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HHS TRANSMITTAL ON HOME HEALTH FACE-TO-FACE ENCOUNTER PROVISIONS

On February 16, 2011, CMS issued Transmittal 139 ("Transmittal") that revises Chapter 7 of the Medicare Benefit Policy Manual to incorporate the new home health face-to-face encounter requirements. The Transmittal notes that due to new provisions mandated by passage of the Affordable Care Act, there are new statutory requirements regarding face-to-face encounters for certifications applicable to the home health program that must be updated in the home health chapter in the Medicare Benefit Policy Manual. Accordingly, the Transmittal states that for episodes with starts of care beginning January 1, 2011 and later, prior to initially certifying a home health patient's eligibility, the certifying physician must document that the physician or an allowed non-physician practitioner (NPPs) had a face-to-face encounter with the patient. The Transmittal also states that the face-to-face encounter and documentation are a condition of payment, and that the initial certification is incomplete without them.

As noted above, the Transmittal indicates that the face to face encounter can either be made by the certifying physician or by an allowed NPP. However, when an NPP performs a face-to-face encounter, the Transmittal notes that the NPP must inform the certifying physician regarding the clinical findings exhibited by the patient during the encounter and the *certifying physician* must document the encounter and sign the certification. The documentation must include, among other things, a brief narrative composed by the certifying physician who describes how the patient's clinical condition as seen during the encounter supports the patient's homebound status and need for skilled services.

The Transmittal makes clear that while it is acceptable for the certifying physician to verbally communicate the encounter to one of the physician's support personnel to type, or for the documentation to be generated from the physician's electronic health record, it is not acceptable for the physician to verbally communicate the encounter to a home health agency and then have the agency document the encounter as part of the certification for the physician to sign.

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The Transmittal also discusses timeframes for the certification, the use of telehealth in performing face-to-face encounters in approved originating sites, and the circumstances under which an encounter between a home health patient and the attending physician who cares for the patient during an acute or post-acute setting may satisfy the face-to-face encounter.

As noted above, the contents of the Transmittal are incorporated into the Medicare Beneficiary Policy Manual, Chapter 7, Section 30.5.1. Further explanation is also available at http://www.cms.gov/MLNMattersArticles/downloads/SE1038.pdf.

HHS IMPOSES FIRST CIVIL MONETARY PENALTY FOR HIPAA VIOLATION

In the first civil monetary penalty (CMP) imposed by the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) for a covered entity's violation of the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS notified Cignet Health, Cignet Health Center, Cignet Health Plan, and/or Cignet Health Care (Cignet) in a Notice of Final Determination, dated February 4, 2011, that Cignet had violated HIPAA and was subject to a CMP in the amount of approximately $4.3 million.

According to OCR's Notice of Proposed Determination (NPD), dated October 20, 2010, Cignet failed to provide 41 patients access to their medical records when requested between September 2008 and October 2009. More specifically the NPD recites the following findings of fact: Cignet maintained medical records containing protected health information (PHI) relating to 41 individuals who received physician services from members of Cignet's workforce. Several of the individuals had advised Cignet that they were requesting copies of their records so they could obtain health care services from physicians other than those who were members of Cignet's workforce. When Cignet failed to respond to the requests, 38 of the individuals filed complaints with OCR. OCR notified Cignet of its investigation of the 38 complaints and made multiple attempts to contact Cignet. Cignet failed to produce the medical records and failed to respond to OCR in any way. OCR issued a subpoena *duces tecum* for certain of the records, and when Cignet failed to respond to the subpoena, and to a subsequent letter from OCR, OCR filed a petition with the U.S. District Court for the District of Maryland to enforce the subpoena. Cignet failed to appear at the hearing and OCR obtained default judgment against Cignet, with the Court directing Cignet to produce the medical records at issue by April 7, 2010.

According to the NPD, on April 7, 2010, Cignet delivered 59 boxes of original medical records to OCR. Included in the 59 boxes were not only the requested medical records, but also the medical records of 4,500 individuals "for whom OCR made no request or demand and for whom Cignet had no basis for the disclosure of their protected health information to OCR." The NPD notes that in August 2010, OCR advised Cignet in a letter that OCR's investigation of the complaints indicated that Cignet failed to comply with the HIPAA regulations, and provided Cignet with an opportunity to furnish written evidence of mitigating factors or affirmative defenses for OCR's consideration in making its determination and/or evidence that would support a waiver of a CMP. The NPD states that Cignet failed to respond to OCR. OCR therefore determined that there was no affirmative defense to and no waiver of the CMP and obtained the authorization of the U.S. Attorney General prior to issuing the NPD to impose a CMP. The NPD was delivered to Cignet and, once received,

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Cignet had 90 days to request a hearing. The Notice of Final Determination recites that Cignet did not request a hearing, and since there was no settlement of the matter, OCR imposed the CMP in the total amount of $4,351,000.

