Department of Health & Human Services
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Refer to: [redacted]

July 22, 2011

[redacted]

Re: Denial of Hospital Off-Site Location, [redacted]

Dear [redacted]:

It has been determined that the following location fails to meet the Centers for Medicare and Medicaid Services' (CMS's) provider-based criteria for determining the entity to be a component of [redacted]:

[redacted]

Regulations in 42 CFR §413.65 and CMS Program Memorandum A-03-030 describe the criteria and procedures for determining whether a facility or organization is provider-based. These criteria include the complete financial and administrative integration of the facility or organization with the main provider, full integration of clinical services with the main provider, and public awareness of the facility or organization as part of the main provider. CMS has determined that Name of Non Provider-Based Entity fails to meet the following provider-based criteria:

413.65(d)(1) Licensure

(1) *Licensure*. The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

The State of Indiana requires that additional hospital practice locations meet certain requirements and that they be added to the State's hospital license. The radiology department at [redacted] is not included on [redacted]

Hospital's license with the Indiana State Department of Health, thus precluding it from meeting this essential provider-based status requirement.

Shared Space Prohibition: 413.65(a)(2) Definitions & 413.65(g)(3) Compliance with Hospital's Provider Agreement

413.65(a)(2) Definitions

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under §489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term "department of a provider" does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

To the extent that a facility does not meet the definition of a department of a provider, the facility cannot have provider-based status as a department of a provider. A department of a provider requires sufficient separation from any other facility. Sufficiently separated space is indicated by such features as exclusive entrance, waiting, and registration areas, permanent walls, and a distinct suite designation recognized by the United States Postal Service if the hospital department does not occupy an entire building.

413.65(g)(3) Compliance with Hospital's Provider Agreement

Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

To the extent that the facility operates as a freestanding facility it does not operate under the terms of the hospital's provider agreement with Medicare.

Rationale for 413.65(a)(2) and 413.65(g)(3)

The Centers for Medicare & Medicaid Services (CMS) has learned that [redacted] Hospital shares space with [redacted] Center, Inc., a freestanding healthcare facility. CMS does not recognize facilities that share space with freestanding facilities to meet the definition of a "department" of a hospital. A facility that shares space with a freestanding facility cannot have provider-based status as a department of a hospital. The framework for this position is found in the Title XVIII of the Social Security Act (SSA), the Code of Federal Regulations (CFR), and official CMS guidance found in the Internet-Only Manual (IOM) 100-07 the State Operations Manual. This distinction is necessary to maintain the integrity of what CMS considers to be a hospital and to protect the Medicare program and its beneficiaries from possible abuses as hospitals seek to maximize Medicare reimbursement.

Hospitals are recognized as "providers of service" in SSA 1861(u). Hospitals themselves are defined at SSA 1861(e). Under SSA 1866(a), any provider of services may be qualified to participate in Medicare if it enters into an agreement with Medicare. Such agreements with Medicare must apply to the provider in its entirety. Hospitals are not permitted to "carve out" areas as non-hospital spaces. The SSA does permit certain provider types to exist as distinct parts of other institutions where defined in the statue. For example, Section 1861(f)

of the SSA, which defines a "psychiatric hospital," specifically allows an institution that contains a distinct part that satisfies the statutory definition to have that distinct part considered a "psychiatric hospital." Similarly, Section 1819(a), which defines a "skilled nursing facility," specifically allows an institution that contains a distinct part that satisfies the statutory definition to have that distinct part considered a "skilled nursing facility." On the other hand, the Section 1861(e) definition of a hospital has no such provision allowing only a part of a hospital to be considered a hospital. Absent a statutory exception similar to that found for psychiatric hospitals, and SNFs, CMS interprets the statutory definition of a hospital to apply to the hospital in its entirety.

