
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 143

Date: July 31, 2015

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 2, The Certification Process and Appendix W, Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

I. SUMMARY OF CHANGES: Revisions are being made to portions of Chapter 2, section 2256 and Appendix W, tags C-0160, C-0162, C-0165, C-0168 to reflect the revised regulation at 42 CFR 485.610(b)(5), concerning loss of rural status due to adoption of the latest Office of Management and Budget metropolitan statistical area delineations. Additional revisions are needed to clarify existing guidance related to requirements concerning CAH location requirements relative to other CAHs or hospitals.

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 31, 2015

IMPLEMENTATION DATE: July 31, 2015

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	2/2256 RO Procedure for CAH Approval/Section 2256A Verification Criteria
R	2/2256 RO Procedure for CAH Approval/Section 2256H Off-Campus CAH Facilities
R	Appendix W/C-0160/§485.610 Condition of Participation: Status and Location
R	Appendix W/C-0162/§485.610(b) Standard: Location in a Rural Area or Treatment as Rural
R	Appendix W/C-0165/[§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification]
R	Appendix W/C-0168/[§485.610(e)(2) and (3) §485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:]

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

(Rev.143, Issued: 07-31-15)

2256A - Verification Criteria

(Rev.143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

If the provider is a hospital, CAH verification requires that the RO review the facility file to determine if the prospective CAH is in compliance with the hospital CoPs in 42 CFR Part 482 at the time it made application for designation as a CAH (see [42 CFR 485.612](#)). If the provider is a closed hospital or a downsized hospital, it is not necessary that they meet hospital CoPs at the time of application or on conversion.

The RO will reverify compliance with 42 CFR 485.610(a) and (b) and has primary responsibility to verify compliance with 42 CFR 485.610(c) and (d).

***NOTE:** A hospital applying for CAH certification should **not** be surveyed until after the RO determined that the applicant is compliant with the CAH location and distance requirements. If the survey is conducted prior to the RO making a determination regarding the applicant's compliance with the location and distance requirements, and the RO finds that the applicant is noncompliant, the application must be denied. The applicant may submit a reapplication for CAH certification in connection with the initial enrollment application – using the guidance in Chapter 2 of the SOM, §2005A2.*

Rural location

Among other requirements, pursuant to 42 CFR 485.610(b), all CAH applicants and existing CAHs, *including necessary provider CAHs*, must either be:

- Located in a rural area; or
- Treated as rural in accordance with 42 CFR 412.103

in order to be eligible for CAH designation *and certification*.

Only the CMS Regional Office makes the determination whether a CAH applicant or existing CAH meets the rural location requirement, following the instructions below. However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey. If the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

- *Located in a rural area – i.e., outside a Metropolitan Statistical Area (MSA)*

Under 42 CFR 485.610(b)(1)(i), a rural area is any area that is outside a MSA, as defined by the Federal Office of Management and Budget (OMB). *In making a determination*

regarding the rural status of a CAH, the CMS RO first consults the latest OMB MSA delineations that have been adopted by CMS.

OMB conducts a comprehensive review of its MSA delineations once a decade and also conducts periodic updates between decennial censuses based on Census Bureau data. When OMB releases revised statistical area delineations, typically CMS adopts the new delineations in the next hospital Inpatient Prospective Payment System (IPPS) rule, which is usually proposed in April of each year, published as a final rule in August and effective on October 1st following the final rule publication date. If an IPPS final rule has been released during a time when OMB has not released revised statistical area delineations, the most recently-released OMB delineations adopted by CMS remain in effect. Accordingly, the RO must consult the MSA delineations used for the purpose of the final IPPS rule that is in effect at the time of:

- The Medicare Administrative Contractor's (MAC) determination that a hospital has submitted a complete application to convert to CAH certification; or*
- At the time of the RO's recertification review of an existing CAH.*

The most recent final IPPS rules can be found on CMS' Acute Inpatient PPS webpage:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>

ROs may use the following instructions to locate the OMB MSA delineations in effect at the applicable time for a rural location determination:

