DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-19-16-CAH

DATE: **August 08, 2019**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Critical Access Hospitals (CAHs) Adding a Provider-based Location

Memorandum Summary

Updates to the State Operations Manual (SOM) Chapter 2: The Centers for Medicare & Medicaid Services (CMS) updated the SOM Chapter 2 for CAHs adding a provider-based location:

- **SOM Chapter 2 Section 2004 - Provider-Based Determinations:** A sentence has been added to the end of the section instructing "For Critical Access Hospitals (CAHs) adding a provider-based location - also see SOM Chapter 2 Section 2256H - Off-Campus CAH Facilities – Process Requirements."

- **SOM Chapter 2 Section 2256H - Off-Campus CAH Facilities:** This section has been updated to clarify the process for CAHs adding a provider-based location to ensure the inclusion of verifying the CAH's continued compliance with the distance requirements at 42 CFR 485.610(e)(2).

Background

The *general* process for providers require the submission of a Form CMS-855 application to their respected Medicare Administrative Contractor (MAC). The MAC reviews the submission for compliance with the provider-based requirements at 42 CFR 413.65 and submits their recommendation to the applicable CMS Regional Office (RO). The CMS RO Division of Financial Management and Fee for Service Operations (DFMFFSO) makes the final determination under 42 CFR 413.65.

However, the CMS RO Division of Survey and Certification (DSC) verifies that the CAH, including its off-campus provider-based locations, 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, as required at 42 CFR 485.610(e)(2) and as described in section 2256H of the SOM.

This clarification is intended to ensure that *both reviews* (the CMS RO DSC review for compliance with the CAH distance requirements at 42 CFR 485.610(e)(2) and the MAC/RO DFMFFSO review for compliance with the provider-based rules at 42 CFR 413.65) are to be conducted prior to adding any new practice location(s) for CAHs.

The following is a summary of the clarifications made in the SOM to the process for when a CAH seeks to add a provider-based location:

If a CAH submits a provider-enrollment application (Form CMS-855) to its affiliated MAC noting that it is adding a provider-based location, the CAH should also submit documentation noting how it continues to comply with the CAH distance requirements at 42 CFR 485.610(e)(2) to ensure that the CAH will retain its status as a CAH.

The MAC reviews the CAH's Form CMS-855 for the addition of a provider-based location and, once completed, forwards the form and any submitted documentation to their CMS RO DSC for review of compliance with 42 CFR 485.610(e)(2). If the CAH does not submit documentation noting how it continues to comply with the CAH distance requirements in the provider-enrollment application (Form CMS-855), the CMS RO DSC requests that information from the CAH during their distance review.

The CMS RO DSC reviews the Form CMS-855 and any corresponding documentation from the CAH, as well as any information received from the SA, for evidence that the **CAH's off-campus provider-based location 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.**

If the CMS RO DSC verifies that the CAH **will continue to meet** the CAH distance requirements with the added provider-based location, the CMS RO DSC issues a tie-in notice and notifies the MAC, the CMS RO Division of Financial Management and Fee for Service Operations (DFMFFSO), and the SA of the tie-in.

However, if the CMS RO DSC review verifies that the CAH's provider-based location **does not meet** the CAH distance requirements at §485.610(e)(2), the CMS RO DSC notifies the CMS Central Office (CO), the MAC, the CMS RO DFMFFSO, and the SA. Once notified of the CMS RO DSC review:

- The MAC does not take further action on the submitted CAH Form CMS-855 to add the provider-based location (under Chapter 15 of the Medicare Program Integrity Manual) until the MAC is notified of the CAH's decision as outlined below.

- The CMS RO DSC informs the CAH that its provider-based location causes the CAH to no longer meet the 42 CFR 485.610(e)(2) distance requirement and offers the CAH the following options (A, B, or C):

    A. **Termination of participation:** By adding the provider-based location, the CAH would be placed on a 90 day involuntary termination track (as outlined in Section 3012 of the SOM) or the CAH can voluntarily terminate its participation from the program all together.

B. **Continued CAH certification:** The CAH may retain its CAH status by terminating the off-campus provider-based location arrangement that led to the non-compliance with the 42 CFR 485.610(e)(2) distance requirements within the 90 day termination period or by physically moving the provider-based location so that the distance requirements are met.

