

Meet Robert Hussar

Perspective from someone who has played 4 different compliance roles:

- ▶ Compliance Officer
- ▶ Consultant
- ▶ Health Law Attorney
- ▶ State Medicaid First Deputy IG

See page 16



22

**A timeline for change:
A discussion of the
Affordable Care Act
provisions**

Bruce A. Johnson
and Joseph T. Van Leer

33

**Hospital
self-audits of
“provider-based”
status**

Lawrence W. Vernaglia
and Jeffrey R. Bates

41

**Reimbursement
for quality-of-care
issues: What’s
a signature
worth?**

Susan Nance

45

**HIPAA Notice
of Privacy
Practices:
Don’t forget
the basics**

Elizabeth A. Kastner

by Lawrence W. Vernaglia and Jeffrey R. Bates

Hospital self-audits of “provider-based” status

- » Providers should periodically review their compliance with the provider-based rules.
- » Self-audits can be an important component of such periodic reviews.
- » Foundational audits review the hospital’s initial provider-based process.
- » Focused audits review key risk areas for compliance with the provider-based requirements.
- » Comprehensive audits assess whether provider-based status is currently appropriate.

Lawrence W. Vernaglia (lvernaglia@foley.com) is a partner in the Boston office of Foley & Lardner LLP and **Jeffrey R. Bates** (jbates@foley.com) is special counsel in the Los Angeles office of Foley & Lardner LLP.

Many hospitals currently treat certain inpatient and outpatient areas or operations as “provider-based” departments or entities of the hospital. When a hospital department or other entity has provider-based status, it is treated as an integral part of the hospital, and not as a freestanding provider. There are many effects of treating hospital areas and operations as provider-based, including the ability in many cases to obtain higher Medicare (and sometimes Medicaid) reimbursement as a result of having such status. For example, the Medicare payment for certain services is higher when such services are provided in an outpatient area of the hospital than when similar services are provided in a freestanding clinic. In addition, a hospital may benefit from higher disproportionate share hospital (DSH), graduate medical education (GME), and indirect medical education (IME) payments that result when the services are treated as hospital services. Also, hospitals that participate in the Section 340b drug pricing program may extend discounted drug pricing to their provider-based facilities.

In many cases, there are significant costs associated with the conversion of a freestanding operation into a provider-based facility, because provider-based status fundamentally changes the nature of the service. These costs are driven by the requirements that the Centers for Medicare & Medicaid Services (CMS) imposed in 2000 when it implemented new regulations setting forth detailed obligations of providers that wished to treat a given facility as provider-based. These requirements are found at 42 C.F.R. § 413.65.

In recognition of the potential increased Medicare reimbursement that hospitals may obtain as a result of an entity having provider-based status, the Office of the Inspector General (OIG) has for several years listed provider-based status as one of the areas of focus in its annual Work Plan. For example, the OIG Work Plan for 2011 states:

We will review cost reports of hospitals claiming provider-based status for inpatient and outpatient facilities. Pursuant to 42 CFR § 413.65(d), Medicare may permit hospitals that own and operate multiple provider-based facilities or departments in



Vernaglia



Bates

different sites to operate as a single entity, so long as specific requirements are met. Hospitals that receive this “provider-based status” may receive higher reimbursement when they include the costs of a provider-based entity on their cost reports. Freestanding facilities may also benefit from enhanced disproportionate share hospital (DSH) payments, upper payment limit (UPL) payments, or graduate medical education payments for which they would not normally be eligible. Provider-based status for outpatient clinics may increase coinsurance liability for Medicare beneficiaries. We will determine the appropriateness of the provider-based designation and the potential impact on the Medicare program and its beneficiaries of hospitals improperly claiming provider-based status for inpatient and outpatient facilities.¹

Although the OIG did not include provider-based status in its 2012 Work Plan, it did include other issues that are related to provider-based status, such as whether services are billed with the correct place of service (POS) code.

In light of the government’s interest in provider-based entities and hospital compliance obligations, hospitals should periodically review their compliance with the provider-based rules. This is particularly important for providers that undertook significant efforts to comply with the 2000 regulations, but have not subsequently audited or assessed continued compliance with the requirements. For example, some providers have changed the use of various provider-based locations, and may not have performed a re-evaluation of their continued compliance with the regulations. Best practices suggest that hospitals should conduct routine auditing and monitoring of many different aspects of their operations, which may include provider-based status, as an important part of an effective compliance plan.