- 1. Go to the Acute Inpatient PPS webpage noted above.*
- 2. Select the link for the IPPS final rule in effect at the applicable time for the initial applicant or at the time of the recertification decision for an existing CAH. For example, if a CAH is up for recertification and the RO is evaluating the CAH's compliance with the rural location requirement on February 1, 2016, the most recent OMB MSA delineations adopted by CMS would be those effective October 1, 2015 and the RO would select "FY 2016 IPPS Final Rule Home Page" from the list of IPPS rules on the left-hand column. On the other hand, if the RO is evaluating the existing CAH's compliance on September 10, 2015, it would select the FY 2015 IPPS Final Rule Home Page, since the FY 2016 rule would not go into effect until October 1, 2015.*
- 3. Select the link for final rule data files. For example, on the FY 2015 IPPS Final Rule Home Page, select the link titled "FY 2015 Final Rule Data Files."*
- 4. In the Downloads section at the bottom of the page, select the link for the "County to CBSA Crosswalk File."*
- 5. Select the Excel file. For example, for the FY 2015 IPPS final rule, select the file titled "CBSAtoCountycrosswalk_FY15_FR.xlsx."*
- 6. Search for the county in which the CAH is located. If the IPPS rule has adopted revised OMB statistical delineations, the revised information will be found in column*

“G”, which is titled, “New CBSA” (Blanks are Rural).” Column G includes the CBSA code for each county. If the cell is blank, the county is a rural county. If all of Column G is blank, this means that the final IPPS rule did not include adoption of revised OMB statistical delineations, and that the delineations from a prior final rule remain in effect.

- **Even if the *existing* CAH or CAH applicant is located outside an MSA and therefore is in a rural area, it is also necessary to determine that it is also not:**
 - Located in an area that has been recognized as urban in accordance with 42 CFR 412.64(b), excluding §412.64(b)(3);
 - Classified as an urban hospital in accordance with 42 CFR 412.230(d) *(NOTE: 42 CFR 412.230(d) became 412.230(d) in 2001)*; or
 - Redesignated to an adjacent urban area in accordance with 42 CFR 412.232.

Financial staff in the RO should be able to provide information on whether the CAH applicant falls in one of the above three categories, since 42 CFR Part 412 are regulations developed primarily for payment purposes.

- *Located within an MSA, but treated as rural*

Even if the CAH applicant is located in an MSA, it may nevertheless qualify to be “treated” as rural if it is a hospital that has been reclassified as rural in accordance with 42 CFR 412.103, i.e., it was reclassified based on:

- Being located in a rural census tract of a MSA per the most recent version of the Goldsmith Modification or the Rural-Urban Commuting codes, as determined by the Office of Rural Health in the Health Resources and Services Administration. (See http://www.hrsa.gov/ruralhealth/policy/definition_of_rural.html);

Or

- It would qualify as a rural referral center or a sole community hospital if it were located in a rural area;

Or

- It is located in an area designated under any State law (including State regulation) as a rural area, or has been designated as a rural hospital under State law (including regulation).

Rural reclassifications are handled by the CMS RO Office of Financial Management. RO survey and certification staff should consult with their financial management

counterparts to determine whether a reclassification has been made that would permit a CAH applicant or existing CAH to be treated as rural.

In the case of an initial application for CAH status by a hospital, the application must be denied if the hospital applicant is located within an MSA or has not been reclassified in a manner that allows it to be treated as rural. If the applicant subsequently succeeds in being reclassified as rural, it may submit a reapplication for CAH certification in connection with the initial enrollment application – using the guidance in Chapter 2 of the SOM, §2005A2 – on or after the effective date of its reclassification. If the hospital was surveyed for compliance with the CAH CoPs as part of its prior denied application, it must nevertheless be surveyed again; however, this survey does not require an on-site visit if the hospital is otherwise in substantial compliance with the CAH CoPs. (NOTE: This should be a rare occurrence as a hospital applying for CAH certification should **not** be surveyed until the RO has determined that the applicant is in compliance with the CAH location and distance requirements). The effective date of its CAH conversion must be no earlier than the date when the applicant demonstrates compliance with all requirements to be certified as a CAH.

In the case of an existing CAH that is being recertified, the RO first determines whether the CAH is outside of an MSA, using the OMB MSA delineations adopted by CMS and in effect at the time the RO is processing the CAH's recertification. If the CAH is no longer outside an MSA, the RO must consult with the RO Office of Financial Management to determine whether there is a reclassification in effect that permits the CAH to be treated as rural.

