAA Regulations](#); [HIPAA Risks Soar As CVS Agrees To Pay \\$2.25 Million To Resolve HIPAA Charges & Stimulus Bill Amends HIPAA](#); [Providence To Pay \\$100,000 & Implement Other Safeguards To Settle HIPAA Penalty Exposures Under HIPAA.](#)

In addition to these civil enforcement actions by OCR, the Department of Justice has secured several criminal convictions or pleas under HIPAA's criminal provisions. OCR data confirms that the covered entities involved in these actions included health care providers, health plans, and others. See, e.g., [2 New HIPAA Criminal Actions Highlight Risks From Wrongful Use/Access of Health Information.](#)

As a result of amendments enacted as part of the HITECH Act, Congress modified and expanded the HIPAA audit obligations of OCR, amended and expanded the potential penalties, made business associates liable for violation of the privacy rules like covered entities, added an obligation for covered entities and business associates to provide notification of breaches of unsecured PHI and tightened other HIPAA obligations. The HITECH Act also gave state attorneys general to bring civil lawsuits against covered entities and business associates that commit HIPAA violations that injure citizens in their state under certain circumstances. Eventually, individuals injured by HIPAA violations will get the right to share in a portion of certain HIPAA recoveries. See [HIPAA Heats Up: HITECH Act Changes Take Effect & OCR Begins Posting Names, Other Details Of Unsecured PHI Breach Reports On Website.](#)

Along side these governmental actions, state courts also increasingly are willing to allow individual plaintiffs to rely on violations of HIPAA as the basis for bringing state privacy, retaliation or other actions. While prior to the recent HITECH Act amendments, federal courts had ruled that private plaintiffs could not sue under HIPAA for damages they incurred from a covered entity's violation of HIPAA, state courts have allowed private plaintiffs to use the obligations imposed by HIPAA as the basis of a covered entity's duty for purposes of certain state law lawsuits. In *Sorensen v. Barbuto*, 143 P.3d 295 (Utah Ct. App. 2006), for example, a Utah appeals court ruled a private plaintiff could use HIPAA standards to establish that a physician owed a duty of confidentiality to his patients for purposes of maintaining a state law damages claim. Similarly, the Court in *Acosta v. Byrum*, 638 S.E. 2d 246 (N.C. Ct. App. 2006) ruled that a plaintiff could use HIPAA to establish the "standard of care" in a negligence lawsuit. Meanwhile, private plaintiffs employed by covered entities also are increasingly pointing to HIPAA as the basis for their retaliation claims. See, e.g., [Retaliation For Filing HIPAA Complaint Recognized As Basis For State Retaliatory Discharge Claim.](#) Coupled with the HITECH Act changes, these and other enforcement actions signal growing potential hazards for covered entities and their business associates that fail to properly manage their HIPAA compliance obligations and risks.

In addition to these HIPAA-specific exposures, wrongful use, access or disclosure of medical information also can expose Covered Entities, members of their workforce and others improperly using, accessing or disclosing protected health information to liability under other federal or state laws. Federal and state prosecutors may and increasingly do bring criminal or civil actions against organizations or individuals for improperly accessing or using medical or other personal information under a variety of other federal or state laws. See e.g., [Cybercrime & Identity Theft: Health Information Security Beyond HIPAA](#); [NY AG Cuomo Announcement of 1st Settlement For Violation of NY Security Breach Notification Law](#); [Woman Who Revealed AIDs Info Gets A Year.](#)

Act To Manage HIPAA Exposures

In response to these expanding exposures, health care providers and other covered entities should review the adequacy of their current HIPAA Privacy and Security compliance policies, monitoring, training, breach notification and other practices taking into consideration the Cignet, Rite Aid, Provident and CVS enforcement actions, emerging litigation and other enforcement data; their own and reports of other security and privacy breaches and near misses, and other developments to determine if additional steps are necessary or advisable.

To minimize the potential that the health plan's sharing of information with the employer will create or spread HIPAA or other privacy risks to the employer or members of its workforce, employers and other plan sponsors and members of their workforce also should take steps to ensure not only that their health plan documents, policies and procedures, as well as those policies and practices applicable to employer, its human resources, and benefits advisors when accessing or handling health plan or other medical information on behalf of the employer, rather than the plan, are appropriately designed and administered. As part of this process, steps that concerned covered entities, business associates and employers should consider include:

- Reviewing the adequacy of the practices, policies and procedures of the Covered Entities, business associates, and others that may come into contact with protected health information within the scope of attorney-client privilege taking into consideration the Corrective Action Plan, published OCR noncompliance and enforcement statistics, their own and reports of other security and privacy breaches and near misses, and other developments to determine if additional steps are necessary or advisable;
- Updating policies, privacy and other notices, practices, procedures, training and other practices as needed to promote compliance and defensibility;
- Renegotiating and enhancing service provider agreements to detail the specific compliance obligations of each party; to clarify the respective rights, procedures and responsibilities of each party in regards to compliance audits, investigation, breach reporting, and mitigation; to clarify rights of indemnification; and other related relevant matters;
- Improving technological and other tracking, documentation and safeguards and controls to the use, access and disclosure of protected health information;
- Conducting well-documented training as necessary to ensure that members of the Covered Entity's workforce understand and are prepared to comply with the expanded requirements of HIPAA, can detect potential breaches or other compliance concerns, and understand as well as are prepared to follow appropriate procedures for reporting and responding to suspected violations;
- Tracking actual and near miss violations and making adjustments to policies, practices, training, safeguards and other compliance components as necessary to deter future concern;
- Establishing and providing well-documented monitoring of compliance;
- Establishing and providing well-documented timely investigation and redress of reported violations or other compliance concerns;
- Establishing contingency plans for responding in the event of a breach;
- Establishing a well-documented process for monitoring and updating policies, practices and other efforts in response to changes in risks, practices and requirements;
- Preparing and maintaining a well-documented record of compliance activities;
- Pursuing other appropriate strategies to enhance the Covered Entity's ability to demonstrate its compliance commitment both on paper and in operation.

