DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-10-10-CAH

DATE: **December 31, 2009**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Critical Access Hospital (CAH) Regulatory Changes**

Memorandum Summary

Regulations effective October 1, 2009:

- **CAH Participation**: Permit continued participation of CAHs located in areas no longer rural, up to September 30, 2011.
- **CAH-Owned Clinical Laboratories**: Require all CAH-owned clinical laboratories to satisfy provider-based and CAH location requirements, effective October 1, 2010.
    - Section 2256H of the State Operations Manual is revised to reflect the change.

On July 31, 2009, the Centers for Medicare & Medicaid Services (CMS) issued the final FY 2010 Inpatient Prospective Payment System (IPPS) rule, effective October 1, 2009. The final rule included the following two changes affecting CAHs:

Reclassification of Certain Counties

The regulations were amended to permit the continued participation by CAHs located in counties that in FY 2009 were not part of a Metropolitan Statistical Area (MSA), but, as of FY 2010, were included as part of such an MSA, through the earlier of either: 1) the date on which the CAH obtains rural designation under the standards at 42 CFR 412.103, or 2) September 30, 2011.

Section 1820(c)(2)(B)(i) of the Social Security Act requires a facility seeking designation as a CAH to be located in a county (or equivalent unit of local government) in a rural area, or to be treated as being located in a rural area. Regulations implementing this requirement are located at 42 CFR 485.610(b). In accordance with those regulations, a facility located outside an MSA, as defined by the Federal Office of Management and Budget (OMB), or an area recognized as urban under 42 CFR 412.64(b) is to be considered located in a rural area. Further, 42 CFR 485.610(b)(2) allows a facility located in an MSA to nevertheless be treated as rural in accordance with the provisions of 42 CFR 412.103.

This latter regulation establishes several alternative conditions allowing for reclassification as rural, including, but not limited to: location in a rural census tract of an MSA; location in an area designated as rural under State law or regulation; or designation by State law or regulation as a rural hospital.

Effective October 1, 2009, several previously rural locations are considered to be located in an MSA due to changes announced by OMB. Effective that same date, amended 42 CFR 485.610(b)(4) and 42 CFR 412.103(a)(5) allow CAHs previously located in counties that, in FY 2009 were not part of an MSA, but as of FY 2010 are included as part of an MSA, a two-year period during which they may continue to be treated as rural for purposes of CAH designation. It is anticipated that during this time affected CAHs will seek to be treated as rural in accordance with the provisions of 42 CFR 485.610(b)(2) for a more permanent solution.

Effective October 1, 2011, any CAH affected by these OMB changes that does not satisfy the CAH rural location requirements at 42 CFR 485.610(b) will be subject to having its Medicare provider agreement terminated, unless the CAH successfully converts to a hospital.

Clinical Diagnostic Laboratories

Effective October 1, 2010, the amended regulations at 42 CFR 413.65(a)(1)(ii)(G) exclude clinical diagnostic laboratory facilities which operate as a part of a CAH from the list of facility types for which provider-based determinations are not made. As a result, such CAH laboratories must, as of October 1, 2010, meet the applicable provider-based criteria at §413.65 in order to be considered provider-based to the CAH. Additionally, any off-campus laboratories operating as part of the CAH and created or acquired on or after January 1, 2008 must satisfy not only the provider-based requirements but also the provisions of §485.610(e)(2) concerning the off-campus facility's minimum distance from a hospital or another CAH.

CAH-owned clinical diagnostic laboratory facilities that do not satisfy the provider-based and, if applicable, distance requirements, by October 1, 2010 may continue to participate in Medicare, but will not be considered part of the certified CAH and will be paid under the Clinical Laboratory Fee Schedule (CLFS). CAHs should also be mindful that, if they satisfy the requirement at 42 CFR 485.635(b)(2) for direct provision of laboratory services on the basis of a CAH-owned laboratory that, as of October 1, 2010, is no longer considered part of the CAH, they will be in violation of the CAH Condition of Participation requirement at §485.635(b)(2) governing direct provision of services. CAHs should anticipate and avoid this problem by making such changes as are necessary to ensure the requirement regarding direct provision of laboratory services is satisfied.

The revised guidance concerning off-campus provider-based CAH locations may be found in updated State Operations Manual (SOM) section 2256H, an advance copy of which is attached. The final version of the SOM will be released at a later date and may differ slightly from this copy.

If you have any questions regarding this memorandum, please contact Kimberly DeMichele at Kimberly.DeMichele@cms.hhs.gov

Effective Date: This guidance is effective immediately.

Training: This information should be shared with all survey and certification staff, surveyors, and the affected provider community.

