

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

The "Spring Cleaning" Edition: A Round-Up of Smaller But Noteworthy CMS Issuances

May 28, 2008

In addition to recent major regulatory releases by the Centers for Medicare & Medicaid Services ("CMS") regarding proposed and final updates to various prospective payments systems,¹ CMS has posted a number of smaller releases that, while perhaps not attracting as many headlines as the other releases, are nonetheless worthy of note. Specifically, CMS has issued updated guidance regarding (a) the Emergency Medical Treatment and Active Labor Act ("EMTALA"), (b) the revised CMS-855 Medicare enrollment applications, and (c) CMS-855 enrollment applications submitted via the Internet. This "spring cleaning" edition of our Health Law Update summarizes these recent releases.

EMTALA Guidance

State Operations Manual Changes

On March 21, 2008, CMS released an advance copy of the revised State Operations Manual Appendix V, EMTALA Interpretive Guidelines (the "EMTALA Appendix").² The final version is expected to be released later this year and may differ somewhat from the advance copy. The revisions update the EMTALA Appendix to incorporate all guidance previously provided in Survey and Certification memoranda issued from April 22, 2005 to December 7, 2007. Likewise, CMS has revised certain regulatory citations in the EMTALA Appendix to conform to the current regulatory text. For example, the EMTALA Appendix now reflects the amended definition of "labor" found at 42 CFR § 489.24(b). Additionally, the revised EMTALA Appendix now reflects the current

¹ For the inpatient prospective payment system, see 73 Fed. Reg. 23528 (April 30, 2008), for the skilled nursing facility prospective payment system, see 73 Fed. Reg. 25918 (May 7, 2008), and for the long-term acute care hospital system, see 73 Fed. Reg. 26787 (May 9, 2008).

² Survey & Certification Group, Ref: S&C-08-15, "Hospitals – Revised State Operations Manual Appendix V – EMTALA," available at <http://www.cms.hhs.gov/surveycertificationgeninfo/downloads/SCLetter08-15.pdf> (March 21, 2008).

statutory and regulatory provisions concerning waiver of EMTALA requirements during a national emergency.³

CMS has also updated the Tag numbers in the EMTALA Appendix to reflect those presently used in surveys and has provided separate Tag numbers for Hospitals and Critical Access Hospitals (Tag numbers for Hospitals begin with an "A" prefix and Tag numbers for Critical Access Hospitals begin with a "C" prefix).

Potential Future EMTALA Regulatory Changes

In the proposed changes to the inpatient prospective payment system ("IPPS") for 2009 published in the Federal Register on April 30, 2008, CMS has proposed regulatory changes affecting patient transfers under EMTALA.⁴ Specifically, CMS has proposed to amend 42 CFR § 489.24(f) to state that when an individual covered by EMTALA is admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual.⁵ In other words, although the admitting hospital's EMTALA responsibilities are fulfilled by admitting an individual as an inpatient,⁶ the EMTALA obligations of other hospitals with specialized capabilities that may later properly receive the individual with an emergency medical condition must still be fulfilled.

CMS has also proposed clarifications to the EMTALA physician on-call requirements by relocating certain regulatory provisions and by addressing shared/community call obligations. CMS is proposing to delete the provision in Section 489.24(j)(1) that requires hospitals to maintain a list of on-call physicians because this concept is already included in the regulations as a hospital provider agreement requirement in Section 489.20(r)(2). In order to make the provider agreement regulations more consistent with the EMTALA statute,⁷ the language being deleted from Section 489.24(j)(1) will, if the proposal is finalized as written, become replacement language for the existing Section 489.20(r)(2).⁸

Additionally, CMS has proposed to allow hospitals to participate in shared/community call, a welcome change given the difficulties faced by many hospitals in obtaining call coverage in all specialties. Section 489.24(j) would be amended to provide that hospitals may comply with the on-call list requirement specified at the proposed Section 489.20(r)(2) by participating in a formal community call plan that meets the minimum elements proposed by CMS. CMS has further proposed to revise the regulations to state that, notwithstanding participation in a community call plan, hospitals are still required to perform medical screening examinations on individuals who present seeking treatment and to provide for an appropriate transfer when suitable.

³ For a complete list of the advance copy EMTALA updates, see *id.*

⁴ 73 Fed. Reg. 23669-23672.

