Health Law Advisory

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CMS Provides Guidance on Enrollment and Certification During Mergers and Acquisitions

On September 6, 2013, CMS issued a survey and certification letter to state survey agency directors that provides guidance on the automatic assignment of Medicare provider agreements in health care transactions including mergers and acquisitions. Providers and suppliers who engage in these transactions should be familiar with the guidance, as the decision of whether to assume another party's Medicare provider agreement could have real impact on post-closing cash flows.

One of the many decisions providers and suppliers must make early on in a health care transaction is whether they, as the acquiring party, should take assignment of the other party's Medicare provider agreement. Under current regulations, Medicare provider agreements are automatically assigned unless they are rejected by the acquiring party. In cases where the acquiring party takes assignment, the new owner enjoys uninterrupted participation in the Medicare program (no survey is required), albeit with a potential cash flow delay.

When an acquiring party chooses to structure a transaction as an asset acquisition with the express purpose of being able to *avoid* the assumption of the other party's outstanding liabilities, many times the acquiring party rejects the assumption of the target's Medicare provider agreement. This usually happens because of potential overpayment and other compliance-related liabilities (e.g. Stark, anti-kickback, fraud and abuse) that are unknown to the parties at the time of the deal, difficult to discover, and, if they exist, are of a size that would otherwise undermine the deal.

The CMS guidance letter is an important positional statement that should be taken into account when acquiring an enrolled Medicare provider or supplier. In the guidance, CMS

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Save the Date!

The 25th Annual Baird Holm Health Law Forum will be held Friday, November 22, 2013 at the Marriott Regency in Omaha. This year's agenda will cover the ongoing implementation of the Affordable Care Act and a variety of other developments affecting health care organizations. Please watch your e-mail for registration details. ■

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reminds state survey agencies that if a new owner *rejects* assignment of a Medicare provider agreement, the acquired provider or supplier must be treated as an *initial applicant* if it seeks to participate in Medicare post-closing. Initial applicants must undergo a full site certification prior to enrollment in the Medicare program. CMS reminds state survey agencies that these initial survey visits must be unannounced. CMS will be suspect of situations where assignment of the Medicare provider agreement is rejected and the state agency performs a site visit and initial survey at the time of or shortly after the transaction closes. In CMS' opinion, such timing raises doubt as to whether the initial survey was truly unannounced.

Accordingly, CMS issued the following reminders to state survey agencies as to the appropriate timing of surveys when assignment of the Medicare provider agreement has been rejected:

- The survey must not occur until after the deal closes.
- The survey may not occur until the Medicare Administrative Contractor (MAC) has recommended approval of the 855.
- The new provider must be fully operational.
- The provider or supplier should not know the date or approximate date of the survey. "[A]ny survey that takes place, for example, within fourteen days after the effective date of an acquisition that involves rejection of assignment of the provider agreement warrants closer review by the RO of the circumstances of the case and the timing of the survey."
- Initial surveys are of the lowest priority to state agencies. State agencies should be able to demonstrate that they are able to address all higher priority workload prior to performing initial surveys. If a state agency performs an initial survey on a provider that rejected assignment of the provider agreement while having outstanding higher priority workload, it raises doubt as to whether the survey was truly unannounced.

One of the keys to any transaction is minimizing the potential Medicare cash flow delay or loss post-closing. When a Medicare provider agreement is not assumed, CMS reminds us that "[t]he effective date [of the new provider agreement] is *not* the date of the acquisition of the provider or supplier. Rather, the effective date of the Medicare agreement is the date when the *last* applicable Federal requirement has been met, and not earlier." Thus, when a provider agreement is rejected, there will certainly be Medicare cash flow loss due to the gap in time between closing and the new survey, presuming that no deficiencies are identified in that survey. The effective date of the new provider agreement will not relate back to the date of closing.

To mitigate this risk, parties to a transaction where the provider agreement will be rejected should try to work with the state survey agency to arrange for a survey as soon after closing as possible. However, CMS' letter likely means that state survey agencies will be more difficult to work with in planning a transaction, as the guidance says that survey agencies are not allowed to schedule initial survey visits on an announced basis and that surveys that closely coincide with transaction closing dates will be treated as suspect.