This article describes three types of self-audits or assessments that a hospital could consider in evaluating whether a hospital facility is properly treated as having provider-based status. Depending on such factors as the period of time that the entity has been in operation, the nature of the provider-based entity, and the entity’s relationship to the rest of the hospital, it may be appropriate to undertake one or more of these assessments.

Background on requirements for provider-based status

The requirements for provider-based status are set forth in the Medicare regulations at 42 C.F.R. § 413.65. These requirements apply when a hospital provides inpatient or outpatient hospital services at a remote location of a hospital or at a satellite facility, as well as when it provides other types of services in provider-based entities. A remote location of a hospital, satellite facility, or other entity is entitled to provider-based status only if it meets the regulatory requirements.

The determination of provider-based status affects the manner in which services provided in a facility may be billed to the Medicare program. If an entity is provider-based, a provider may bill for the entity’s services as rendered in a hospital department. If a facility is not provider-based, the services must be billed as furnished in a freestanding facility or physician’s office. Payment levels often differ based upon the site of service, with payment generally being higher when the service is provided in a provider-based entity, although professional fees are usually reduced by a “site of service differential.”

In some cases, the Medicare program may have previously reviewed whether a hospital department or entity is entitled to provider-based status. Such reviews were conducted when a hospital affirmatively requested a determination by CMS that the department

or entity was entitled to provider-based status. This process is called an “attestation.” Hospitals are not required to obtain such a determination or to submit an attestation of provider-based status, and many organizations rely on internal assessments in determining whether to treat locations as provider-based. If a provider submits a complete attestation of compliance with the requirements for provider-based status for an entity which has not previously been found by CMS to have been inappropriately treated as provider-based, the provider may bill and be paid for services of the entity as provider based. If CMS subsequently determines that the provider-based requirements were not met, CMS may attempt to recover the difference between the payments previously made and the amount that CMS estimates should have been paid.

There are numerous types of facilities for which provider-based status determinations are not made. In these cases, the amount of Medicare payment would not be impacted depending on whether or not the entity is treated as provider-based. These facilities include ambulatory surgery centers, home health agencies, skilled nursing facilities, hospices, and inpatient rehabilitation units that are reimbursed under the Medicare inpatient rehabilitation prospective payment system.

Three types of provider-based self-audits and assessments

In light of the significance of provider-based status to Medicare reimbursement and the complexity of the regulatory requirements, some providers conduct voluntary self-audits or assessments of the provider-based status of their constituent facilities and entities. There are a variety of options on how to conduct these reviews. We describe three models that provide different degrees of benefit to an organization. We categorize these as: (1)

foundational, (2) focused, and (3) comprehensive audits or assessments.

Foundational assessments

A foundational assessment is designed to determine if the hospital went through the correct steps when it initiated the service in question, and when it began treating the entity as provider-based. Depending on the year in which the entity was first treated as provider-based, the hospital may have previously submitted an attestation to CMS that the entity met the provider-based requirements. The foundational assessment should review whether the hospital took appropriate steps before submitting such attestation to CMS and/or treating the entity as provider-based.

Among the issues for review in the foundational audit are:

- ▶ the extent of the review done by the hospital staff at the time to determine if the entity was entitled to provider-based status;
- ▶ whether legal counsel, outside consultants, or compliance officers were involved; and
- ▶ whether appropriate hospital staff were consulted and were made aware of the importance of provider-based status.

Ultimately, the foundational review assesses whether the hospital’s internal determination of provider-based status was conducted appropriately and whether the provider-based decision was reached through a correct process.

The foundational assessment provides a view as to whether the service met the provider-based rules at the time of initiation, and it does not evaluate whether current operations are in compliance, nor does it audit behind the source material for the initial assessment. This is a good first step to the audit process, and can be conducted without any further review. If the hospital’s

foundational assessment determines that proper steps were not followed when a particular entity was initially treated as provider-based, the hospital should then conduct an inquiry into the current operations. In addition, a foundational assessment is important in assessing whether the hospital currently has in place appropriate policies and procedures for assuring that the provider-based requirements are met prior to treating an entity as provider-based.

Focused audit/assessment

A focused audit or assessment is designed to highlight the key risk areas in provider-based compliance, and to review these specific risk areas. The focused audit or assessment can be done through a review of applicable records, but an on-site visit may be desirable in certain cases. The focused audit should help assess whether the hospital has controls in place that appropriately review risk areas that have been identified by CMS and the OIG as problematic.

