



SETTING UP SUCCESSFUL VENDOR ARRANGEMENTS UNDER THE PROVIDER-BASED RULE

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MEDICARE PROVIDER-BASED RULES: WHAT ARE THEY?

- The Provider-Based Regulation: 42 C.F.R. § 413.65

Centers for Medicare & Medicaid Services, HHS

§ 413.65

provider will be adjusted by the contractor, notwithstanding any other regulation or program instruction regarding the timing or manner of such adjustments, to a level necessary to insure that no overpayment to the provider is made.

(j) *Interest payments resulting from judicial review*—(1) *Application*. If a provider of services seeks judicial review by a Federal court (see § 405.1877 of this chapter) of a decision furnished by the Provider Reimbursement Review Board or subsequent reversal, affirmation, or modification by the Secretary, the amount of any award of such Federal court will be increased by interest payable by the party against whom the judgment is made (see § 413.153 for treatment of interest). The interest begins to accrue on the first day of the first month following the 180-day period described in § 405.1835(a)(3)(i) or (a)(3)(ii) of this chapter, as applicable.

(2) *Amount due*. Section 1878(f) of the Act, 42 U.S.C. 1395oo(f), authorizes a

which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 36713, July 19, 1994; 64 FR 41682, July 30, 1999; 65 FR 41211, July 3, 2000; 66 FR 41394, Aug. 7, 2001; 67 FR 56056, Aug. 30, 2002; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004; 73 FR 30267, May 23, 2008]

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions*. (1) *Scope*. (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

SCOPE OF PRESENTATION

- This presentation is applicable to all locations where hospital services are provided to Medicare beneficiaries
- This includes:
 - Hospital inpatient units
 - Hospital outpatient departments
 - Satellite locations of a hospital
 - Remote locations of a hospital
 - Any hospital campus
 - Any other locations of a hospital where services are billed to Medicare as hospital services
- This presentation does not address COVID-19 Public Health Emergency waivers that may apply to provider-based arrangements

MEDICARE PROVIDER-BASED RULES: WHY DO HOSPITALS CARE?

- The provider-based rules address what locations are considered to be part of the Medicare “provider” – the hospital
- A provider-based location may bill services to Medicare as hospital services
 - Medicare payment was historically higher under hospital rates than if the same service was furnished in a non-hospital (“freestanding”) setting
 - Medicaid and some other payors still pay higher rates
- In order to be eligible for outpatient drug discounts through the 340B Program, a location generally must be a provider-based location of a hospital
- Failure to comply with provider-based rules may result in requirement to refund the difference between what was paid for the services as hospital services and what would have been paid if the services were billed as “freestanding”
 - Voluntary attestation process may provide some protection

MEDICARE PROVIDER-BASED RULES: WHY SHOULD VENDORS CARE?

- Vendors seeking to partner with hospitals should be aware of the requirements for a location to be considered eligible for hospital billing/reimbursement and, if applicable, 340B eligibility
- Entering into an arrangement that does not comply with the provider-based rules may result in lower than anticipated revenue and significant federal health care program compliance risks to the hospital
 - Management agreement requirements
 - “Under arrangements” requirements
 - Integration requirements
 - Financial
 - Administrative
 - Operational
 - Clinical
 - Governance

MEDICARE PROVIDER-BASED RULES: WHY DOES THE GOVERNMENT CARE?

- Potential for higher costs to the federal government
- Potential for higher out-of-pocket costs to Medicare beneficiaries

Resulting in...

Government and public scrutiny



PROVIDER-BASED STATUS: GOVERNMENT SCRUTINY

- The 2022 HHS-OIG Work Plan includes “Comparison of Provider-based and Freestanding Clinics”:
 - “Provider-based facilities often receive higher payments for some services than freestanding clinics. The requirements that a facility must meet to be treated as provider-based are at 42 CFR §413.65(d). We will review and compare Medicare payments for physician office visits in provider-based clinics and freestanding clinics to determine the difference in payments made to the clinics for similar procedures. We will also assess the potential impact on Medicare and beneficiaries of hospitals' claiming provider-based status for such facilities.”
- This has been a regular part of the HHS-OIG Work Plan for the past several years

