ROBINSON & COLE LLP
ATTORNEYS AT LAW

Attorney Advertising

UPDATE
Health Law Pulse

MARCH 2011

In this Issue...

NEW FRAUD FIGHTING TOOLS CHANGE SCREENING AND ENROLLMENT REQUIREMENTS FOR PROVIDERS

On March 25, 2011, Medicare and Medicaid providers will be subject to new enrollment and screening regulations (New Regulations). The New Regulations were developed by the Centers for Medicare and Medicaid Services (CMS) and were enacted as a result of changes imposed by the Patient Protection and Affordable Care Act on the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP). The changes aim to improve the integrity of the programs and combat fraud, waste, and abuse. The New Regulations are available here.

Enrollment Screening

The New Regulations establish a revised screening process for provider and supplier enrollees of Medicare, Medicaid, and CHIP (Enrollees). Enrollees will be sorted into one of three screening tiers based on the associated risk of fraud, waste, and abuse of the provider type: limited risk, moderate risk, and high risk. Limited risk entities include hospitals, physicians, non-physician practitioners, medical groups and clinics. Moderate risk entities include currently enrolled home health agencies and currently enrolled durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. High risk entities include newly enrolling home health agencies and DMEPOS suppliers.

Enrollees will be subject to various screening requirements depending on their risk level. All Enrollees will be subject to license verification and program-specific requirements. Moderate risk Enrollees will also be subject to unannounced site visits. High risk enrollees will be subject

to all of the limited and moderate risk requirements and will also have to undergo fingerprinting and background checks prior to enrollment. While new Enrollees will be subject to the screening regulations on March 25, 2011, currently-enrolled providers and suppliers will not be subject to the screening procedures until March 23, 2012, unless they revalidate their enrollment prior to that date.

Application Fee

Certain Medicare institutional providers will be required to pay an application fee to cover the cost of the new screening requirements under the New Regulations. Institutional providers include hospitals, home health agencies, DMEPOS suppliers, mammography centers, radiation therapy centers, outpatient physical therapy/occupational therapy centers, independent clinical laboratories, and hospices. Institutional providers do not include physician and non-physician practitioner organizations. The application fees do not apply to Medicare Part B medical groups or clinics or individual physicians. In addition to the Medicare application fee, the New Regulations permit states to impose an application fee on any provider who bills a state Medicaid program or CHIP on a fee-for-service basis, other than individual physicians, non-physician practitioners and providers enrolled in Medicare or another state's Medicaid plan. The fee for both Medicare and Medicaid applications will be set in accordance with a statutorily-derived formula. All Medicare and Medicaid providers subject to the new fees will have to pay the fees for every new enrollment, new practice location, and enrollment revalidation. In 2010, the Medicare and Medicaid application fees were $500 per application. The fees, which will be adjusted every year according to the consumer price index, apply to new institutional providers starting March 25, 2011 and currently-enrolled providers on March 23, 2012, except that a currently-enrolled provider who revalidates after March 25, 2011, will be subject to the new rules in connection with such revalidation.

Revalidation

The New Regulations require that Medicaid agencies, similar to the current Medicare requirement, must revalidate or reenroll all providers at least every five years. Further, if a provider enrollment number has been deactivated for any reason, the state Medicaid agency must re-screen the provider under all applicable enrollment requirements and charge the provider all applicable fees.

Temporary Moratorium

The New Regulations allow Medicare and Medicaid agencies to establish temporary enrollment moratoria on new provider and supplier types and new practice locations in certain geographic areas when necessary to combat fraud, waste, or abuse. Prior to enacting a moratorium, CMS will announce the provider or supplier type and the reasons for such moratorium in the Federal Register. Moratoria may only be imposed for up to six months but may be extended in six-month increments.

Suspension of Payments and Termination

The New Regulations establish new guidelines for suspension of payments and termination of Medicaid providers. Medicare and state Medicaid agencies may now suspend payments when there is a credible allegation of fraud. However, the Secretary of Health and Human Services has discretion to determine whether there is good cause to continue payments. The New

Regulations also include new ancillary provisions. For example, under the New Regulations Medicare payment suspensions based on credible allegations of fraud are subject to an 18-month cap rather than the current Medicare suspension time limit of 180 days. Also, the New Regulations provide that no prior notice is required for Medicaid terminations based on credible allegations of fraud. Moreover, Medicaid agencies must terminate the enrollment of any provider or supplier that has had their privileges terminated in another state's Medicaid program or by CMS in the Medicare program.