The NPD indicates that $1,351,600 of the total CMP was imposed for Cignet's failure to provide each individual with access to his or her medical records (each such failure constituted a separate violation, and each day a violation continued constituted additional, separate violations). In addition, the NPD indicates that $3,000,000 of the total CMP was imposed for Cignet's failure to cooperate with OCR's investigation of each complaint (each such failure constituted a separate violation, and each day a violation continued constituted additional, separate violations). It appears from OCR's calculation of the portion of the CMP related to Cignet's failure to cooperate with OCR's investigation (which is attached to the NPD as Attachment C), that Cignet could have faced a significantly greater penalty were it not for the $1.5 million annual cap on penalties set forth in the HIPAA regulations. For example, Attachment C of the NPD indicates that the 2010 potential penalty for Cignet's failure to cooperate with OCR's investigation would have been $4,850,000 *per individual*, had the annual penalty cap not been in place.

MASS GENERAL HOSPITAL PAYS $1 MILLION TO SETTLE POTENTIAL HIPAA VIOLATIONS

On February 14, 2011, The General Hospital Corporation and Massachusetts General Physician Organization, Inc. (Mass General) entered into a Resolution Agreement with the U.S. Department of Health and Human Services (HHS), Office of Civil Rights (OCR) to settle claims that Mass General violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA) by failing to safeguard the protected health information (PHI) of 192 patients of Mass General's Infectious Disease Associates outpatient practice, including patients with HIV/AIDS.

The Resolution Agreement states that the following events that ultimately gave rise to the Resolution Agreement occurred: On March 6, 2009, a Mass General employee removed documents containing PHI from Mass General's premises for the purpose of working on the documents from home. The documents consisted of billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis and name of provider of 66 patients, as well as the daily office schedules for 3 days containing the names and medical record numbers of 192 patients. On March 9, 2009, while commuting to work on the subway, the Mass General employee removed the documents from her bag and placed them on the seat beside her. The documents were not in an envelope and were bound with a rubber band. Upon exiting the train, the Mass General employee left the documents on the seat beside her and they were never recovered.

An HHS News Release, dated February 24, 2011, indicated that OCR opened an investigation of Mass General after a complaint was filed by a patient whose PHI was lost on March 9, 2009. According to the News Release, 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 Resolution Agreement notes that although Mass General has not admitted any liability or

wrongdoing, and has not admitted to any HIPAA violation, it agreed to pay HHS $1,000,000 and to enter into a three-year Corrective Action Plan. The Corrective Action Plan requires, among other things, that Mass General develop and implement a comprehensive set of policies and procedures governing the physical removal and transport of PHI, laptop encryption, and USB encryption, that are consistent with HIPAA's Privacy and Security Rules and that address the incident that led to the Resolution Agreement; provide specific training on the policies and procedures to all workforce members who have access to and use PHI; and designate an internal monitor who will assess Mass General's implementation of and compliance with the Corrective Action Plan's requirements and periodically provide a written report to HHS. The monitor's reports to HHS must also include a description of any workforce member's violation of the policies and procedures, and the steps Mass General took to address the matter(s) and mitigate any harm, as well as any "significant violations" of the Correction Action Plan.

The Resolution Agreement states that although the Resolution Agreement is not a concession by HHS that Mass General is not in violation of HIPAA and not liable for civil monetary penalties, it was entered into to avoid the parties' uncertainty, burden and expense of HHS' further investigation and any subsequent formal proceedings.

HITECH ONE YEAR LATER

In late February 2011, an accounting firm in the State of Florida, Kaufman, Rossin & Co., released a study in which it analyzed all of the breaches that occurred in the twelve-month period between September 23, 2009, and September 23, 2010, that were posted on the U.S. Department of Health and Human Services' (HHS) website (that is, breaches involving 500 or more individuals). September 2010 marked the end of the first year that breaches involving 500 or more individuals were required to be reported to HHS under the Health Information Technology for Economic and Clinical Health Act, commonly referred to as the "HITECH Act."

The study revealed that 166 breaches were reported to HHS in this time period and that the breaches involved 4,905,768 individuals. The largest reported breach, which involved the theft of an unencrypted laptop, occurred in December 2009 and affected 1,220,000 individuals. According to the study, laptops were the greatest sources of breaches and affected the largest number of individuals.

