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MOON set to rise March 8, 2017

By Nina Adatia Marsden

Beginning March 8, 2017, Medicare-participating hospitals, including critical access hospitals, are required to provide the Medicare Outpatient Observation Notice (MOON) to all Medicare beneficiaries receiving observation services for more than 24 hours. This article highlights CMS' guidance on some of the more pressing questions related to the implementation of the MOON.

The Centers for Medicare and Medicaid Services (CMS) developed MOON as the means for hospitals to comply with the Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act). The NOTICE Act, effective on August 6, 2016, adds to the Medicare provider agreement the requirement that hospitals provide oral and written notification to individuals receiving observation services as outpatients for more than 24 hours, explaining the status of the individual as an outpatient, not an inpatient, and the implications of such status.

As enacted, the statute lacked detail regarding how hospitals were expected to comply with the requirement. Among other things, providers had questions about the intended recipients of the notice, the form of the notice, and when the notice was to be provided. Following enactment of the statute, CMS sought and responded to comments from the public regarding implementation of the federal requirement, and has now adopted new regulations, manual provisions, and the MOON, which together, provide guidance on many important questions.

In This Issue

The Shape of the MOON

The NOTICE Act states that the required notice must be provided in writing and orally, but defers to the Secretary to prescribe any specific required language or form for the written notice. Accordingly, CMS developed and adopted the MOON as the standardized notice that hospitals must use to comply with the statute.

The MOON and an associated set of instructions are available online at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html?redirect=/BNI/.

- The MOON contains specific language regarding notice of the patient's status and financial obligations, as well as blank fields for the provider to insert information specific to a given patient's circumstances, including patient identifying information, the reason(s) the patient is being seen as an outpatient, and additional information as the hospital deems appropriate.
- The MOON must be printed as a two-page document and cannot be altered by the hospital.

Who Gets the MOON

The NOTICE Act provides that notice must be provided to each individual who receives observation services as an outpatient for more than 24 hours. In the preamble to the MOON requirements, CMS explains that the

term "individual" refers to a person entitled to Medicare, whether or not the services are actually payable under Medicare. This includes beneficiaries who are enrolled in a Medicare Advantage plan or other Medicare health plan. The notice must also be provided when the primary payer is a commercial plan and the secondary payer is Medicare or Medicare Advantage.

CMS further clarified that the circumstances at the time of the patient's stay will determine whether notice is required. Specifically, CMS explained that when a patient is seen as an inpatient, but after discharge, CMS denies the claim because the inpatient admission was not medically reasonable and necessary, or when the hospital, through its utilization review process, determines that the inpatient admission was not necessary and bills the services to Medicare Part B, the NOTICE Act requirements would not apply because the status of the patient would remain inpatient.

The MOON's Orbit

The MOON must be provided no later than 36 hours after observation services are initiated, or sooner if the individual is transferred, discharged, or admitted as an inpatient. In the preamble, CMS expressly noted that nothing in the statute precludes hospitals from delivering the notice before an individual has received more than 24 hours of observation services, provided that the information in the notice is accurate. However, CMS also expressly discouraged hospitals from delivering the MOON at the initiation of outpatient observation services, since providing the notice early would defeat the purpose of the MOON and would likely overwhelm patients.

With regard to how to measure the patient's time in observation, CMS clarified that the start time for observation services is the "clock time" at which observation services are initiated, as documented in the patient record, and that the time would be measured as elapsed time, and not billed time. Observation time ends, according to CMS, when all medically necessary observation services are completed, or when the patient is discharged from the hospital or admitted as an inpatient.

Other Moons

CMS acknowledges that certain state laws may also require hospitals to provide notice to observation patients. However, CMS states that the MOON must be delivered to Medicare beneficiaries entitled to notice notwithstanding any similar notice that hospitals may have to deliver under state law or otherwise. For hospitals subject to state law or other requirements to provide specific notice to observation patients, CMS suggests that the hospitals use the free text field in the MOON to communicate any additional content, or attach the state-law required notice to the MOON.

The California Moon

California hospitals will have to balance the delivery of the MOON with the new outpatient observation notice required under state law. The state law, which went into effect January 1, 2017, requires an acute care hospital to provide written notice to all patients assigned to an observation unit, stating that they are receiving observation services. The notice must notify the patient that he or she is being seen on an outpatient basis and that this status may affect his or her health care coverage reimbursement and eligibility for post-hospitalization care and must be provided "as soon as practicable." Because the federal statute and the state statute apply to different patient populations and have different requirements for when the notice must be provided, California hospitals should carefully consider how they will identify patients who are due notice and when they will provide notice.

The California Department of Public Health is expected to provide specific guidance to hospitals on how to comply with the state law requirements in light of what the federal law now requires.

For more information, please contact Ms. Marsden in Los Angeles at 310.551.8153 or Steve Lipton in San Francisco at 415.875.8490.

Resources for this Article

42 U.S.C. § 1395cc(a)(1)(Y).
81 Fed. Reg. 24,945, 25,131-25,134 (Apr. 27, 2016)
81 Fed. Reg. 56,761, 57,037-57,052 (August 22, 2016)
42 U.S.C. § 489.20(y)
Medicare Claims Processing Manual, Pub 100-04, Chapter 30, § 400
California Health & Safety Code §1253.7.

The Price of Delahying HIPAA Compliance

By Paul T. Smith

The Office for Civil Rights of the Department of Health and Human Services announced a civil money penalty of $3.2 million against a Dallas hospital on February 1. (see https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/childrens). The penalty stems from the loss in 2010 of an iPad with

protected health information of 22 individuals, and the theft in 2013 of an unencrypted laptop with PHI of 2,462 individuals. OCR's press release on this penalty is entitled, "Lack of timely action risks security and costs money."