The CMS does recognize that components of hospitals may be separately housed from the main provider. In these instances, the provider agreement applies to these components in their entirety. Official CMS guidance on this issue is found in the State Operations Manual (SOM), Chapter 2, Section 2026. This guidance specifically requires the State Certification Agency to evaluate each general hospital as a whole for compliance with the Conditions of Participation and to certify the hospital as a single provider institution, including all components. The SOM adds that it is not permissible to certify only part of a general hospital. The provider-based requirements and obligations found at 42 CFR Section 413.65 lists all of the criteria for components of the hospital to be considered as parts of the hospital, whether those components are located on or off of the main campus of the main provider.

Under the provider-based status regulation at 42 CFR 413.65, a "department of a provider" means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility.

That a hospital department includes the space, equipment, and personnel used to furnish hospital services is consistent with the position that CMS must consider hospital space in its entirety when considering the component's compliance with applicable statutory and regulatory requirements and official CMS guidance pertaining to the definition of a "hospital." When a would-be hospital department shares space with freestanding offices, CMS must consider the entire space that contains the purported hospital department and the space's relationship to the hospital's Conditions of Participation (CoPs) at 42 CFR Part 485 Subpart F and compliance with the provider-based status requirements and obligations of 42 CFR 413.65. Since hospital components must be considered in their entirety, it is not possible to consider only parts of a singularly-contained, clearly-defined space. CMS may consider a suite in a medical office building to be a singular component for compliance with the hospital CoPs and Medicare provider-based status requirements and obligations for the component to be considered a part of a hospital. However, CMS cannot consider only portions of a singular component when determining if these criteria are met.

A main provider hospital may not lease or otherwise obtain use of a portion of a singular component and create a smaller component within that space. Certain features, such as shared entryways, interior hallways, bathroom facilities, treatment rooms, waiting rooms, and registration areas are all indications that a purported hospital space may instead be a part of a

larger component. Building plans that do not clearly demarcate a purported hospital space as a distinct space is another possible indicator that the space is not a self-contained component. Rent that is paid to a tenant of a building rather than directly to the building owner or landlord may also be an indication that a space does not itself constitute a singular component.

In addition to non-compliance with Medicare's CoPs, failure to recognize components of hospitals in their entirety as singular entities puts the Medicare program at risk for abusive practices. Were CMS to permit hospitals to carve out spaces or services at freestanding facilities, hospitals and physicians would be able make arrangements that would allow for the maximization of reimbursement for services depending on how certain services are reimbursed in certain settings. This topic is discussed in the Federal Register, April 7, 2000 edition in the final rule for the Prospective Payment System (PPS) for Hospital Outpatient Services where the provider-based status regulation was first implemented. Implementation of PPS methods of reimbursement for hospital services created financial incentive and pressures for hospitals to acquire control of non-provider treatment settings, such as physician offices. The provider-based requirements and obligations were deemed essential to distinguish between provider-based and freestanding facilities or organizations and allow Medicare to make appropriate determinations of provider-based status. As stated in this final rule, "[b]y failing to distinguish properly between provider-based and free-standing facilities or organizations, we risk increasing program payments and beneficiary coinsurance with no commensurate benefit to the Medicare program or its beneficiaries and we jeopardize the delivery of safe and appropriate health care services to our beneficiaries." To allow hospitals to acquire only portions of a freestanding space to treat as a department of the hospital is contrary to the very concern that made the provider-based status regulation necessary.

Hospitals may not situate themselves inside a freestanding office space and consider certain services furnished therein as "hospital" services while other services furnished within the same overall space are not. This is true even when the hospital attempts to create a subsection of the overall space through a sublease or other agreement. CMS must consider hospitals in their entirety, including any components housed away from the main campus, as singular entities. Similarly, any components situated away from the main campus of the provider must also be considered in their entirety. This distinction is necessary to the integrity of the Medicare program.