C. **Conversion:** The CAH may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. The effective date of the CAH's hospital certification would coincide with the effective date of termination of CAH status. See Section 2005 of the SOM for the Medicare enrollment process.

Once the CMS RO DSC notifies the MAC of its review that the CAH is in compliance with 42 CFR 485.610(e)(2) distance requirements or, if not in compliance, of the CAH's choice of option A, B, or C (as described above), the MAC then proceeds with sending the Form CMS-855 and its recommendation for approval on the provider-based location to its affiliated CMS DFMFFSO for a determination under 42 CFR 413.65.

- The CMS RO DFMFFSO reviews the Form CMS-855 and confers with CMS CO and RO DSC on specific issues as needed.

- The CMS RO DFMFFSO sends the CAH/Hospital (Form CMS-855 applicant) a notice letter with the determination on its request for provider-based location designation, with copies sent to the MAC, CMS RO DSC, and the SA.

Updates to Publication 100-07 - SOM Chapter 2 are attached. The CMS Center for Program Integrity (CPI), Provider Enrollment Division released Publication 100-08, Program Integrity Manual, Chapter 15 to align with this guidance which will instruct the MACs.

Contact: If you have questions or concerns regarding this information, please send an email to the CAH program within the Division of Acute Care Services at QSOG_CAH@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David Wright
Director

Attachment – Advanced Copy SOM Chapter 2, Sections 2004 and 2256H

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal **Date:**

SUBJECT: Revisions to Medicare State Operations Manual (SOM) Chapter 2 The Certification Process, Section 2004 - Provider-Based Determinations and Section 2256H - Off-Campus CAH Facilities.

I. SUMMARY OF CHANGES: Revisions are being made to SOM Chapter 2 to clarify the process for Critical Access Hospitals (CAH) adding a provider-based location.

NEW/REVISED MATERIAL –
EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	SOM Chapter 2/ 2004/ Provider-Based Determinations
R	SOM Chapter 2/ 2256/ H/ Off-Campus CAH Facilities

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2019 operating budgets.

IV. ATTACHMENTS:

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

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Chapter 2 - The Certification Process

Table of Contents
(Rev.)

"Distinct Part" and "Provider-Based" are not synonymous terms. When a location, department, remote location or satellite is established as being provider-based, it is an integral part of the provider, covered by the provider's Medicare agreement, and therefore subject to the same Medicare conditions of participation as any other part of that provider. Unless covered by a specific exception listed in the rule, the provider-based regulations at §413.65 apply to any provider of services under the Medicare program, as well as to physicians' practices or clinics or other suppliers that are not themselves providers, but which the provider asserts are an integral part of that provider.

Providers are not required to seek a determination from CMS that all of their provider-based components satisfy the provider-based rules at 42 CFR 413.65, but they may voluntarily seek such determinations. The RO Division of Financial Management makes provider-based determinations in response to a specific request. If a provider requests the SA for a provider-based determination under the Medicare program for one or more of its component services, the SA must notify the RO immediately so that the request can be routed appropriately to the RO Division of Financial Management. In the case of a request concerning an off-campus department, remote location or satellite, the provider's survey and certification file about the locations included under its provider agreement must not be revised to add the new location until and unless the provider is issued a positive determination about its request.

For Critical Access Hospitals (CAHs) adding a provider-based location – also see SOM Chapter 2, Section 2256H – Off-Campus CAH Facilities – Process Requirements.

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.

If a non-IHS or non-Tribal CAH operates an off-campus provider-based facility, its proximity to an IHS or Tribal CAH or hospital is not considered when determining compliance with these requirements. Similarly, if an IHS or Tribal CAH operates an off-campus provider-based facility, its proximity to a non-IHS or non-Tribal CAH or hospital is not considered when determining compliance.

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."
>
> "**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."
>
> **"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 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 departments of a hospital or CAH, 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 were in operation prior to April 7, 2000, which are permitted to retain their 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 or under development 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.

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 *should* seek an advance determination of compliance with the *CAH* location requirements for any off-campus provider-based facility established on or after January 1, 2008.**

If a CAH submits a provider-enrollment application (Form CMS-855) to its affiliated Medicare Administrative Contractor (MAC) noting that it is adding a provider-based location, the CAH should also submit documentation noting how it continues to comply with the CAH distance requirements at §485.610(e)(2) to ensure that the CAH will retain its status as a CAH.