/s/
Thomas E. Hamilton

Attachment (1)

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations

Provider Certification (Advance Copy)

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal **Date:**

SUBJECT: Revised Chapter 2, Section 2256H

I. SUMMARY OF CHANGES: Section 2256 is revised to reflect regulatory changes at 42 CFR 413.65(a)(1)(ii)(G) that affect the interpretation of 42 CFR 485.610(e)(2).

REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 2, Section 2256H

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2010 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

2256H – Off-Campus CAH Facilities

(Rev.)

Section 42 CFR 485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined in §485.647, that was created or acquired on or after January 1, 2008, then the off-campus facility must meet the requirement at 42 CFR 485.610(c) to be more than a 35 mile drive (or *a* 15 mile *drive* in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement. The drive to another hospital or CAH is calculated from the off-campus facility's location to the main campus of the other hospital or CAH.

Definitions related to provider-based status are found at 42 CFR 413.65(a)(2):

> "**Campus:** means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings, but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."
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> "**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 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."
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> **"Remote location of a hospital:** means a facility or organization that is either created by, or acquired by, a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in §412.22(h)(1) and §412.25(e)(1) of this chapter."
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> **"Provider-based entity**: means a provider of health care services, or a Rural Health Clinic (RHC) as defined in §405.2401(b) of this chapter, that is either created or acquired by the main provider for the purpose of furnishing health care services of a different type from those of the main provider under which the ownership and administrative and financial control of

the main provider, in accordance with the provisions of this section. A provider-based entity 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 the facility. A provider-based entity may, by itself, be qualified to participate as a provider under §489.2, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity."

"Provider-based status: means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or a satellite facility, that complies with the provisions of this section."

The CAH off-campus location regulations at §485.610(e)(2) apply to off-campus distinct part units, as defined at §485.647, *to* departments that are off-campus, *to* remote locations of CAHs, as defined at §413.65(a)(2), *and, on or after October 1, 2010, to off-campus facilities that furnish only clinical diagnostic laboratory tests operating as parts of CAHs*. The requirements apply, regardless of whether the CAH is a grandfathered necessary provider CAH or not. However, the regulations also specifically state that they do not apply to RHCs that are provider-based to a CAH.

These regulations also do not apply to the following types of facilities/services owned and operated by a CAH, because such facilities or services generally are not eligible for provider-based status, in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASCs);
- Comprehensive outpatient rehabilitation facilities (CORFs);
- Home Health Agencies (HHAs);
- Skilled nursing facilities (SNFs);
- Hospices;
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, *other than those operating as parts of a CAH,* or facilities that furnish only some combination of these services.
- ESRD facilities;
- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g., laundry, or medical records department; and
- Ambulances.

In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based, it is unlikely that there are new FQHCs that meet the provider-based criteria, since Health Resources and Services Administration (HRSA) requirements for separate FQHC governance make it unlikely an FQHC could meet provider-based governance requirements. However, there are grandfathered FQHCs that are eligible for provider-based status.

Provider-based determinations are site-specific and based on the facility's location with respect to the main campus when the attestation is made to the RO. If a CAH relocates an off-campus facility, including off-campus facilities that were in existence prior to January 1, 2008, and are currently grandfathered, the off-campus facility must comply with the requirements at §485.610(e)(2) and the provider-based rules at §413.65. The CAH will resubmit an attestation to the RO for the new location to determine if it meets all the requirements at the new location.

In addition, if the main campus of the CAH relocates, it may wish to obtain a provider-based determination for all of its off-campus locations. However, this is a voluntary decision on the part of the CAH. There is no need for a new determination of compliance with the CAH location requirements at §485.610(e)(2) when there is no change of location of the off-campus facilities. If the CAH seeks a provider-based determination, the RO conducts the review in the same manner as described below.

CAH Provider-based Locations "Under Development"

CAHs that were in the process prior to January 1, 2008, of building or acquiring off-campus facilities for which they intend to seek provider-based status are evaluated on a case-by-case basis by the RO to determine if the project was "under development" prior to January 1, 2008. In determining whether a provider-based location was "under development" prior to January 1, 2008, the RO considers whether the following (among other factors) had occurred as of that date:

- Architectural plans were completed;
- Letting of bids for construction;
- Purchase of land and building supplies;
- Expenditure of funds for construction;
- Financing commitments were secured;
- Zoning approvals were received;
- Application for certificate of need received; and
- Necessary approvals from appropriate State Agencies were received.

In some cases, all of these steps may not have been completed, but the specific facts of the case provide ample evidence that the project was in an advanced stage of development. For example, construction of a facility might have been completed in December, but the State might not have completed processing the CAH's application to add the facility to the CAH's license before January 1, 2008. Thus, while all of the factors will be considered, the RO will make case-by-case determinations. In addition, the RO may consider any other evidence that it believes would indicate whether an off-campus provider-based location was under development as of January 1, 2008. If the RO determines that an entity was not under development as of January 1, 2008, then the off-campus facility will not be considered a grandfathered provider-based location (72 FR 66879).