PROVIDER-BASED STATUS: GOVERNMENT SCRUTINY

Department of Justice

U.S. Attorney's Office

Northern District of New York

FOR IMMEDIATE RELEASE

Thursday, October 16, 2014

Our Lady Of Lourdes Memorial Hospital Has Paid More Than \$3.37 Million To Resolve Self-disclosed Billing Improprieties

ALBANY, NEW YORK – Our Lady of Lourdes Memorial Hospital, Inc. (Lourdes), a 242-bed hospital located in Binghamton, New York, has paid \$3,373,898.28 to resolve False Claims Act liability stemming from Medicare billing improprieties that the hospital self-disclosed to the federal government, announced United States Attorney Richard S. Hartunian.

During the course of an internal review, Lourdes determined that from February 2008 through September 2013, it had improperly billed and was thus overpaid by the Medicare program for hyperbaric oxygen therapy services rendered by a third party in a facility that failed to satisfy the requirements for “provider-based status” set forth in federal regulations. The hospital promptly took corrective steps to remedy the problem and then brought its findings to the government’s attention. Due in large part to Lourdes’s decision to self-disclose these issues and its cooperation throughout the government’s investigation, the hospital was required to pay far less than the treble damages and penalties that the United States is authorized to seek under the False Claims Act. Furthermore, the Department of Health and Human Services’ Office of Inspector General (HHS-OIG) decided that Lourdes would not have to enter into a corporate integrity agreement or adopt other compliance measures.

PROVIDER-BASED STATUS: GOVERNMENT SCRUTINY

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, May 10, 2021

University of Miami to Pay \$22 Million to Settle Claims Involving Medically Unnecessary Laboratory Tests and Fraudulent Billing Practices

The University of Miami (UM) has agreed to pay \$22 million to resolve allegations that it violated the False Claims Act by ordering medically unnecessary laboratory tests, and submitting false claims through its laboratory and off campus hospital based facilities ("Hospital Facilities").

According to court documents, the United States alleged that UM engaged in three practices that violated the False Claims Act. First, the government alleged that UM knowingly engaged in improper billing relating to its Hospital Facilities. Medicare regulations allow medical systems to convert physician offices into Hospital Facilities provided they satisfy certain requirements. Billing as a Hospital Facility results in higher costs to the Medicare program and beneficiaries. Hospital Facilities are required to give notice to Medicare beneficiaries that explains the financial ramifications of receiving services at Hospital Facilities as opposed to physician offices. Here, the government alleged that UM converted multiple physician offices to Hospital Facilities, and then sought payment at higher rates without providing beneficiaries the required notice, even after being advised by a Medicare Administrative Contractor that its notice practices were deficient.

PROVIDER-BASED STATUS: PUBLIC SCRUTINY

FierceHealthcare

Care shifts from physician offices to outpatient settings and costs go up, HCCI study finds

by Joanne Finnegan | Apr 4, 2019 12:51pm

There are two trends going on in healthcare. More care is taking place in outpatient settings than physician offices and there's a higher price for those services.

Those are the main findings of an **analysis** by the Health Care Cost Institute (HCCI) and it comes at a time when more medical practices are being taken over by hospitals and health systems.

When it comes to cost, it does matter where a patient receives healthcare, the analysis found.

Services are increasingly taking place in the outpatient setting, where services are more expensive, according to the study, which looked at prices for 46 different services ranging from ultrasounds to drug administration. For all the services, the average price was always higher in an outpatient setting than an office setting.

AJC

Atlanta. News. Now.

NEWS | July 06, 2013

By Carrie Teegardin, The Atlanta Journal-Constitution

Everything was the same about Mike Rosenberg's routine visit to Atlanta Cancer Care in February – everything, that is, but the bill.

Rosenberg went to the same office and saw the same staff to get the same blood work and the same medication he gets every month.

But the cost difference was remarkable: Rosenberg's out-of-pocket charge increased from \$20 to \$212. What his insurer had to pay exploded from \$2,735 to \$5,661.

