BAIRD HOLM LLP
ATTORNEYS AT LAW

Health Law ADVISORY
Current legal insights for health care executives

April 30, 2008
Julie A. Knutson, Editor

CMS Releases Sample Interview and Document Request for HIPAA Security Onsite Investigations and Compliance Reviews

When word spread of the HIPAA security investigation conducted by the Department of Health and Human Services at Atlanta's Piedmont Hospital in March of last year, there was much speculation as to whether this signaled the beginning of a new approach to government enforcement of the HIPAA Security Rule. CMS clearly answered that mounting speculation with a resounding "yes" when it recently released the Sample Interview and Document Request for HIPAA Security Onsite Investigations and Compliance Reviews ("Sample Document").

The Sample Document was published by the Office of E-Health Standards and Services (OESS) within the Centers for Medicare and Medicaid Services (CMS), which has the enforcement authority regarding potential HIPAA Security Rule violations. While enforcement of the HIPAA Privacy Rule has been entirely complaint-driven thus far, CMS has indicated that it will use contracted services to assist with enforcement of the Security Rule through onsite investigations and onsite compliance reviews. CMS states that "[o]nsite investigations may be triggered by complaints alleging non-compliance, while onsite compliance reviews will typically arise from non-complaint related sources of information such as media reports or self-reported incidents. OESS will exercise its discretion to determine whether or not an onsite investigation or onsite compliance review is warranted on a case-by-case basis."

When CMS sites *media reports* as a potential source for triggering an onsite compliance investigation, every provider should be thinking - *we could be next*. So what should you do to prepare? The Sample Document provided by CMS is a great tool to begin your self-critical analysis now. Look at the list of personnel that CMS indicates could be interviewed. It includes senior administration (President, CEO, Director) all the way to the computer hardware specialists and anyone in between who has some defined responsibility for Security Rule compliance. Are those on this list familiar with HIPAA? In an interview, can they describe your organization's approach to HIPAA Security Rule compliance? Can they name the HIPAA Security Officer? Do they know where to find relevant policies and procedures and can they explain the

ALSO IN THIS ISSUE

Physicians and Patients May Now Seek a Prior Determination of Medical Necessity 2

Nebraska's CON Statute Amended 3

CMS Acts on TAG Recommendations for EMTALA 4

Use of Copyrighted Music in Health Care Facilities: Q and A on the Basics 7

Find back issues of our newsletters at: www.bairdholm.com/subpages/newsletters.aspx

basic concepts covered by such policies? Mock interviews with key personnel is recommended in order to be prepared for such interviews by CMS.

Examine the list of documents that may be requested for investigation or review. Do all of these potential documents exist in your organization? If you readily identify that many of the documents not exist, start with the "low-hanging fruit." Look for the areas that are most critical and present the biggest threat to the organization's overall security compliance and get those documents in place first. Then move through the rest of the list in order of greatest security risk to the organization. CMS points out that the Sample Document is not a comprehensive list of applicable investigation/review areas, but the list does highlight most key areas of vulnerability where comprehensive policies and procedures may not exist.

This tool is a great starting point for a self-assessment of your organization's Security Rule compliance and will provide a head start in preparation for a CMS onsite security compliance review.

Vickie J. Brady

Physicians and Patients May Now Seek a Prior Determination of Medical Necessity

Effective March 24, 2008, CMS implemented a process by which physicians and beneficiaries can receive coverage determinations regarding medical necessity for certain services prior to actually performing or receiving those services. Under current law, a physician is prohibited from billing or collecting from a beneficiary for services for which Medicare reimbursement is denied unless the physician had the beneficiary sign an advance beneficiary notice (ABN). Consequently, CMS feared that the ABN process caused beneficiaries to refrain from seeking necessary services due to the fear that they would be held financially responsible for the services rendered in the event that CMS denied their claim. Thus, CMS crafted this prior determination for medical necessity process to provide physicians and beneficiaries with more certainty than an ABN as to whether Medicare would pay for the services rendered as reasonable and medically necessary.

CMS crafted this prior determination... to provide physicians and beneficiaries with more certainty than an ABN...

Only an "eligible requester" may seek a prior determination of medical necessity. According to the rule, either a physician or a beneficiary can be an eligible requester. However, in order for a physician to seek a determination, he or she must first receive the consent of the beneficiary to do so on his or her behalf, and in order for a beneficiary to seek a determination he or she must have received an ABN from his or her physician.