MARYLAND HEALTH CARE GROUP MUST PAY $4.3 MILLION FOR HIPAA VIOLATIONS

On February 22, 2011, the Department of Health and Human Services (HHS) imposed a civil monetary penalty of $4.3 million on Cignet Health Center, Cignet Health Plan, and Cignet Healthcare (collectively "Cignet") for violating the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Specifically, Cignet refused to grant patients access to their medical records and refused to cooperate with HHS during its investigation. HIPAA requires that entities subject to HIPAA (covered entities) provide patients with access to their own medical records within 30 days of their request and that covered entities must cooperate with complaint investigations. If a covered entity does not comply with HIPAA, HHS is permitted to levy monetary penalties against such covered entity. Cignet was fined $1.3 million for the HIPAA violation and $3 million for refusing to cooperate.

The Investigation

The HHS Office for Civil Rights (OCR), the HHS office responsible for enforcing these types of HIPAA violations, began to investigate Cignet after it received 41 patient complaints against Cignet from September 2008 through October 2009. The patients all complained that they had requested copies of their medical records from Cignet and that Cignet was not responding to their requests. Many of the patients wanted their records to obtain services from providers outside of the Cignet network.

During the initial months of the investigation, OCR attempted to contact Cignet to notify the entity of its investigations and Cignet failed to respond. After numerous failed attempts to contact Cignet, OCR obtained a subpoena in June 2009 requiring Cignet to produce the medical records of the first 11 complainants. Cignet did not produce the records or respond to OCR's subpoena. Consequently, in February 2010, OCR filed a petition to enforce the subpoena in federal court. Cignet did not appear at the hearing or respond to the petition. In March 2010, the court directed Cignet to produce the requested copies and Cignet complied.

Based on its investigation, OCR sent Cignet a letter in August 2010 stating it had preliminarily found that Cignet violated HIPAA and refused to cooperate. The letter also informed Cignet that it could submit evidence to defend or mitigate its actions. Cignet did not respond by the required date. OCR then sought and obtained authorization of the proposed monetary penalty by the Attorney General of the United States and sent notice to Cignet that it would be subject to the monetary penalty. Cignet was given 90 days to respond and request a hearing. Cignet failed to request a hearing, and the monetary penalty was imposed in February 2011.

The Penalty

The final penalty totaled $4,351,600. Under HIPAA and the Health Information Technology for

Economic and Clinical Health Act, failing to provide individuals with access to their medical records constitutes a minimum penalty in the amount of $100 per day per individual. Cignet was penalized a total of $1,351,600 for these violations. The regulations also impose penalties for refusing to cooperate with an investigation. The penalty was set at $50,000 per day per complaint, with a maximum of $1.5 million per calendar year for identical violations. Cignet's refusal to cooperate in 2009 and 2010 reached the maximum in both years. Because Cignet did not request a hearing, the penalty is final and Cignet does not have a right to appeal the determination.

MASS GENERAL SETTLES HIPAA VIOLATION WITH HHS FOR $1 MILLION

On February 24, 2011, the Department of Health and Human Services (HHS) announced a $1 million settlement (Settlement) with General Hospital Corporation and Massachusetts General Physicians Organization, Inc. (Mass General) for alleged violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Settlement was based on an allegation that a Mass General employee lost confidential patient records containing protected health information (PHI), in violation of HIPAA. Mass General did not concede to any HIPAA violations and has been released from any HIPAA-based claims or causes of action by HHS arising from the incident as long as it complies with the terms of the Settlement.