As providers explore transactions and determine whether to assume or reject another party's Medicare provider agreement, the timing of potential surveys and the likelihood of lost Medicare cash flows should be taken into account. If the provider assumes the target's Medicare provider agreement in order to avoid lost Medicare cash flows, greater time and resources must be committed to the due diligence process to root out and discover potential liabilities or other pertinent issues and should be taken seriously. Furthermore, if assuming a provider agreement, transactional documents should contain protections, indemnifications and/or claw-back provisions to provide the acquiring party further protections against unknown liabilities that may arise in the future under the Medicare provider agreement due to pre-closing transgressions. ■

Andrew D. Kloeckner

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Reminder of New DME Face-to-Face Requirements

The Centers for Medicare and Medicaid Services ("CMS") recently announced that enforcement of the face-to-face requirement for providers ordering durable medical equipment ("DME") will be postponed until 2014. While implementation of the rules has been delayed, providers and suppliers should be familiar with the requirements. The following set of questions and answers provides a good refresher of the scope and implications of the new rules.

What does the law require?

Section 6407 of the Patient Protection and Affordable Care Act requires a physician, physician assistant, nurse practitioner, or clinical nurse specialist to have an in-person or telemedicine meeting with a patient during the six-month period prior to prescribing certain types of DME (listed below). The meeting must be documented in the patient's medical record and signed/co-signed by a physician.

What types of DME are affected?

Examples of DME covered by the new face-to-face requirements include, but are not limited to: hospital beds and accessories, oxygen, nebulizer compressors, CPAP/BiPAP, seat lift mechanisms, and manual wheelchairs. The rule does not apply to power mobility devices ("PMDs") and does not supersede other regulations specific to PMDs.

What must the DME order include?

At a minimum, the written DME order must: include the beneficiary's name, the item of DME ordered, the prescribing practitioner's NPI, the signature of the prescribing practitioner, and the date of the order. The order for DME cannot be completed before the face-to-face encounter.

What documentation of the face-to-face encounter is required?

In order to receive payment after the face-to-face encounter occurs, all of the following items must be documented in the patient's medical record: evaluation of the patient, a needs assessment, treatment plan, and relevant diagnosis. The record must clearly establish that the patient was evaluated and/or treated for a condition that supports the item(s) of DME ordered. If a non-physician practitioner conducts the face-to-face examination, a physician must sign or co-sign the patient's medical record documenting that the encounter occurred.

What are the supplier notification requirements?

Following the encounter, when an order is sent to the DME supplier, the ordering physician must also provide the DME supplier with the medical record and any other supporting documentation. This is required because the DME supplier that submits the claims for the DME items must make this documentation available to CMS upon request.

There is no particular method required for transmitting documentation of the face-to-face encounter. Practitioners and suppliers can communicate the required information through existing business processes.

Is there compensation for face-to-face encounters?

Face-to-face encounters conducted by a physician may be billed using an Evaluation and Management ("E&M") code. If a non-physician practitioner conducts the encounter and the physician signs/co-signs the order, a billing code G0454 may be used. If a non-physician practitioner orders multiple items of DME the G-code may only be used once.

Do Medicare beneficiaries discharged from the hospital need a separate face-to-face encounter?

No, so long as the physician who performed the face-to-face encounter in the hospital issues the DME order within six months after the patient's date of discharge from the hospital.

Does this requirement apply retroactively to orders already written?

No. The face-to-face requirement is for new DME orders only.

What are the next steps?