This has to be a mistake, Rosenberg thought, but there was no mistake. He learned instead that the higher charges resulted from a carefully planned business move. In January, Northside Hospital took over two of Georgia's largest oncology groups – Atlanta Cancer Care and Georgia Cancer Specialists.

Because it is a hospital, Northside can bill at significantly higher rates for the same services at the same offices. Northside and the doctors who executed the deal say the change is positive for patients because it will enable the clinics to offer a host of new services. Plus, they say, it was a necessary step for survival in a transforming health care marketplace.

PROVIDER-BASED REQUIREMENTS: ALL LOCATIONS

- Licensure
- Clinical Integration
- Financial Integration
- Public Awareness



PROVIDER-BASED STATUS: LICENSURE

- **Licensure**
 - The provider-based location must be operated under the same license as the main hospital
 - Except if the state requires a separate license or does not permit licensure as part of the hospital

PROVIDER-BASED STATUS: CLINICAL INTEGRATION

- **Clinical Integration**

- The clinical services offered at the location must be integrated with the services of the main provider, as demonstrated by the following:
 - The location's professional staff must have clinical privileges at the main hospital
 - The location must be subject to the same clinical monitoring and oversight as other hospital departments
 - Medical Director of the location reports to Chief Medical Officer/Medical Director of the main hospital with the same frequency, intensity and accountability as any other medical director in the hospital
 - The hospital's medical staff committees or other professional committees are responsible for medical activities at the provider-based location, including quality assurance, utilization review and the coordination and integration of services between the location and the hospital.
 - Medical records are integrated into a unified system of the main hospital

PROVIDER-BASED STATUS: FINANCIAL INTEGRATION

- **Financial Integration**

- The financial operations of the provider-based location must be integrated into the main hospital
- The financial status of the provider-based location must be incorporated into the main provider's trial balance
- The costs of the provider-based location are reported in a cost center of the main hospital on the hospital's cost report

PROVIDER-BASED STATUS: PUBLIC AWARENESS

- **Public Awareness**
 - The provider-based location must be held out to the public and payors as part of the main hospital
 - Patients must be aware that they are entering a location of the main hospital and will be billed accordingly



PROVIDER-BASED STATUS: HOSPITAL OUTPATIENT DEPARTMENTS

- **All hospital outpatient departments must:**
 - Treat all Medicare patients as hospital patients
 - Submit Medicare claims under Medicare hospital billing and coding rules
 - Comply with applicable terms of the Medicare provider agreement
 - Ensure physicians providing services at the location comply with the following federal laws:
 - Civil Rights Act
 - Rehabilitation Act
 - Age Discrimination Act
 - Comply with Medicare Hospital Conditions of Participation
 - Comply with EMTALA
 - If on-campus or a dedicated emergency department

PROVIDER-BASED STATUS: OFF-CAMPUS LOCATIONS

- **Off-campus** provider-based locations must meet additional requirements:
 - Location
 - Ownership
 - Control
 - Administration
 - Supervision
- NOTE: A location is considered to be “**off-campus**” if it is located more than 250 yards from the main campus of the hospital that provides inpatient services

OFF-CAMPUS PROVIDER-BASED LOCATIONS: LOCATION

- **Location**
 - In general, the provider-based location must be within a 35-mile radius of the main campus
 - There are exceptions for locations and hospitals that meet certain criteria

OFF-CAMPUS PROVIDER-BASED LOCATIONS: OWNERSHIP AND CONTROL OF THE MAIN PROVIDER

- **Operation Under Ownership and Control of the Main Provider**
 - 100% owned by the main provider
 - Same governing body as the main provider
 - Operated under the same organizational documents as the main provider
 - The following actions are subject to the approval of the main provider:
 - Administrative decisions:
 - Contracts with outside parties
 - Personnel actions
 - Personnel policies
 - Medical staff appointments

OFF-CAMPUS PROVIDER-BASED LOCATIONS: ADMINISTRATIVE SUPERVISION

- **Administrative Supervision**
 - Must be the same as for departments located within the main provider
 - Direct supervision by the main provider
 - Same monitoring and oversight
 - Administrative leader who reports to the main provider with the same frequency, intensity, and accountability as directors of on-campus departments
 - The following administrative services of the provider-based location are integrated with the main provider:- --
 - Billing services
 - Records
 - Human Resources
 - Payroll
 - Employee benefits
 - Salary structure
 - Purchasing services