The Investigation

In March 2009, the HHS Office for Civil Rights (OCR) began investigating the allegations. The investigation revealed that in early March 2009 a hospital employee took hospital records from Mass General's premises to work on them at home and, subsequently, left the records on the subway. The lost records contained PHI including the names, diagnoses, birth dates, health insurance information, and HIV/AIDS status of 66 patients, as well as a three-day appointment schedule that included the names and medical record numbers of 192 patients. The records were never recovered. The investigation also revealed that Mass General did not have reasonable and appropriate safeguards implemented to protect patient privacy when documents were removed from the premises.

The Agreement

To avoid further litigation, Mass General agreed to a $1 million penalty, payable to HHS, and a three-year Corrective Action Plan (CAP). The CAP requires three tasks. First, Mass General must develop written policies that comply with HIPAA and address how it protects PHI, including, among other things, the transport and removal of PHI, laptop encryption, and USB drive encryption. Mass General must develop and submit the policies to HHS for approval within 90 days of the effective date of the CAP. It must then implement the policies within 90 days of HHS's approval of the policies. Once it receives the approval, it must distribute the policies to its employees within 30 days and train them on the content of such policies within 90 days.

Second, Mass General must designate an internal monitor who assesses its progress with the CAP and prepares semiannual reports describing its compliance. Additionally, the monitor must report any violations of the CAP to HHS within 10 business days and ensure that

documents demonstrating compliance with the CAP are properly retained.

Lastly, Mass General must submit to HHS a report within 120 days of the CAP attesting to its implementation of the CAP and provide annual reports thereafter. The annual reports must include, among other things, training materials, schedules, revisions to any policies developed under the CAP, the internal monitor's reports, and a summary of reportable events. The reports must be signed by a Mass General officer who attests to reviewing the annual reports.

IRS ANNOUNCES DELAYED FILING OF FORM 990 FOR CERTAIN TAX-EXEMPT HOSPITALS

On February 23, 2011, the Internal Revenue Service (IRS) announced that certain tax-exempt organizations are being granted an automatic three-month extension of time to file. The automatic extension applies only to organizations operating one or more hospital facilities that would otherwise be required to file an annual informational return (that is, Form 990, including Schedule H, Hospitals) for the 2010 tax year before August 15, 2011. The extension is being granted so that the IRS can revise its forms in response to the passage of the Patient Protection and Affordable Care Act of 2010.

The IRS is directing any newly-formed organizations that believe they are affected by the announcement and have not filed a Form 990, including Schedule H, for the 2009 tax year to request an extension using Part I of Form 8868.

PPACA UPDATE: IRS RELEASES UPDATED FORM 990 INSTRUCTIONS FOR NONPROFIT HOSPITALS

On February 24, 2011, the Internal Revenue Service (IRS) posted the long-awaited Form 990 Schedule H and accompanying instructions for tax-exempt hospitals. The Patient Protection and Affordable Care Act of 2010 (PPACA) amended the Internal Revenue Code (Code) to include new requirements for hospitals that wish to remain tax-exempt. The new Schedule H and its instructions reflect those changes.

Revised Schedule H, in alignment with PPACA, asks hospital organizations new questions about community health needs, financial assistance policies, rates and charge limits, and billing and collection practices. All questions are effective for tax years beginning after March 23, 2010, with the exception of those relating to community health needs, which are only required for tax years beginning after March 23, 2012. Major revisions are reflected in Part V, where hospital organizations are now required to list all their licensed, registered, or similarly recognized hospital facilities and each listed facility's policies and procedures on community needs assessment, financial assistance, billing and collections, emergency medical care, and charges. The IRS states it will continue to refine Form 990 and Schedule H to fully implement PPACA.

The instructions, the only agency guidance released on the new Schedule H, explain how to properly complete a Schedule H and fulfill PPACA requirements. For example, the instructions clarify that each hospital facility must perform a needs assessment at least once every three

years while the Code states that every organization must conduct a needs assessment.

If you have any questions about new Medicaid, Medicare, or CHIP rules; HIPAA; Form 990; or the content in these articles, please contact any member of Robinson & Cole's Health Law Group.

Lisa M. Boyle	Theodore J. Tucci	Stephen W. Aronson
Pamela H. Del Negro	Michael J. Kolosky	Susan E. Roberts
Kimberly E. Troland	B. Moses Vargas	Meaghan Mary Cooper