The process does not apply to all physician services. CMS has set forth in its rule that it will publish a list of those physician services eligible to receive a prior determination. That list will include those "most expensive" physician services that are performed at least 50 times per year and plastic and dental surgeries that may be covered by Medicare which cost at least $1,000 on the physician fee schedule. CMS intends that these lists will be updated annually in the annual physician fee schedule.

Once a Medicare contractor receives a

request from an eligible requester, it has 45 days to issue a written determination. If there is a local or national coverage determination regarding any such service, the contractor can dispose of the request without any further determination by sending the coverage determination to the requester. A determination issued by the contractor is binding upon the contractor and CMS absent fraud or misrepresentation.

CMS has stated that it will publish procedures for seeking a prior determination of medical necessity in manual instructions. CMS recognized that this rule is not mandatory and does not prevent a physician and/or beneficiary from proceeding with the normal ABN process and submitting a claim after the service is rendered. Furthermore, a prior determination denial does not prevent a physician accepting assignment or a beneficiary from submitting the claim for reimbursement after the services are rendered.

Andrew D. Kloeckner

Ed. Note

CMS released a revised ABN (CMS-R-131) on March 3, 2008 which providers were authorized to use immediately. Beginning September 3, 2008, all providers, practitioners and suppliers paid under Part B and hospice providers and religious non-medical health care institutions paid exclusively under Part A, must use the revised ABN in place of the ABN-G (CMS-R-131-G) and ABN-L (CMS-R-131-L). Revised manual instructions will be published in Chapter 30 of the Claims Processing Manual (Pub. 100-04) within a few weeks and a Medicare Learning Network article will also be released at the same time. The revised ABN and instructions may be accessed at http://www.cms.hhs.gov/bni.

Nebraska's CON Statute Amended

A long-standing question arising from the language of Nebraska Revised Statutes 71-5829.03 has been resolved by the Unicameral's recent enactment of LB 765. The Bill was signed by the Governor on April 11, 2008 and will be effective July 18, 2008.

The question has been the correct base number to be used to calculate additional bed capacity under the so-called "10:10:2 rule." The rule, set out in Section 71-5829.03(2), ***used to*** state that a certificate of need was required for: "[a]n increase in the long-term care beds or rehabilitation beds of a health care facility by more than ten beds or more than ten percent of the total bed capacity, whichever is less, over a two-year period."

Regulatory definitions of "bed capacity" did not help to resolve the issue of whether the "total bed capacity" was that of the total facility or strictly of the long-term care or rehabilitation unit.

The revised statute makes it clear that the calculation is [based on] the total bed capacity of the... unit with the result that smaller units will have limited capability of adding beds.

The revised statute makes it clear that the total bed capacity for the calculation of additional long-term care beds is the bed capacity of the long-term care or rehabilitation unit with the result that smaller units will have limited capability of adding beds. For example, a 20 bed rehabilitation unit within a 200 bed hospital would be able to increase its rehabilitation beds by the lesser of ten beds or ten percent of the beds in its rehabilitation unit. In this case, 10% (2 beds) is the lower number, and would be the most beds that could be added to the rehabilitation unit within a two-year period.

The initial establishment of long-term

care beds or rehabilitation beds through conversion of any type of acute hospital beds continues to be based on the total bed capacity ***of the hospital*** converting the beds.

The Bill also addresses the moratorium on rehabilitation beds which prohibits a certificate of need to be granted for additional rehabilitation beds unless all rehabilitation beds in Nebraska have exceeded ninety percent occupancy during the most recent three calendar quarters. An alternative was added that permits a certificate of need to be granted for up to three additional rehabilitation beds if occupancy for the most recent three calendar quarters is eighty percent.

Julie A. Knutson

CMS Acts on TAG Recommendations for EMTALA

In 2003, Congress established a Technical Advisory Group (TAG) to advise the Secretary of HHS on issues relating to EMTALA. The TAG included the CMS Administrator, the Inspector General, and hospital, physician and enforcement agency representatives, meeting seven times to receive testimony from the interested public. Its thirty-month term ended in September, 2007, culminating in a final report with 55 recommendations.

Some of the recommendations require regulatory change; others are simply a matter of agency interpretation. On April 15, 2008, CMS published proposed regulations changing IPPS for FY 2009, some of which respond to the TAG. In the preamble, CMS reports that it had already acted upon five of the 55 recommendations, which are summarized at the end of this article. Two additional recommendations are addressed in the proposed rule for IPPS FY 2009:

1. The 2003 EMTALA regulations specifically excluded inpatients from the protection of EMTALA. Those regulations did not address whether receiving hospitals were obligated to accept transfer of unstable inpatients requiring "specialized care." CMS has proposed regulations to clarify that inpatients who remained unstable since their admission to inpatient care continue to enjoy the protection of EMTALA for purposes of transfer for specialized care. Under the proposed regulation, a receiving hospital with specialized capabilities (and capacity) is required to accept transfer of an inpatient requiring those capabilities who has remained unstable since admission to inpatient care.