If the existing CAH previously was outside an MSA, but is now in an MSA and has not been reclassified as rural, the CAH may continue to retain its CAH status up to two years after the effective date of CMS's adoption of the OMB MSA delineations that changed the CAH's rural status. The CAH is responsible at all times for ensuring that it meets the requirement at §485.610(b) to be considered rural. Therefore, in order to continue participating in the Medicare program, during the two-year grace period the CAH is expected either to successfully be reclassified to be treated as rural or to have completed conversion to a Medicare-certified hospital, including demonstrating compliance with the hospital CoPs at 42 CFR Part 482. Note that a recertification review of the CAH's status and location by the RO is triggered any time:

- An SA conducts a full survey of a CAH, whether for recertification of a non-accredited CAH, for a validation survey of a deemed status CAH, or when following up on a prior complaint survey and the RO requires a full survey; or
- An accrediting organization reaccredits a deemed status CAH and recommends to the RO continued deemed status.

If the recertification review of the CAH takes place more than two years after the effective date of the CMS adoption of revised OMB MSA delineations that resulted in the CAH's loss of rural status and the CAH has not been reclassified to be treated as rural,

the CAH is substantially noncompliant with the CAH Status and Location CoP (§485.610) and the RO takes action to terminate the CAH's Medicare agreement.

Examples:

- *Example 1: The RO is conducting a recertification review of a CAH in January, 2016. When CMS initially certified the CAH, it determined that the CAH was located outside of an MSA. However, for the purposes of this example, the OMB MSA delineations that were adopted by CMS and effective October 1, 2014 resulted in the CAH being located within an MSA. The CAH had a maximum of two years – up to and including October 1, 2016 - to retain its CAH certification status. However, the CAH did not seek reclassification to be treated as rural. After conducting its January 2016 review, the RO would notify the CAH that it no longer satisfies the CAH rural status requirement and could remain certified as a CAH only until October 1, 2016. The CAH would then have 10 months to either be reclassified as rural or to complete conversion to CMS-certified hospital status in order to avoid termination of its Medicare agreement.*
- *Example 2: The CAH in Example 1 was not reviewed for recertification until January 2017, a date more than two years after the effective date of its changed MSA status. Additionally, the CAH had not been reclassified as rural and had not converted to hospital certification. In this situation, the CMS RO would determine that the CAH does not satisfy the CAH rural status requirement and would take action to terminate the CAH's Medicare agreement.*
- *Example 3: For the purposes of this example only, revised OMB MSA delineations were released in May 2014, proposed for adoption by CMS as part of the IPPS rule in April 2015, adopted by CMS August 8, 2015, and became effective October 1, 2015. Furthermore, a MAC determined that an initial CAH applicant's application was complete and could be recommended to the RO and SA for approval as of June 5, 2015, contingent upon the CAH being certified by CMS. Also the CAH applicant was recommended for deemed status by a CMS-approved Medicare CAH accreditation program, with an August 15, 2015 accreditation effective date. In this case, the RO would use the OMB MSA delineations that CMS had most recently adopted as of June 5, 2015, i.e., those adopted by CMS effective October 1, 2014, in making its determination about rural status, and found that the CAH was outside an MSA and certified it as a CAH effective August 15, 2015. The RO does this even though OMB released more recent delineations in May 2014 and CMS has already adopted a rule incorporating the later OMB MSA delineations. Since the adoption of the later delineations is not effective until October 1, 2015, the RO must use the MSA delineations previously adopted by CMS and applicable on June 5, 2015.*
- *Example 4: Finally, using the CAH in Example 3, the CAH is now located inside an MSA based on revised OMB MSA delineations adopted by CMS effective October 1, 2015. As a result, the CAH no longer meets the rural location requirement as of October 1, 2015, but may retain its CAH status until October 1, 2017. Note that in*

this case the CAH is not due for reaccreditation and recertification until August 2018, which is after the end of the grace period. If the CAH has neither been successfully reclassified as rural nor converted to a hospital by October 1, 2017, the RO would take action to terminate the CAH's Medicare agreement.

In all of the above examples, the CAH has primary responsibility for monitoring changes in its rural status resulting from CMS's adopted revised OMB MSA delineations, and taking appropriate action if it loses its rural status on the basis of the revised delineations.