Additional Rationale

CMS must consider both the purported hospital space as well as the freestanding space that, taken together, comprise the singular component when considering the component's compliance with Medicare's CoPs and the provider-based requirements and obligations. Since CMS must consider the purported hospital spaces and services as well as the freestanding space and services, certain requirements are necessarily not met when a would-be hospital component shares space with freestanding offices. First and foremost, the public awareness requirement is not met to the extent that the singular component is held out as a freestanding supplier of services, even if it is also held out to the public as a furnisher of hospital services. The provider-based requirements and obligations are also not met to the extent that the freestanding services are not integrated with the hospital. The freestanding services are not clinically or administratively integrated with services at the main provider.

The freestanding office space is not owned and operated as part of the main provider. Patients receiving services in the freestanding space are not registered as hospital patients and the services they receive are not billed as hospital services. Additionally, if the main provider leases the subspace of a component from a freestanding provider or supplier who also leases the space, the main provider may not even have ultimate control of the subspace, further putting the main provider out of compliance with requirements.

413.65(d)(2) Clinical Services

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

To the extent that services are furnished at [redacted] Center, LLC which are not hospital services, the facility is not integrated with [redacted] Hospital, the main provider hospital. For example, the medical director of [redacted] Center, LLC does not maintain a reporting relationship similar to other departments at the main provider. Additionally, the main provider is not responsible for medical activities such as utilization review and quality assurance, and the medical records of patients at the freestanding facility are not integrated with medical records at the main provider.

413.65(d)(3) Financial Integration

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

To the extent that operations at the facility are not financially integrated with hospital operations, the facility is not financially integrated with the main provider hospital. That the facility operates as a freestanding facility is evidence that these services are not financially integrated with those at the main provider. For example, operations of [redacted] Center, LLC are not reported as a cost center on the main provider's Medicare cost report.

413.65(d)(4) Public Awareness

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

The CMS must consider the facility in its entirety and how it is held out to the public. When a facility contains both freestanding and purported hospital space, some confusion of the two is unavoidable. There are many elements that are common to shared space arrangements that are likely to cause confusion between purported hospital space and freestanding space. These include a shared entrance into the facility, shared registration and waiting areas, passing through a freestanding area to get to the purported hospital area, co-mingling of staff, and signage indicating that a single facility is both hospital space and freestanding space. Insofar as these elements can lead to confusion in the identity of a facility as a hospital facility, the public awareness criterion is not met. To the extent that [redacted] Center Radiology Department is also held out to the public as the freestanding facility [redacted] Center, LLC, it is not held out to the public as a component of the main provider hospital. Therefore, a single facility that is co-mingled hospital and freestanding space is not in compliance with the public awareness requirement to have provider-based status.

The name of the purported provider-based department [redacted] Center Radiology Department, is more closely associated with the freestanding entity that the facility shares space with, [redacted] Center LLC., than it is with its main provider entity, [redacted] Hospital.

413.65(e)(1) Operation Under the Ownership and Control of the Main Provider

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.

(ii) The main provider and the facility or organization seeking status as a department of the main provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

To the extent that the facility is owned and operated by [redacted] Center, LLC, it is not under the ownership and control of the main provider hospital. For example [redacted] Center, LLC does not operate under the same governing body as the main provider and is not subject to its bylaws.

413.65(e)(2) Administration and Supervision

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

To the extent that the facility is under the administration and supervision of [redacted] Center, LLC, it is not under the administration and supervision of the main provider hospital. For example, [redacted] Center, LLC is not under the direct supervision of the main provider and does not maintain a reporting relationship with the main provider.

Next Steps

In accordance with 42 CFR §413.65(k), Medicare will recover overpayments made from the date of this letter back to the date on which your attestation was submitted. Since it was necessary for the CMS Chicago Regional Office to obtain additional information from the provider prior to making its determination, CMS will consider the date of this letter as the date that the attestation was submitted. The amount of the overpayment is the difference between the amount of payments that actually was made since the attestation was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with provider-based requirements. CMS will not seek recovery of overpayments for dates earlier than October 1, 2002.