As part of these compliance and risk management efforts, most covered entities and their business associates will find it advisable to devote significant attention to the business associate relationship and its associated business associate agreements.

Proper management of the expanded compliance obligations and liability exposures created by the HITECH Act generally will necessitate that health plans and other covered entities and their business associates focus significant attention on the reworking of their operating and contractual relationships. Even before the HITECH Act changes took effect, a strong need for more detailed contracting and planning of these relationships already existed. Since the enactment of HIPAA, the practice of many covered entities and their business associates of appending generic "business associate" representations onto existing services contracts without specific tailoring and planning has created undesirable ambiguities in these agreements. In response to the HITECH Act and other recent developments, both covered entities and their business associates generally also should seek to tighten business associate and other service agreements to promote the improved cooperation, coordination, management and oversight required to comply with the new breach notification and other HIPAA requirements by specifically mapping out these details. Among other things, both covered entities and business associates generally will should:

- Conduct well-documented due diligence on each other's practices and procedures to improve their ability to demonstrate both their commitment to compliance and their realistic efforts to ensure that these commitments are operationalized in performance;
- Renegotiate their service provider agreements to detail the specific compliance obligations of each party relating to for auditing compliance, investigating potential breaches; providing required breach notifications; specify leadership and required cooperation in the event of a breach, charge, or other concern; indemnification and other liability allocations; and other related matters; and
- Pursue appropriate liability and other protection as appropriate.

For Help With Compliance, Investigations Or Other Needs

If you need assistance auditing or tightening your existing HIPAA and other confidentiality practices or addressing other health care related risk management, compliance, enforcement or management concerns, the author of this update, attorney Cynthia Marcotte Stamer, may be able to help. Vice President of the North Texas Health Care Compliance Professionals Association, Past Chair of the ABA Health Law Section Managed Care & Insurance Section and the former Board Compliance Chair of the National Kidney Foundation of North Texas, Ms. Stamer has more than 23 years experience advising health industry clients about these and other matters. Ms. Stamer has extensive experience advising and assisting health care providers and other health industry clients to establish and administer medical privacy and other compliance and risk management policies and to respond to OCR, FTC, medical board and other health care industry investigation, enforcement and other compliance, public policy, regulatory, staffing, and other operations and risk management concerns. A popular lecturer and widely published author on health industry concerns, Ms. Stamer continuously advises health industry clients about compliance and internal controls, workforce and medical staff performance, quality, governance, reimbursement, and other risk management and operational matters. Ms. Stamer also publishes and speaks extensively on health and managed care industry regulatory, staffing and human resources, compensation and benefits, technology, public policy, reimbursement and other operations and risk management concerns including a number of programs and publications on Medicare quality and other compliance concerns. Her publications and insights on HIPAA and other related matters appear in the Health Care Compliance Association, Atlantic Information Service, Bureau of National Affairs, World At Work, The Wall Street Journal, Business Insurance, the Dallas Morning News, Modern Health Care, Managed Healthcare, Health Leaders, and a many other national and local publications. You can get more information about her health industry experience [here](#). If you need assistance with these or other compliance concerns, wish to inquire about arranging for compliance audit or training, or need legal representation on other matters please contact Ms. Stamer at (469) 767-8872 or via e-mail [here](#).

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- [HHS Imposes 1st HIPAA Privacy Civil Penalty of \\$4.3 million](#)
- [ONC Giving Small Critical Access And Rural Hospitals Added Electronic Health Records Funds](#)
- [Health Care Employer's NLRB Settlement Shows Care Necessary When Using Social Networking & Other Policies Restricting Employee Communications](#)
- [Medicare Proposes To Require Providers To Notify Patients Of Quality Of Care Complaint Rights](#)
- [OIG Launch of Health Care Fraud "Most Wanted" List Sign of Enforcement Risks](#)
- [Rhode Island DHS Must Provide Translation, Other Services For Limited English, Other Language Impaired Persons](#)
- [Texas Doctor, Pharmacy Suspension Reminder of Pain Management Prescribing Risks](#)
- [Supreme Court Ruling Medical Resident Stipend Are Wages Highlights Advisability of Compliance Review](#)
- [CMS Physician Compare Tool Gives Patients New Info On Physicians & Other Providers](#)
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- [EEOC Attacks Medical Leave Denials As Prohibited Disability Discrimination](#)
- [Affordable Care Act's Health Plan External & Internal Review Safe Harbor & Other Regulations Require Health Plan Updates](#)
- [Employers Concerned About New Union Powers As NLRB Orders Union Elections In 31 California Health Care Facilities To Proceed](#)
- [HHS Announces Adjustments to Federal Medical Assistance Percentage \(FMAP\) Rates](#)
- [Rite Aid Agrees to Pay \\$1 Million to Settle HIPAA Privacy Case As OCR Moves To Tighten Privacy Rules](#)

- **CMS Adopts ESRD Facility Prospective Payment System & Proposes New Quality Incentive Program**
- **CMS Rule Clarifies When Outpatient Services Subject to 3-Day Rule & Finalizes FY 2011 Inpatient Payment Rates**

If you or someone else you know would like to receive future updates about developments on these and other concerns, please be sure that we have your current contact information – including your preferred e-mail – by creating or updating your profile [here](#). For important information concerning this communication click [here](#).

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