The MAC reviews the CAH's Form CMS-855 for addition of a provider-based location and, once completed, forwards the form and any submitted documentation to their CMS affiliated Regional Office (RO) Division of Survey and Certification (DSC) for review of compliance with §485.610(e)(2). If the CAH does not submit documentation noting how it continues to comply with the CAH distance requirements in the provider-enrollment application (Form CMS-855), the CMS RO DSC requests that information from the CAH during their distance review.

The RO *DSC* reviews the *Form CMS-855 and any corresponding documentation from the CAH as well as any information received from the SA* for evidence that the **CAH's off-campus *provider-based location* 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.**

*If the RO DSC verifies that the CAH **will continue to meet** the §485.610(e)(2) distance requirements with the added provider-based location, the RO DSC issues a tie-in notice and notifies the MAC, the CMS RO Division of Financial Management and Fee for Service Operations (DFMFFSO), and the SA of the tie-in.*

*However, if the RO DSC review verifies that the CAH's provider-based location **does not meet** the CAH distance requirements at §485.610(e)(2), the RO DSC notifies the CMS Central Office (CO), the MAC, the RO DFMFFSO, and the SA. Once notified of the RO DSC review:*

- *The MAC does not take further action on the submitted CAH Form CMS-855 to add the provider-based location (under Chapter 15 of the Medicare Program Integrity Manual) until the MAC is notified of the CAH's decision as outlined below.*

- *The RO DSC informs the CAH that its provider-based location causes the CAH to no longer meet the §485.610(e)(2) distance requirement and offers the CAH the following options (A, B, or C):*

  A. ***Termination of participation:*** *By adding the provider-based location, the CAH would be placed on a 90 day termination track (as outlined in Section 3012 of the SOM) or the CAH can voluntarily terminate its participation from the program all together.*

  B. ***Continued CAH certification:*** *The CAH may retain its CAH status by terminating the off-campus provider-based location arrangement that led to the non-compliance with the §485.610(e)(2) distance requirements within the 90 day termination period or by physically moving the provider-based location so that the distance requirements are met.*

  C. ***Conversion:*** *The CAH may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. The effective date of the CAH's hospital certification would coincide with the effective date of termination of CAH status. See Section 2005 of the SOM for the Medicare enrollment process.*

Once the RO DSC notifies the MAC of its review that the CAH is in compliance with §485.610(e)(2) distance requirements or, if not in compliance, of the CAH's choice of option A, B, or C (as described above), the MAC then proceeds with sending the Form CMS-855 and its recommendation for approval on the provider-based location to its affiliated RO DFMFFSO for a determination under §413.65.

- *The RO DFMFFSO reviews the Form CMS-855 and confers with CMS CO and RO DSC on specific issues as needed.*

- *The RO DFMFFSO sends the CAH/Hospital (Form CMS-855 applicant) a notice letter with the determination on its request for provider-based location designation, with copies sent to the MAC, RO DSC, and the SA).*

The CAH must comply with all applicable requirements at *§485.610(e)(2) for the distance requirements and §*413.65 *for the provider-based rules*.

During the review process, CMS *RO DFMFFSO also* considers *additional* issues such as the following (this list is provided for informational purposes only; it is not all-inclusive):

- 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 *that is* found *to be* 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 *noncompliance within this 90-day period,* by terminating 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) *distance requirements* 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 th*e* scenario *of a CAH not meeting the CAH distance requirements at §485.610(e)(2), the CAH would have the choice of A, B, or C –*

A. ***Termination of Participation:*** *By adding the provider-based location, the CAH would be placed on a 90 day termination track (as outlined in Section 3012 of the SOM) or the CAH can voluntarily terminate its participation from the program all together.*

B. ***Continued CAH certification:*** *The CAH may retain its CAH status by terminating the off-campus provider-based location arrangement that led to the non-compliance with the §485.610(e)(2) distance requirements within the 90 day termination period or by physically move the provider-based location so that the distance requirements are met.*

C. ***Conversion:*** *The CAH may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. If the CAH fails to comply with the CAH CoPs, and fails to convert and comply to the hospital CoPs, the provider agreement will be terminated. If* the CAH appl*ies* to convert back to a hospital *and meets the hospital CoPs,* the effective date *of the CAH's hospital certification would* coincid*e* with the *effective* date of termination of CAH status. A new CCN number would be assigned accordingly. *See Section 2005 of the SOM for the Medicare enrollment process.*

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.