In the preamble, CMS acknowledges the concern of receiving hospitals that this obligation will encourage patient dumping on hospitals with specialized capabilities. CMS notes that this proposed clarification is not intended to encourage transfers, and expressly states that the admitting/transferring hospital should ensure that it provides needed treatment within its capabilities prior to transferring the individual. Unfortunately, the CMS preamble makes the additional statement: "This means that an individual with an unstabilized emergency medical condition should be transferred only when the capabilities of the admitting hospital have been exceeded." This statement is unfortunate because it ignores a number of variables in the EMTALA equation: the patient's right to request transfer, and the receiving hospital's discretion to accept a lateral transfer.

Discussion of lateral transfers has been highly charged due to an overstatement in the CMS Interpretive Guidelines which has been corrected in an Advance Copy

Discussion of lateral transfers has been highly charged due to an overstatement in the CMS Interpretive Guidelines which has been corrected...

published by CMS on March 21, 2008. The new Advance Copy of the Interpretive Guidelines results in the following revisions: "Lateral transfers, that is, transfers between facilities of comparable resources, are not ~~sanctioned~~ mandated by §489.24 because ~~they would not offer enhanced care benefits to the patient~~ the benefits of such transfer [sic] would not be likely to outweigh the risks, except where ~~there is~~ the sending hospital has a serious capacity problem, a mechanical failure of equipment, ~~no ICU beds available,~~ or similar situations. ~~However, if the sending hospital has the capability but lacks the capacity, then the individual would most likely benefit from the transfer.~~" The new language more accurately reflects a prior preamble, which stated that receiving hospitals were not required to accept lateral transfers, and removes the proscriptive implication that has led to inappropriate and over- reporting of transfer violations based solely on the fact that they were lateral transfers.

This clarification that lateral transfers are not *per se* violations of EMTALA is critical for hospitals to laterally transfer stabilized patients to hospitals where the patients may be entitled to health care services at reduced costs (e.g., Iowa Cares and Indian Health Service). The very existence of federal and state funding for qualified beneficiaries at limited facilities signals governmental intent that patients will be transferred in order to enjoy those benefits. If the receiving facilities and/or the enforcement agencies have an unfounded bias against lateral transfers, it will be dangerous for transferring hospitals to assist their patients to avail themselves of those benefits by transfer. Recent enforcement activity suggests that all lateral transfers will be peer reviewed to determine whether the patient was stable at the time of transfer. Ironically, in the event of stabilization, the receiving facility is not compelled by EMTALA to accept the transfer. However, the facility-specific governmental funding sources (Iowa Cares and the Indian Health Service) imply a governmental expectation that such transfers will be accepted.

Despite the desire of CMS to limit unnecessary transfers (which may add unnecessary ambulance cost under the Medicare program), the EMTALA regulations expressly state that, when an individual has been determined to be in an emergency medical condition, the hospital has two alternatives, providing either:

a. "Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition." or

b. "For transfer of the individual to another medical facility in accordance with paragraph (e) of this section."

42 C.F.R. § 489.24(d). Paragraph (e) sets forth requirements for "transfer" and "appropriate transfer" including, most importantly to this discussion of lateral transfers, physician certification that the medical benefits outweigh the risks, the receiving facility accepts transfer, and the transferring facility provides medical treatment within its capacity to minimize the risks to the individual's health. If the services needed by a patient are available at the transferring hospital, it is difficult to construct an argument that the medical benefits of transfer outweigh the risks, unless one looks at overall and longer term health implications of burdensome, unpaid health care bills as opposed to full payment under the government programs as a result of transfer. For that reason, the transferring hospitals should make every effort to stabilize such patients prior to seeking a lateral transfer, and to fully document the health care professionals' observations demonstrating the patient's stability.

... the transferring hospitals should make every effort to stabilize such patients prior to seeking a lateral transfer...

2. The second area of TAG recommendations addressed by the

FY 2009 IPPS proposed regulations relates to on-call obligations. First, CMS proposes to move the regulation requiring hospitals to maintain an on-call list from §489.24(j)(1) (the "meat" of the EMTALA regulations) to §489.20(r)(2) (requirements under the provider agreement). The stated reason for this regulatory change is to for consistency with the statutory basis for on-call lists. However, the principal significance of this move is to remove the on-call obligation from among the violations subject to civil monetary penalties.