OFF-CAMPUS PROVIDER-BASED LOCATIONS: MANAGEMENT AGREEMENTS

- An off-campus provider-based location may be operated by another entity under a management agreement, but must meet all of the following requirements:
 - The main provider employs the location's clinical staff who are directly involved in the delivery of patient care
 - Management staff do not need to be employed by the main provider
 - Physicians, nurse practitioners and physician assistants who furnish clinical services that are separately billed to Medicare do not need to be employed by the main provider
 - The administrative functions of the provider-based location are integrated with the administrative functions of the main provider
 - The main provider has significant control over the operations of the provider-based location
 - The management contract must be with the main provider itself; the management contract cannot be held by a parent organization that has control over both the main provider and the provider-based location

PROVIDER-BASED STATUS: JOINT VENTURES

- Very common area of confusion
 - Provider-based rule states that on-campus JVs are permitted
- But, may not be possible for a separate legal entity JV to comply with the other applicable state and federal requirements
 - Hospital CoP for governance
 - The entire hospital must be under the authority of the same governing body
 - Hospital license
 - Most states will not allow a separate legal entity to be included on a hospital's license
 - Integration
 - Meeting the integration requirements may be difficult/impossible for a separate legal entity joint venture
- Contractual JVs and JV management companies may be an alternative option – but note that these may pose fraud and abuse concerns

COMPARISON OF PROVIDER-BASED REQUIREMENTS: ON-CAMPUS AND OFF-CAMPUS

	On-Campus Provider-Based Locations	Off-Campus Provider-Based Locations
Location	Location is within 250 yards from the provider's main buildings	Location is within a 35-mile radius of the main provider's main campus (with special exceptions)
Ownership and Control	Location may be operated as a joint venture, but subject to compliance with Medicare hospital Conditions of Participation	Location operated under the ownership and control of the main provider
Written Notice	No written notice needs to be provided to Medicare beneficiaries	Medicare beneficiaries must receive written notice of their potential financial liability for services received in the location
Enrollment	Provider-based locations must be listed as "practice locations" of the hospital on the CMS-855A Medicare enrollment form	
Licensure	The provider-based location must be operated under the same license as the hospital	
Clinical Integration	The main provider maintains monitoring and oversight over clinical services provided in the location	
Financial Integration	The financial operations of the location are fully integrated into the main provider's financial system	
Public Awareness	Location must be held out to the public and other payors as part of the main provider	








PROVIDER-BASED REQUIREMENTS: SPECIAL RULES

- RHCs are exempt from the provider-based public awareness requirements
- CMS does not make provider-based determinations for certain types of facilities, including the following:
 - Ambulatory surgical centers
 - Comprehensive outpatient rehabilitation centers
 - Inpatient rehabilitation units that are excluded from the inpatient PPS
 - Home health agencies
 - Skilled nursing facilities
 - Facilities that provide only provide outpatient physical, occupational or speech therapy
 - Rural health clinics associated with hospitals with 50 or more beds

EXAMPLE VENDOR ARRANGEMENTS

- Services furnished by a vendor in hospital space
 - For example, a digital health company uses hospital space to provide medical devices to the hospital's patients under a contract with the hospital
- Vendor engaged to manage a particular hospital outpatient service line
 - For example, a hospital's cancer center is managed by an independent third party

GENERAL GUARDRAILS

-  Understand when and why services must meet “provider-based” requirements
-  Ensure contractual arrangements are evaluated for compliance with provider-based services furnished under management agreements
-  Be aware of the public awareness requirements, particularly if the services are furnished in an off-campus location
-  Ensure hospital documentation (i.e., organizational charts, signage, business cards) support provider-based compliance
-  Ensure hospital has necessary oversight of the services furnished
-  Ensure contracts are consistent with hospital vendor contracting policies
-  Review arrangement for compliance with applicable state laws – particularly licensure



QUESTION & ANSWER

THANK YOU!

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