Process Requirements

Under the general provider-based rules at §413.65, hospitals and CAHs are not required to seek an advance determination from CMS that their provider-based locations meet the provider-based requirements, but many choose to do so rather than risk the consequences of having erroneously claimed provider-based status for a facility. However, §485.610(e)(2) provides that a CAH can continue to meet the location requirement at §485.610(c) only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or 15 mile drive in the case of mountainous terrain or in areas where only secondary roads are available) from a hospital or another CAH. Therefore, a CAH must seek an advance determination of compliance with the location requirements for any off-campus provider-based facility established on or after January 1, 2008.

A facility that seeks such a determination must submit an attestation to the RO documenting how the facility complies with the CAH provider-based location requirements at §485.610(e)(2).

The RO survey and certification staff reviews the attestation for evidence that the CAH's off-campus facility is more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH. The RO utilizes the same process employed for assessing the compliance of a CAH applicant's main campus with the minimum distance criteria.

The RO financial management staff reviews the CAH's attestation for completeness and consistency with the provider-based rules. For purposes of this review, CMS considers issues such as the following. This list is provided for informational purposes only; it is not all-inclusive. The CAHs must *review* and comply with all applicable requirements at 42 CFR 413.65.

- The off-site facility must operate under the same license of the main provider, except in areas where the State requires a separate license for facilities that Medicare would treat as the department of the provider or in areas where State law does not address licensure.

- The clinical services of the off-site facility and the CAH main provider are fully integrated as evidenced by:

    - Professional staff have clinical privileges at the main provider;

- The main provider maintains the same monitoring and oversight of the off-campus facility as it does for any other department of the provider;

- The medical director or other similar official of the off-campus facility maintains a reporting relationship with the chief medical officer or other similar official of the main provider and is under the same type of supervision and accountability, and reporting as any other director, medical or otherwise of the main provider;

- Medical staff committees or other professional committees at the main provider are responsible for medical activities in the off-campus facility and the main provider. This includes quality assurance, utilization review, and the coordination and integration of services, to the extent practical, between the off-campus facility and the main provider;

- Medical records for patients treated in the off-campus facility are integrated into a unified retrieval system (or cross-referenced) of the main provider; and

- Inpatient and outpatient services of the off-campus facility and the main provider are integrated, and patients treated at the off-campus facility 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 of the main provider.

- The financial operations of the off-campus facility are fully integrated within the financial system of the main provider;

- The off-campus facility is held out to the public as part of the main provider. When patients enter the off-campus facility, they are made aware they are entering the main provider and will be billed accordingly;

- The off-campus facility is operated under the ownership (100 percent) and control of the main provider;

- The reporting relationship between the off-campus facility and the main provider must have the same frequency, intensity, and level of accountability that exists between the main provider and one of its existing departments;

- The off-campus facility is located within a 35 mile radius of the main provider. This distance is measured in radial miles or a straight line measurement between the main provider and the provider-based department, remote location, and/or distinct part unit;

- Off-campus outpatient departments must also comply with the following:

    - Physician services furnished in a department of the CAH must be billed with the correct site of service so that appropriate physician and practitioner payment amounts can be made;

- CAH outpatient departments must comply with all of the terms of the CAH's provider agreement, including the CAH Conditions of Participation at 42 CFR Part 485, Subpart F;

- Physicians working in departments of the main provider are obligated to comply with the non-discrimination provisions in §489.10(b);

- CAH outpatient departments must treat all Medicare patients, for billing purposes, as CAH outpatients; and

- When Medicare beneficiaries are treated in CAH outpatient departments that are located off-campus, the treatment is not required to be provided by the anti-dumping rules in §489.2, unless the off-campus facility meets the EMTALA definition of a dedicated emergency department found at 42 CFR 489.24(b).

Termination for Noncompliance

A CAH found out of compliance with the off-campus location requirements at §485.610(e)(2) is subject to termination of its Medicare provider agreement. In such cases the CAH is placed on a 90-day termination track, as outlined in §3012. If the CAH corrects the situation, by terminating during this 90 day period the off-campus provider-based arrangement that led to the non-compliance, then the provider agreement is not terminated.

A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.

Beginning October 1, 2010, off-campus CAH-owned clinical diagnostic laboratory facilities that do not satisfy the requirements to be provider-based to a CAH, including applicable distance requirements, may continue to participate separately in Medicare as a clinical diagnostic laboratory, but will no longer be considered to be part of the certified CAH.