In addition, the TAG has recommended that hospitals be permitted to participate in "shared or community call," if the hospitals have formal agreements recognized in their policies and procedures, as well as backup plans; such arrangements should not remove the hospital's obligation to perform a medical screening examination (MSE). In response, CMS has proposed regulations allowing formal community call plans which meet the following standards:

a. The plan includes a clear delineation of the on-call coverage responsibilities; when each hospital is responsible for coverage.

b. The plan defines the specific geographic area subject to the plan.

c. The plan is signed by a representative of each participating hospital.

d. The plan ensures that any local and regional EMS system protocols formally include information on the community call plan.

e. Participating hospitals engage in an analysis of the specialty on-call needs of the community for which the plan is effective.

f. The plan includes a statement that even if an individual arrives at the hospital that is not designated as the on-call hospital, that hospital still has an EMTALA obligation to provide a MSE and stabilizing treatment within its capacity, and participating hospitals must abide by the EMTALA regulations governing appropriate transfers.

g. There is an annual reassessment of the plan by the participating hospitals.

A final EMTALA change appearing in the FY 2009 IPPS proposed regulations is a technical correction, adding language which was inadvertently omitted from the FY 2008 IPPS final rule, relating to the Pandemic and All-Hazards Preparedness Act, relieving hospitals from EMTALA sanctions for a 72-hour period for inappropriate transfers during a national emergency or relocations pursuant to a State emergency preparedness plan.

... the TAG has recommended that hospitals be permitted to participate in "shared or community call," if [they] have formal agreements...

The five TAG recommendations previously acted upon by CMS include:

1. Definition of "Labor" was revised to permit nurse-midwives and other qualified medical personnel working within the scope of licensure to certify that a woman is experiencing false labor. The prior regulations allowed such certification only by physicians. This recommendation was acted upon initially in 2006 by a survey and certification letter, and later by amendment adopted in the FY 2007 IPPS final rule.

2. Participating hospitals with specialized capabilities are bound to accept transfer of unstable patients requiring those capabilities if they have the capacity to treat them. This requirement applies even to hospitals with no dedicated emergency department, as a result of regulatory amendment adopted in the FY 2007 IPPS final rule.

3. CMS has clarified a pre-existing letter of guidance concerning a hospital's obligation to receive patients transferred by ambulance. The agency addresses the practice of delaying acceptance of

transfer by "parking" the ambulance stretcher until an ED bed is available. A survey and certification letter describes the hospital's obligation to promptly triage such patients to prioritize their screening among individuals who may already be waiting for screening.

4. A survey and certification letter clarifies CMS's position that a hospital cannot refuse to accept an appropriate transfer on the grounds that it (the receiving hospital) does not approve the method of transfer arranged by the attending physician).

5. The CMS Interpretive Guidelines have been revised to eliminate discussion of telehealth/telemedicine, and to clarify instead that the treating physician has the authority to decide whether an on-call physician should come to the emergency department, and that the treating physician may use a variety of methods of communication (e.g., consultation) with the on-call physician. A potential violation occurs only if the treating physician asks the on-call physician to come to the ED and the on-call physician refuses.

Barbara E. Person

Use of Copyrighted Music in Health Care Facilities: Q and A on the Basics

Most hospitals and health care facilities make use of radios and/or televisions in areas throughout their facilities, such as patient rooms, cafeterias and waiting rooms. But many of these facilities do so without having the appropriate license agreements in place – agreements which may be necessary to avoid claims of copyright infringement. In order to help explain when a license agreement may be appropriate for your facility, we've answered the following commonly asked questions about performing rights in music:

... generally, no one may publicly perform copyrighted works without the permission of the copyright owner...

Q: Why does a health care facility need a license to play music?

A: The Constitution authorizes Congress "to Promote the Progress of Science and Useful Arts" by granting exclusive rights to authors, which insures that people can earn a living from their works and creations and provides incentive for the creation of more works. Federal copyright law establishes property rights in musical works and grants creators and owners of copyrighted musical works specific rights, including the exclusive right to perform or authorize the performance of their works publicly. This means that, generally, no one may publicly perform copyrighted works without the permission of the copyright owner and the owner has the right to be paid for the use of his property.

Q: What is a public performance?

A: Copyright law defines a public performance as one "in a place open to the public or at any place where a substantial number of persons outside of a normal circle of a family and its social acquaintances is gathered." The law requires users to obtain authorization not only for performances by live musicians, but also for performances by mechanical means, including videotapes, CDs, MP3 players, tapes, music-on-hold, karaoke, juke boxes, radio and TV reception and personal computers. Think about where your facility uses music – in music therapy classes, in lobbies and elevators, in patient rooms, or even on your telephone on-hold system. Each of these uses constitutes a public performance.