⁵ The transfer of the individual must otherwise be an appropriate transfer and the participating hospital with specialized capabilities must otherwise have the capacity to treat the individual.

⁶ CMS notes that once a hospital has admitted an individual as an inpatient, the individual is protected under Medicare Conditions of Participation and may have additional protections under State law. *Id.* at 23670.

⁷ See 42 USC §§ 1395cc, 1395dd.

⁸ The proposed revised Section 489.20(r)(2) language would read as follows: "An on-call list of physicians on its medical staff available to provide treatment necessary after the initial examination to stabilize individuals with emergency medical conditions who are receiving services required under § 489.24 in accordance with the resources available to the hospital; and".

The minimum elements of a formal community call plan are as follows:

- Include a clear delineation of each hospital's on-call coverage responsibilities;
- Define the specific geographic area to which the plan applies;
- Be signed by an appropriate representative of each hospital participating in the plan;
- Ensure that any local and regional EMS system protocol formally includes information on community on-call arrangements;
- Participating hospitals would engage in an analysis of the specialty on-call needs of the community for which the plan is effective;
- Include a statement specifying 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 medical screening examination and stabilizing treatment within its capability, and participating hospitals must abide by the EMTALA regulations governing appropriate transfers;
- Annual reassessment of the community call plan by the participating hospitals.

In addition, CMS has proposed a technical change to the EMTALA regulations to address an area where language was inadvertently omitted in prior changes.⁹ CMS is proposing to revise the language at Section 489.24(a)(2) to conform to changes made to that section in the FY 2008 IPPS final rule¹⁰ regarding the nonapplicability of the EMTALA provisions in an emergency area during an emergency period.¹¹

Revised CMS-855 Medicare Enrollment Applications

CMS revised the CMS-855 Medicare enrollment applications in March 2008.¹² Medicare contractors will accept the 2006 version of the Medicare enrollment application through June 2008; however, this allowance does not apply to providers enrolling as a specialty hospital on the CMS-855A. In addition, CMS recommended that providers and suppliers begin to use the new Medicare enrollment applications immediately. The following paragraphs summarize the significant revisions to the Medicare enrollment applications.

⁹ 73 Fed. Reg. 23672-23673.

¹⁰ 72 Fed. Reg. 47413 (August 22, 2007).

¹¹ The proposed Section 489.24(a)(2) would read as follows: "*Nonapplicability of provisions of this section.* Sanctions under this section for an inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location pursuant to an appropriate State emergency preparedness plan or, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan do not apply to a hospital with a dedicated emergency department located in an emergency area during an emergency period, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided for by section 1135(e)(1)(B) of the Act."

¹² MLN Matters, No. SE0810, "Announcing the Release of the Revised CMS-855 Medicare Enrollment Applications," available at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0810.pdf>. Electronic copies of the applications are available at <http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp>.

CMS-855A: Changes for Institutional Providers. CMS:

- Revises Section 2A2 to include a specific box that specialty hospitals must check when completing the application. Instructions explaining the definition of a "specialty hospital" are also added to the form.
- Clarifies the term "primary practice location" in the instructions in Section 4.
- Inserts additional information about the National Provider Identifier ("NPI") – legacy association and expands the number of NPI – legacy combinations that a provider may enter in Section 4A from one (1) to five (5).
- Removes the data element "Medicare Year-End Cost Report Date" from Section 2.
- Removes the requirement in Section 17 that providers attach their NPI notification that is received from the National Plan and Provider Enumeration System ("NPPES").

CMS-855B: Changes for Clinics/Group Practices and Certain Other Suppliers. CMS:

- Removes the supplier type "Voluntary Health/Charitable Agency" from Section 2A.
- Clarifies reporting timeframes throughout the CMS-855B.
- Inserts additional information about the NPI – legacy association and expands the number of NPI – legacy combinations that a provider may enter in Section 4A from one (1) to five (5).
- Removes the requirement in Section 17 that providers attach their NPI notification that is received from the NPPES.
- Requires that an Independent Diagnostic Testing Facility ("IDTF") submit copies of its comprehensive liability insurance policy in Section 17.
- Adds a list of the new IDTF standards found in 42 CFR § 410.33(g) on a separate page in Attachment 2.
- Adds instructions that explain the IDTF liability insurance requirements in 42 CFR § 410.33(g)(6) to Attachment 2.