Necessary Provider Status and Rural Reclassification

Necessary provider certification only provides an exemption from the CAH distance requirements relative to other CAHs and hospitals. Necessary provider CAHs are still required to meet the rural location requirement; therefore, if a necessary provider CAH is located within an MSA as a result of a change in the OMB MSA delineations adopted by CMS, it must follow the same procedures noted above as any other CAH.

Location relative to other facilities or necessary provider certifications:

In addition, the regulations at 42 CFR 485.610(c) specify that one of the following 3 *minimum driving* distances from other facilities requirements must be met:

- **35-Mile Distance**: The CAH must be located more than a 35-mile drive from any hospital or other CAH; or
- **15-Mile Distance**: In the case of mountainous terrain or in areas with only secondary roads available, the CAH must be located more than a 15-mile drive from any hospital or other CAH; or
- **No Distance Requirement**: In the case of a CAH that was designated by the State as being a necessary provider of health care services to residents in the area before January 1, 2006, there is no minimum distance requirement.

In determining whether a currently certified CAH or a CAH applicant meets the location requirements at §485.610(c), the proximity of IHS/Tribal hospitals or CAHs and non-IHS/Tribal hospitals or CAHs to each other is not considered.

The following examples clarify how determinations are to be made when IHS or Tribal hospitals or CAHs are in the vicinity of non-IHS or non-Tribal hospitals or CAHs:

- *Example 1: Hospital A is seeking CAH certification and is a 10-mile drive from Hospital B, an IHS hospital. Hospital C is the next nearest hospital/CAH and is a 42-mile drive from Hospital A. The distance to Hospital B is not considered; Hospital A meets the minimum distance to another CAH or hospital requirement.*

- *Example 2: CAH A is a tribal facility that is being reviewed as part of the recertification process. It is a 17-mile drive from a non-tribal/non-IHS CAH (CAH B). It is also a 75-mile drive from an IHS hospital (Hospital C). The distance to CAH B is not considered; CAH A continues to meet the minimum distance to another CAH or hospital requirement.*
- *Example 3: Hospital A is a tribal hospital seeking CAH certification and is a 33-mile drive along primary roads to an IHS hospital, Hospital B. It is also a 50-mile drive to Hospital C, a non-IHS/non-tribal hospital. The distance to Hospital B is considered; Hospital A does not meet the minimum distance to another CAH or hospital requirement.*

If a CAH is located on an island and the location meets the following characteristics, the CAH is considered to be in compliance with the distance requirements relative to other hospitals and CAHs under §485.610(c):

- *The island is entirely surrounded by water;*
- *The CAH is the only hospital or CAH on the island; and*
- *The island is not accessible by any roads.*

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

In demonstrating that it meets the standard for more than a 35-mile drive, a CAH applicant must document that there is no driving route from the applicant to any other CAH or hospital that is 35 miles or less in length.

Application of the more than 15-mile drive standard, based on mountainous terrain

Slope and ruggedness of the terrain around the CAH, together with absolute altitude (the distance above sea level), determine many of the fundamental characteristics of mountainous terrain.¹ However, being located at a high elevation does not, in and of itself, constitute “mountainous terrain,” nor does being located at the foot of a mountain or where mountains can be viewed. Further, the absolute altitude required to constitute mountainous terrain will vary in different regions. For example, the altitude of the Appalachian Mountains is considerably lower than that of the Rocky Mountains, yet the slope and ruggedness of the terrain in many portions of the Appalachians is mountainous. Furthermore, roads passing through mountainous terrain are characterized by certain typical engineering features. For the purposes of determining a CAH’s eligibility for the 15-mile drive standard based on mountainous terrain, the roads on the travel route(s) to hospitals or other CAHs must meet the following criteria:

¹ United Nations Environment Programme World Conservation Monitoring Centre. (2002). *Mountain Watch*. Retrieved August 11, 2010, from http://www.unep-wcmc.org/mountains/mountain_watch/pdfs/.