Q: How does my facility obtain permission to perform music?

A: There are three licensing organizations – American Society of composers, Authors, and Publishers (ASCAP), Broadcast Music, Inc. (BMI), and SESAC –that license the right to perform each organization's members' musical works. Each organization is made up of composers, songwriters, music publishers and recording artists and act on behalf of their members to license the rights to the public performance of their works. If appropriate, your facility will need to enter into license agreements with one or all of these organizations.

Q: What will a license cover?

A: Each of the three licensing organizations offers a blanket facility license, which covers nondramatic performances by live musicians and/or recorded performances (videotapes, CDs, MP3 players, tapes, music-on-hold, karaoke, juke boxes, radio and TV reception and personal computers). A blanket facility license will typically cover:

- Music therapy
- Music in aerobics, physical therapy and weight loss classes
- Music in patients' rooms, elevators and common areas, including over loudspeakers and on TVs and radios
- Music in birthing rooms and Lamaze classes
- Music in restaurants and gift shops

Q: How is the license fee determined?

A: Generally, the licensing organizations determine the fee based on the size of the facility (there may be additional licensing fees for separate clinics and offices affiliated with a hospital). Facilities of a similar size will pay a similar fee.

Q: Our facility pays for cable. Shouldn't this cover the use of music in TV programs?

A: TV, cable, and radio stations enter into license agreements with the licensing organizations. However, these agreements do not cover the re-broadcast of such TV, cable, and radio to the public. Public performances of radio and TV are specifically addressed in Title 17, Section 110 (5) of the U.S. copyright law, which states that any establishment, other than a food service or drinking establishment, that is 2000 square feet or larger must secure public performance rights for TVs or radios if the following conditions apply:

For TV, if the facility is using:

1. More than four TVs;
2. More than one TV in any one room; or
3. If any of the TVs used have a diagonal screen size greater than 55 inches.

For radio, if the facility is using:

1. More than six loudspeakers; or
2. More than four loudspeakers in any one room.

Most of your facilities will likely fall into

Think about where your facility uses music – in music therapy classes, in lobbies and elevators, in patient rooms, or even on your telephone on-hold system. Each of these uses constitutes a public performance.

one or both of these categories.

Q: Is a license required for music on-hold?

A: Yes. Transmission of music to the public is considered to be a "public performance." Agreements between a licensing organization and radio stations specifically exclude any further performances of the stations' broadcasts – so no radio station should represent to your facility that its agreement authorizes retransmission of the station's broadcasts by means of a music-on-hold telephone system. However, license agreement with background music services (e.g., Muzak, Music Choice) include coverage for music-on-hold. So, if your use of music-on-hold is provided by one of these (or a similar) service, no separate license is required.

Q: What happens if I use music without permission?

A: If your facility uses an artist's copyrighted music without permission, the facility can be assessed damages for infringement. These damages run from a minimum of $750 to a maximum of $30,000 for each song infringed.

Grayson J. Derrick
Technology & Intellectual Property Practice Group

Questions? Ideas?

We welcome your questions, ideas and suggestions.

E-mail jknutson@bairdholm.com and help make the Advisory interactive!

BAIRD HOLM LLP
ATTORNEYS AT LAW

HEALTH CARE GROUP

Vickie J. Brady
402.636.8230
vbrady@bairdholm.com

Alex (Kelly) M. Clarke
402.636.8204
kclarke@bairdholm.com

John R. Holdenried
402.636.8201
jholdenried@bairdholm.com

Andrew D. Kloeckner
40.636.8222
akloeckner@bairdholm.com

Julie A. Knutson
40.636.8327
jknutson@bairdholm.com

Barbara E. Person
402.636.8224
bperson@bairdholm.com

All attorneys are admitted to practice in Nebraska and Iowa.

MEMBER
LEX MUNDI
THE WORLD'S LEADING ASSOCIATION OF INDEPENDENT LAW FIRMS

Health Law Advisory is intended for distribution to our clients and to others who have asked to be on our distribution list. If you wish to be removed from the distribution list, please notify healthupdate@bairdholm.com.

BAIRD HOLM LLP
1500 Woodmen Tower
Omaha, NE 68102
402.344.0500
402.344.0588
www.bairdholm.com

©2008 Baird Holm LLP

*The contents of this advisory are intended for general informational purposes only and should not be construed as legal advice. Readers are urged not to act upon the information contained in this publication without first consulting an attorney.