The study also found that of the seven types of breaches noted on the HHS website, theft was the primary cause of the breaches (58 percent) and affected the largest number of individuals (3,123,800). Loss was the second most frequent cause of breaches (14 percent) and affected 1,038,814 individuals (the study noted that category of "loss" was tied with the category of "other" as a reason for breaches, with both at 14 percemt). Twenty percent of the incidents involved business associates, while the rest involved covered entities. Thirty-two percent of the breaches were reported within three months from the date of the breach and date it was posted on the HHS website, with the fastest notification taking only 6 days and the longest notification taking 276 days.

In addition to reporting on the number, types and locations of reported breaches, the study offered certain recommendations for preventing breaches, including, without limitation, encrypting new and existing laptops, reviewing

and/or creating policies and procedures, performing security and risk assessments, and retraining all employees on all information security and privacy policies and procedures.

HHS PROPOSES RULE ON PROHIBITING REIMBURSEMENT FOR CERTAIN PREVENTABLE CONDITIONS

On February 17, 2011, CMS published a proposed rule that, if finalized in its current form, would prohibit payments made under the Medicaid program for Provider Preventable Conditions. The term "Provider Preventable Conditions" (PPCs) is an umbrella term for hospital and nonhospital conditions identified by States for nonpayment under Medicaid. PPCs fall into two general categories: health care-acquired conditions (HCACs), and other provider-preventable conditions (OPPCs).

The proposed rule builds on Section 5001(c) of the Deficit Reduction Act of 2005 (DRA), which amended Section 1886(d)(4) of the Social Security Act (the Act) to prohibit Medicare payments to certain hospitals for certain preventable hospital acquired conditions (HACs). Under the provisions of the Act, no Medicare payment for hospital services may be made for certain HACs identified by the Secretary. Further, when an HAC is not present on admission (POA), but is reported as a secondary diagnosis associated with the hospitalization, the Medicare payment to the hospital may be reduced to reflect that the condition was hospital-acquired. More specifically, the hospital discharge cannot be assigned to a higher paying MS-DRG if the secondary diagnosis associated with the HAC would otherwise have caused this assignment. If the HAC were POA, then the Medicare payment to the hospital would not be reduced. According the proposed rule, the list of current HACs include, without limitation, foreign object retained after surgery, stage II and IV pressure ulcers, falls and trauma, catheter-associated urinary tract infections, surgical site infections following certain procedures, and deep vein thrombosis.

As noted in the proposed rule, Section 5001(c) of the DRA addressed only the Medicare program and did not require that Medicaid programs implement nonpayment policies for HACs. Rather, States were encouraged to adopt payment prohibitions on provider claims for HACs to coordinate with the Medicare prohibitions. To accomplish this, in 2008, CMS issued a State Medicaid Director Letter that was flexible in its guidance on State Medicaid handling of the issue. The Letter stated, among other things, that States seeking to implement HAC nonpayment policies could do so by amending their Medicaid State plans to specify the extent to which they would deny payment for an HAC.

This flexible approach appears to have resulted in wide variation among State nonpayment policies, with States varying in such areas as the authority used to enact the policies, the terminology used, the conditions identified, the reporting requirements, and the State's utilization of the current Medicare HAC list. According to the proposed rule, 29 States currently do not have an HCAC-related nonpayment policy, and many of those that have adopted the Medicare HAC list have been more restrictive than Medicare in that they have, among other things, expanded the diagnosis codes and settings where the nonpayment policy would apply. States that have implemented HCAC-related nonpayment policies have also included provisions to protect the State from cost shifting that may occur when dually eligible beneficiaries have claims denied by Medicare.

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In March 2010, the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) was signed into law. The Affordable Care Act directed the Secretary of HHS to issue regulations, effective as of July 1, 2011, prohibiting Federal payment to States under Section 1903 of the Social Security Act for any amounts expended for providing medical assistance for HCACs specified in regulations. The regulations must ensure that the prohibition on payment for HCACs does not result in a loss of access to care or services for Medicaid beneficiaries. The Affordable Care Act set out a general framework for the application of Medicare prohibitions on payment for HCACs to the Medicaid program.

Accordingly, consistent with the framework set out in the Affordable Care Act, the proposed rule attempts to codify provisions that would allow States flexibility in identifying PPCs that include, at a minimum, the HACs identified by Medicare, but may also include other State-identified conditions. The flexibility would also extend to allowing States to apply nonpayment provisions to service settings beyond the inpatient hospital setting. Under the proposed rule, however, States are required to recognize Medicare's current list of HACs as the minimum Federal standard for the application of this policy.