The focus areas of such an audit will likely include some or all of the following:

- ▶ **State licensure** — The provider-based entity must be operated under the hospital's license where permitted under state law.
 - ▶ **Clinical services** — The clinical services of the entity and the hospital must be integrated.
 - ▶ **Public awareness** — The entity must be held out to the public as part of the hospital. When patients enter the provider-based entity, they must be aware that they are entering the hospital and must be billed accordingly.
 - ▶ **Organizational structure** — If the entity is located off the hospital's campus, it must be 100% owned by the hospital, be subject to the hospital's governing body and bylaws, and be subject to the hospital's control.
 - ▶ **Staffing** — The staff of the provider-based entity must be treated as hospital staff and have reporting relationships to hospital management.
 - ▶ **Integration of medical records** — The medical records of the provider-based entity must be integrated with the hospital's medical records.
- Additional areas that could be the subject of a focused audit include:
- ▶ **Place of service coding** — The physician services furnished in the provider-based entity must be billed with the correct site-of-service code.
 - ▶ **Billing for incident-to services** — Physicians and other practitioners may not bill for services incident-to the practitioners' services in a provider-based entity.
 - ▶ **Outpatient department supervision requirements** — A hospital provider-based entity is subject to the physician supervision requirements applicable to hospital outpatient departments.
 - ▶ **Space leasing and sharing** — There are important Stark Law and Anti-Kickback Statute issues to be considered when outside providers perform services in hospital-owned facilities.
 - ▶ **EMTALA policies** — Some hospital provider-based entities are subject to the EMTALA obligations of hospitals if they satisfy the requirements of a "dedicated emergency department" (DED). Even those facilities that do not meet the DED definitions still fall under the hospital Medicare Conditions of Participation with respect to the treatment of emergency cases.
 - ▶ **Notice of beneficiary coinsurance liability** — Patients may have higher coinsurance obligations when the services are received in a provider-based entity than if the services are provided in a free-standing facility. Off-campus provider-based entities must provide notices to beneficiaries regarding that differential.

- ▶ **Services provided within the applicable DRG payment window** — When a patient is admitted to the hospital as an inpatient after receiving treatment in the provider-based entity, the Medicare payment is subject to the three-day DRG payment window.

Note: Recent statutory and regulatory changes have imposed the bundling requirements of the DRG payment window to diagnostic and non-diagnostic services at facilities that are *not* provider-based, but which are owned or controlled by the hospital. CMS asserts that these non-provider-based entities were always subject to the one- or three-day DRG payment window for diagnostic services, although the extension of the bundling requirements to non-diagnostic services is of recent origin. Many providers with operations now subject to the payment window are re-evaluating their decisions *not* to treat the facility as provider-based.

Comprehensive provider-based audit

A comprehensive provider-based audit is designed to provide confidence that the hospital facility is currently in compliance with the provider-based rules. The hospital assesses each of the elements of compliance under the provider-based rules. Such an audit should include both a foundational assessment and aspects of a focused audit.

Areas to be reviewed, in addition to those listed in the discussion above on foundational and focused audits, include:

- ▶ **Financial integration** — The financial operations of the entity must be fully integrated within the financial system of the hospital, as evidenced by shared income and expenses between the entity and the hospital. The costs of the entity must be reported in an appropriate cost center in the hospital's Medicare cost report.
- ▶ **Location** — If the entity is located off the hospital's campus, it must be located within 35 miles of the hospital, or demonstrate a high level of integration with the hospital by showing that it serves the same patient population as the hospital. The location test can also be met if the hospital is a DSH hospital and certain requirements are satisfied.
- ▶ **Management contracts and joint ventures** — Facilities operated under management contracts or as joint ventures must follow special rules to be considered provider-based.

Conducting audits

The hospital should select the audit scope and methodology thoughtfully. The audit can be done by hospital staff or external resources, but it should be done by someone other than the managers of the departments in question. Hospitals should evaluate whether it would be appropriate to conduct the audits through either hospital counsel or outside counsel, in order to obtain protection for the audit under the attorney-client privilege and the attorney work product doctrine.

Conclusion

In light of the complexity of the provider-based rules, and the changing nature of hospital operations and finance, it may be appropriate for organizations to re-evaluate whether their operations continue to meet the provider-based regulations. A self-audit or assessment may be the prudent method of providing assurances to the organization which may be relied on by the officials responsible for attesting compliance in the cost report and other filings. 🗨️

1. OIG Work Plan Fiscal Year 2011, Reports W-00-10-35424 and W-00-11-35424. Available at http://oig.hhs.gov/publications/workplan/2011/FY11_WorkPlan-All.pdf