CMS-855I: Changes for Physicians and Non-Physician Practitioners. CMS:

- Removes the requirement in Section 17 that providers attach their NPI notification that is received from the NPPES.

CMS-855S: Changes for DMEPOS Suppliers. CMS:

- Adds supplier standards 22 – 25 to the list of DMEPOS supplier standards found on page 31.

Medicare Enrollment Applications Via the Internet

As discussed in a previous Health Law Update,¹³ CMS will soon offer the Provider Enrollment, Chain and Ownership System ("PECOS") and the Provider Statistical and Reimbursement Report System online. The new online access will allow Medicare fee-for-service providers and suppliers to access, update and submit Medicare enrollment applications via the Internet.

On April 4, 2008, CMS published instructions (the "Instructions") for its contractors on the proper handling and processing of CMS-855 enrollment applications submitted online ("PECOS Internet").¹⁴ CMS issued the change request to ensure that contractors process PECOS Internet applications in a consistent and accurate manner. Unless otherwise noted, the Instructions apply only to the PECOS Internet applications and have no applicability to the CMS-855 paper applications. The Instructions refer to business requirements and are summarized below.

Under the Instructions, if a provider fails to submit a signed and dated certification statement to the Medicare contractor within 15 calendar days of the date on which the provider submitted its PECOS Internet application to the contractor, the contractor may, but is not required to, reject the application. Further guidance regarding the 15-day rule and factors to take into account regarding untimely certifications are provided in the Instructions. In particular, the contractor can take into account the following factors: (a) the degree of the provider's cooperation, (b) the time it took for the certification statement to be transferred from the contractor's main mailroom to the provider enrollment department, and (c) the number of days by which the provider missed the 15-day deadline.

In addition, if the contractor determines that additional or clarifying information is needed, the contractor must switch the logging and tracking ("L & T") status to "Returned for Corrections" and send an email (via PECOS Internet) to the provider requesting the additional information and listing the date(s) by which the information and certification statement must be submitted to the contractor. Contractors have certain discretion regarding follow-up after the initial email is sent. Similar to follow-up on paper-based applications after a request for clarifying information, if the requested information for a PECOS Internet application is not received within 60 days from the date the contractor sent the email, then the contractor must follow the procedures found in Section 3.1 of Chapter 10 of the Medicare Program Integrity Manual ("Manual").¹⁵ This section of the Manual addresses pre-screening and application returns. In particular, providers must furnish all missing material within the 60-day period, and if the provider fails to do so, the contractor must reject the application. The determination of whether applicant did provide all requested information within the applicable timeframe is in the discretion of the contractor.

Once the contractor has received all requested information and ties the L & T record to the enrollment record, the contractor cannot undo any transfer of information into PECOS and the application can no longer be returned to the provider for corrections. However, the contractor can

¹³ Health Law Update, "Brave New E-World: Accessing, Updating, and Submitting Medicare Provider Information Online," available at <http://www.bassberry.com/communicationscenter/newsletters/?ServicesNewsletters=19ebe3cf-c07f-4312-ad52-c60785f30f3c> (March 27, 2008), which addresses the information CMS has supplied to providers and suppliers about the online application process and pre-enrollment procedures.

¹⁴ CMS Manual System, Pub 100-08 Medicare Program Integrity, Transmittal 250, Change Request: 5954, "Instructions on the Processing of CMS-855 Enrollment Applications Submitted Via the Web," available at <http://www.cms.hhs.gov/transmittals/downloads/R250PI.pdf> (April 4, 2008).

¹⁵ The Manual is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>.

delete an erroneously created L & T record by moving the L & T record to a "Rejected" status and using the L & T status reason of "Deleted." Finally, in situations in which Chapter 10 of the Manual would otherwise require the contractor to submit a copy of the provider's paper CMS-855 to the State agency, the contractor must instead send a copy of the Application Data Report resulting from the provider's submission of its application via PECOS Internet.

Conclusion

It has been a busy year so far for CMS with both major regulatory releases and smaller, more conforming regulatory changes. If you have any questions on the topics covered in this Health Law Update, please contact any of the attorneys in our Healthcare Industry Practice Area listed below.

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