This case is unusual because OCR typically settles investigations before they reach the formal assessment of civil money penalties. Evidently, attempts at informal settlement failed in this case. The assessment provides insight into how OCR calculates penalties for HIPAA violations.

HIPAA has a scale of penalties for non-compliance, starting at $100 for each violation if the offender did not know and could not reasonably have known of the violation. The next tier is for failures due to "reasonable cause," but not willful neglect; the penalty at this tier starts at $1,000 for each violation (and runs as high as $50,000 per violation). The highest penalties are for violations due to willful neglect - these begin at $10,000 for each violation. Penalties are capped at $1,500,000 per year for identical violations.

OCR says that in 2007 and 2008 two consulting firms had conducted security reviews for the hospital, and had recommended encrypting laptops and other devices. OCR determined that the appropriate penalty tier was reasonable cause - the middle tier. It imposed the minimum penalty for this tier of $1,000 per violation, because the lack of encryption did not result in any known physical, financial or reputational harm to anyone, nor did it hinder anyone's ability to obtain health care.

HIPAA and Privacy Rule Violations Cited

OCR found that the hospital failed to comply with two requirements of the HIPAA security rule, and one of the privacy rule:

- It failed to implement encryption or an equivalent alternative measure until April 9, 2013
- It failed to implement appropriate device and media controls until it completed a full inventory of its information systems on November 9, 2012
- It impermissibly disclosed the PHI of 2,484 people.

For the security rule violations, OCR treated each day as a separate violation, beginning six years prior to the date of its notice of proposed penalties, and ending on the date the violation was remedied - $923,000 for the failure to implement encryption, and $772,000 for the failure to implement device and media controls.

The penalty for the impermissible disclosures was $1,522,000OCR treated the loss of each individual's data as a separate violation - $22,000 for the loss of the iPad, and $1,500,000 for the loss of the laptop (but for the annual cap, the fine here would have been $2,462,000).

This approach is evidently based on the HIPAA enforcement rule (45 CFR § 160.408), which allows OCR to determine the number of violations of a HIPAA provision based on the nature of the covered entity's or business associate's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, the rule says a separate violation occurs each day the covered entity or business associate is in violation of the provision.

Although OCR cites separate regulations, there is arguably some duplication in fining a hospital separately for failing to encrypt a laptop, and again for disclosing PHI when the laptop is stolen. Apparently, however, the hospital in this case did not fight the assessment.

In its press release on this penalty, OCR emphasizes that the lack of timely action risks security and costs money. It certainly does, if each day of non-compliance makes for a new violation.

Hooper, Lundy & Bookman provides a range of legal services relating to health information privacy, security and technology. For more information, please contact: In San Francisco, Paul Smith or Steve Phillips at 415.875.8500; in Los Angeles, Hope Levy-Biehl at 310.551.8140; in Washington, D.C., Bob Roth at 202.580.7701; or in Boston, Amy Joseph at 617.532.2702.

CALENDAR

February 1-3	**The American Health Lawyers Association: Physicians and Hospitals Law Institute Conference, Orlando, FL.** Charles Oppenheim presented "MACRA".
February 3	**The Bipartisan Policy Center: Future of Healthcare: Federal Budget and State Choices, Washington, DC** Keith Fontenot was a panel participant.
February 15	**American Bar Association Webinar: Healthcare Transaction Fundamentals: Strategies for a Successful Deal** Charles Oppenheim moderated the panel.

CALENDAR (continued)

Feb 15, March 1 **CHA Hospital Compliance Seminar, Sacramento, Costa Mesa**
HLB Attorneys are lead faculty for this program. Lloyd Bookman and Felicia Sze present ***OIG Work Plan and Compliance Hot Spots;*** Hope Levy-Biehl presents ***Health Information Private & Security;*** Katherine Dru presents ***Patient Safety Organizations - What Compliance Officers Need to Know;*** Nina Adatia Marsden presents ***Complying with New Observation Requirements.*** Lloyd Bookman also facilitates the ***Compliance Officer Panel Discussion.***

March 22 **The American Health Lawyers Association: Logistics of Obtaining and Maintaining Medicare Enrollment, Webinar** Stacie Neroni will be presenting in ***Part II: Hospitals and Other Facilities.***

March 26-29 **The Health Care Compliance Association: 21st Annual Compliance Institute, National Harbor, MD**
Charles Oppenheim co-presents ***Kickback and Stark Law Developments.***

March 29-31 **The American Health Lawyers Association: Institute on Medicare and Medicaid Payment Issues, Baltimore, MD** Robert Roth is chairing the conference for the fourth year and will also be presenting on the Medicare/Medicaid overpayment 60-day report and return statute. Felicia Sze presents in a session entitled ***Medicaid Litigation Update.*** Please let us know if you will be attending the conference, as HLB will be hosting a dinner on Wednesday, March 29. Contact Bob at rroth@health-law.com or Felicia Sze at fsze@health-law.com.

April 13-14 **The Health Care Financial Management Association Northern California Annual Spring Conference, Sacramento, CA** Charles Oppenheim and Felicia Sze present ***How to Prepare for the Future of Risk-Based Contracting.***

May 2, 10 **HLB Medical Staff Seminar, Oakland and Los Angeles, CA** Save the date for this comprehensive seminar focused on recent developments impacting hospital medical staffs. Registration information will be announced shortly. For additional information, contact Jennifer Hansen at jhansen@health-law.com.

June 16 **The Health Care Compliance Association: Orange County Regional Conference, Orange County, CA**
Charles Oppenheim and Ben Durie co-present ***Key Stark Law Developments: What Every Compliance Officer Needs to Know.***

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