As noted above, the proposed rule includes two categories of PPCs: HCACs and OPCCs. An HCAC is a condition identified as HAC under the Social Security Act relating to the prohibition of payments based on the presence of a secondary diagnosis code specified by the Secretary for purposes of the Medicare program, as well as other HACs identified in the State plan that the State determines meet the requirements of the Act. An OPCC is a condition occurring in any health care setting that meets 5 criteria: the condition (1) could have reasonably been prevented through the application of evidence-based guidelines, (2) has a negative consequence for the beneficiary, (3) is identified in the State plan, (4) is auditable, and (5) includes, at a minimum, wrong surgical or other invasive procedure performed on the patient; surgical or other invasive procedure performed on the wrong body part; or surgical or other invasive procedure performed on the wrong patient.

The proposed rule requires that State plans must provide that no medical assistance will be paid for PPCs (HCACs and OPCCs), and reductions in provider payment may be limited to the extent that (1) the identified PPC would otherwise result in an increase in payment, and (2) the State can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the PPC. Further, Federal financial participation will not be available for any State expenditure for PPCs.

The proposed rule also includes reporting provisions that would require provider reporting in instances where there is no associated bill. Thus, the rule proposes to include a requirement that existing claims systems be used as a platform for provider self-reporting, and State plans must require providers to identify PPCs that are associated with claims for Medicaid payment or with courses of treatment furnished to Medicaid patients for which Medicaid payment would otherwise be available.

The proposed rule would be effective as of July 1, 2011. Comments must be received no later than 5 p.m. on March 18, 2011.

—all of the above authored by Lynn M. Barrett

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JONES WALKER PRESENTS–
HEALTH CARE WEBINAR

Jones Walker will present "**Unnecessary Readmissions—Legal Implications & Prevention Measures**," a health care webinar **April 5, 2011**, from Noon-1:00 p.m. EDT. Featured speakers Jones Walker attorney Myla R. Reizen and Joan Meadows, consultant to the Advisory Board Company, will cover the importance of unnecessary readmissions and will provide a number of best practices for adopting a principled approach to reducing avoidable rehospitalizations.

The webinar is targeted to attorneys, compliance officers, and hospital executives. It will cover the legal implications of unnecessary readmissions. The majority of the webinar will provide concrete measures to prevent certain readmissions.

HEALTH CARE SEMINAR

In addition, Jones Walker will present "**Health Care Legislation Update—Accountable Care Organizations, Medical Home, and Other Key Trends**" seminar **May 26, 2011**. The seminar will be held at the Westin Diplomat Resort and Spa in Hollywood, Florida, beginning at 8:30 a.m. EDT. Jones Walker attorneys David G. Radlauer, Rudolph R. Ramelli, Lynn M. Barrett, and Myla R. Reizen will be presenting. Other speakers include Fred Bayon of the Advisory Board Company and Tim Renjilian of FTI Consulting.

8:45 AM:
Introduction–*Myla R. Reizen*

9:00–9:30 AM:
Accountable Care Organizations, Value-Based Purchasing, Medical Home-What Does This all Mean?–*Lynn M. Barrett*

- This session will provide a high level overview of models under the care reform legislation. Certain legal and compliance risks areas will be identified.

9:30–10:15 AM:
Lessons Learned–*Advisory Board Company Member*

- This session will cover some lessons learned from providers throughout the country: What has worked? What has not worked?

10:15–10:45 AM:
Break

10:45–11:30 AM:
Current Trends–*Advisory Board Company Member*

- What are providers currently doing to respond to the new legislation? This session will provide an overview of the current health care landscape throughout the country.

11:30–12:00 PM:
Antitrust Implications–*David G. Radlauer*

- There are a host of antitrust issues raised as a result of the models proposed by the new legislation. This session will provide an overview of these antitrust landmines.

12:00–1:30 PM:
Lunch

1:30–2:00 PM:
Tax Implications–*Rudolph R. Ramelli*

- This session will provide insight into tax issues raised as a result of the new health care legislation.

2:00–2:45 PM:
Key Trends in Investigations–*Myla R. Reizen* and *Tim Renjilian*

- Health care initiatives, qui tam cases, and settlements continue to be happening throughout the country and Florida is no different. This session will examine some trends in Florida as compared to the rest of the country.

2:45–3:15 PM:
HIPAA Update–*Lynn M. Barrett*

- There have been some fairly significant HIPAA developments in recent months. This session will examine some recent case studies and provide a one year update.

For more information on either the seminar or the webinar, or to register for either of these programs, please contact Courtney Farley at 504.582.8121, or e-mail her directly by clicking here.

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