In the upcoming months, health care providers and DME suppliers should establish internal processes to ensure compliance with face-to-face requirements. ■

Laura A. Feldman

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Reminder: The HIPAA "Omnibus Rule" is Now in Effect

In January 2013, the Office for Civil Rights published its lengthy final rule (often referred to as the "Omnibus Rule") updating the HIPAA Privacy, Security, Breach Notification and Enforcement Rules. The updates were largely driven by HITECH. The Omnibus Rule changes were effective March 26, 2013, but OCR provided a delayed "compliance date" of September 23, 2013, which has now passed. Covered entities may have until September 23, 2014 to update their Business Associate Agreements if an agreement was in place before January of this year and the agreement has not changed, but otherwise *covered entities and business associates should already be applying the HIPAA Privacy and Security Rules as amended.* Among the principal changes:

- The business associate definition was amended to expressly capture subcontractors that act on behalf of business associates and certain HIOs, e-prescribing gateways and other parties that provide data transmission services.

Covered entities may have until September 23, 2014 to update their Business Associate Agreements if an agreement was in place before January of this year and the agreement has not changed.

- Business associates must obtain assurances from their subcontractors comparable to the assurances they give to their covered entities, and required terms of business associate agreements have been changed somewhat.

- The structured risk analysis for assessing whether PHI has been compromised and data breach notification is required has changed. Covered entities and business associates will be expected to apply the new standards in assessing all potential breach situations.

- Rules regarding sale of PHI and use or disclosure of PHI for marketing were materially tightened and clarified. Authorization is now expressly required with added content.

- Covered entities must update their NPPs to include several features, including when authorizations are required and the individual's right to notice of a breach.

- Use of genetic information for underwriting purposes is expressly prohibited.

- Covered entities may continue to disclose PHI to family members or other persons who have been involved in the individual's healthcare following the death of the individual, if consistent with their prior role while the individual was alive and not inconsistent with any prior expressed preference of the deceased individual. This is a very welcome change.

- Individuals have the right to insist that a covered entity not bill their insurer for an episode of care if they notify the covered entity in a timely manner and pay the charge out-of-pocket in full.

There are numerous other changes, some small and some large. The core principles under the Privacy and Security Rules remain the same. ■

Alex M. "Kelly" Clarke

Upcoming Speaking Engagements

Julie Knutson and Michael Chase will present "Ten Common Mistakes You Don't Want to Make in Implementing Your Compliance Program" at the LeadingAge Nebraska Fall Conference on October 2, 2013 from 10:15-11:00 a.m. at the Marriott Regency in Omaha, NE.

Vickie Ahlers and Heidi Guttau-Fox will present "Scary Situations: Protecting Your Hospital from Violent Patients, Employees or Visitors" at the Iowa Hospital Association Annual Meeting on October 9, 2013 from 1:45-2:45 p.m. at Marriott Downtown in Des Moines, IA.

On October 9, 2012, Julie A. Knutson will present "Living with a Corporate Integrity Agreement: a Word to the Wise About Nursing Facility Compliance" at the LeadingAge Iowa Fall Conference in Des Moines. She will co-present with Mike Van Sickle, Gary Jones and Todd Muckey.

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Michael Chase will present a "Compliance Update on Recent Trends for Inpatient and Outpatient Services" at the Midwest Psychiatric Hospital Association Meeting October 17, 2013 from 8:00-9:30 a.m. at Boys Town National Research Hospital in Omaha, NE.

John Holdenried will speak at the American Health Lawyers Association Tax Program on October 21st and 22nd, 2013, in Washington, D.C. His topic is "ACOs and other Models of Care: From Formation to Operation—Tax Considerations and More."

Kelly Clarke and Michael Chase will present "Important HIPAA Developments: The Omnibus Rule and Current Enforcement Activity" at the Iowa Healthcare Financial Management Association's Annual Institute on October 23, 2013 from 10:45 a.m. to 12:00 p.m. at the Hilton Garden Inn, Johnston, Iowa. ■

Baird Holm Welcomes Laura Feldman

On September 3, 2013, Laura A. Feldman joined the Health Care Law Group at Baird Holm. Laura received her Juris Doctor from the University of Iowa College of Law in 2013. She also earned a Masters of Public Health from the University of Iowa in 2013. Laura is a native of Cedar Rapids, Iowa, and has previously worked as a Summer Associate at Baird Holm. ■

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