With this initial determination for denial of provider-based status, [redacted] Hospital has the following three options:

1. The provider may notify CMS in writing within 30 days of the date the notice is issued that the provider intends to make the changes needed for the facility or organization to comply with the provider-based rules and that the provider intends to seek a determination of provider-based status for its facility or organization. If the provider indicates that it will be seeking a provider-based determination for the facility or organization, then CMS will continue to pay for services provided at the facility or organization at a rate estimated for services furnished by a freestanding facility. CMS will continue to pay at this rate for as long as is required for the facility or organization to comply with the provider-based rules, (but not for longer than 6 months), if the provider submits a complete request (not an attestation) for a provider-based determination and all other required information within 90 days after the date of the notice of denial of provider-based status. If the necessary application or information is not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

2. The provider may notify CMS in writing within 30 days of the date the notice is issued that the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility. If the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for billing for services in a free-standing facility, then CMS will continue to pay for services provided at the facility or organization at a rate estimated for services furnished by a freestanding facility. CMS will continue to pay at this rate for as long as is required for the facility or organization to enroll as a freestanding facility, (but not for longer than 6 months), if the facility or organization, or its practitioners, submit a complete enrollment application and furnish all other information needed by CMS to process the enrollment application and verify that other billing requirements are met within 90 days after the date of notice of the denial of provider-based status. If the necessary enrollments or information is not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

3. The provider may choose not to notify CMS within 30 days of the date the notice is issued of whether it intends to pursue provider-based status under item (1) above, or freestanding status under item (2) above. If CMS does not receive a response as described in item (1) or item (2) within 30 days of the date the notice is issued, all payment will end as of the 30th day after the date of the notice.

Notification to CMS as described in items (1) and (2) should be sent to your fiscal intermediary.

Regardless of whether or how [redacted] Hospital responds to the notice in items (1) through (3) above, the provider may choose to appeal its denial of provider-based status within 60 days from the date of the notice of denial. Adverse determinations regarding provider-based status may be appealed under the administrative appeals procedures set forth in 42 CFR Part 498.

Initial Determination Request for Reconsideration

If you are dissatisfied with this determination, you may request reconsideration by filing a written reconsideration request within sixty (60) days from the date on which you receive this letter. Your request must state the issues or findings of fact with which you disagree and the reasons for disagreement. Your reconsideration rights are set forth in the regulations at 42 CFR §498.22. Please address your request for reconsideration to:

Gregory R. Dill
Associate Regional Administrator
Division of Financial Management and Fee for Service Operations
Centers for Medicare & Medicaid Services
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601

Denial of a Reconsideration Request
If you disagree with this first level appeals determination, you or your legal representative may request a hearing before an Administrative Law Judge (ALJ) of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in the regulations at 42 CFR §498.40 et seq. A written request for a hearing must be filed within sixty (60) days from the date on which you receive your first level appeal results. The request should be made to:

Department of Health and Human Services
Departmental Appeals Board, MS6132
Civil Remedies Division
330 Independence Avenue
Cohen Building, Room G-644
Washington, D.C. 20201
Attention: Theodore Kim

Forward a copy of your request for an ALJ hearing to:

Gregory R. Dill
Associate Regional Administrator
Division of Financial Management and Fee for Service Operations
Centers for Medicare & Medicaid Services
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601

and

Alan Dorn
Office of the General Counsel
Department of Health and Human Services
233 N. Michigan Avenue
Suite 700
Chicago, IL 60601

A request for a hearing must identify the specific issues and findings of fact and conclusions of law with which you disagree, and specify the basis for contending that the findings and conclusions are incorrect.

We are notifying your fiscal intermediary, National Government Services, and the Indiana State Department of Health of our determination. If you have any questions regarding this matter, please contact me at (312) 886-5347.

Sincerely,

Gregg McAllister

Gregg McAllister
Policy & Safeguards Branch
Division of Financial Management
and Fee For Service Operations

cc: Indiana State Department of Health
National Government Services