- Over 15 miles of the roads on the travel route(s) from the CAH to any hospital or another CAH must be located in a mountain range, identified as such on any official maps or other documents prepared for and issued to the public;

and

- Since being located within a mountain range in and of itself does not mean that the drive to any other hospital or CAH includes travel through “mountainous terrain,” the roads on the travel route(s) from the CAH to any other hospital or CAH must have either of the following characteristics:

- Extensive sections of roads with steep grades (i.e., greater than 5 percent), continuous abrupt and frequent changes in elevation or direction, or any combination of horizontal and vertical alignment that causes heavy vehicles to operate at crawl speeds for significant distances or at frequent intervals.² (Horizontal alignment refers to the “straightness” of the roadway, vertical alignment refers to the roadway’s “flatness,” and crawl speed is the speed at which a truck has no power to accelerate on long, steep grades.^{3,4} Thus, roads in mountainous terrain are commonly described as winding and steep);

or

- Be considered mountainous terrain by the State Transportation or Highway agency, based on significantly more complicated than usual construction techniques that were originally required to achieve compatibility between the road alignment and surrounding rugged terrain. For example, because the changes in elevation and direction are abrupt in mountainous terrain, roadbeds may require frequent benching, side hill excavations, and embankment fills.⁵

A letter from the State Transportation or Highway agency specific to the travel route(s) in question is required to support the claim of mountainous terrain based on either of these sets of road characteristics.

It is not uncommon for there to be roads (or sections of roads) through mountainous areas that do not meet the criteria for “mountainous terrain.” A CAH would qualify for application of the mountainous terrain criterion if there is a combination of mountainous and non-mountainous terrain between it and any other hospital or CAH, so long as there is no route to any hospital or other CAH with 15 or fewer miles of roads in mountainous terrain. When calculating the mountainous terrain travel distance to any hospital/other

² Mannering, F. L., Washburn, S. S., & Kilareski, W. P. (2009). *Principles of Highway Engineering and Traffic Analysis*. Hoboken, NJ: John Wiley and Sons, Inc

³ *Highway Capacity Manual: 2000 (U. S. Customary Units)* by Transportation Research Board (Dec. 2000). p 23-9.

⁴ Donnell, E. T., Ni, Y., Adolini, M., & Elefteriadou, L. (2001). *Speed prediction models on two-lane rural highways*. Transportation Research Record, 1751, 44-55.

⁵ Mannering, F. L., Washburn, S. S., & Kilareski, W. P. (2009). *Principles of Highway Engineering and Traffic Analysis*. Hoboken, NJ: John Wiley and Sons, Inc.

CAH, subtract the total distance represented by those sections of the travel route that are not considered “mountainous terrain.” For example, if the route to the nearest hospital consisted of 12 miles in mountainous terrain, followed by 5 miles in non-mountainous terrain, followed by 4 miles in mountainous terrain, then the requirement for a total of more than 15 miles would be met (12 miles plus 4 miles – or 21 miles minus 5 miles – yield 16 total miles of mountainous terrain).

Application of the more than 15-mile drive standard, based on secondary roads

To be eligible for the lesser distance standard due to the secondary road criteria under §485.610(c) the CAH must document that there *is a drive of* more than 15 miles between the CAH and any hospital or other CAH where there are no primary roads. A primary road is:

- *Any US highway, including any road:*
 - *In the National Highway System, as defined in 23 US Code §103(b); or*
 - *In the Interstate System, as defined in US Code §103(c); or*
 - *Which is a US-Numbered Highway (also called “US Routes” or “US Highways”) as designated by the American Association of the State Highway and Transportation Officials (AASHTO), regardless of whether it is also part of the National Highway System;*

All US highways are readily identified via signage along the roads and on maps by the presence of “US” or “I” above the highway number, with the letters and number appearing on a distinctive, uniform shield background that is called the six point shield, with five points above and one below. Note: Although the National Highway System and the U.S. Numbered Highway system largely overlap, they are not identical. According to the American Association of the State Highway and Transportation Officials (AASHTO), which is responsible for designation of roads in the U.S. Numbered Highway system, the system is intended to facilitate the movement of interstate traffic in two or more States with the use of uniform markings.⁶

Given the role all US highways are intended to play in interstate commerce, they are, by definition, primary roads.

OR

- A numbered State highway with 2 or more lanes each way;

OR

⁶ *AASHTO Special Committee on U.S. Route Numbering. Retrieved June 17, 2014, from: http://route.transportation.org/Documents/HOI_Policy_Establ_Develop_USRN.pdf*

- A road shown on a map prepared in accordance with the U.S. Geological Survey's Federal Geographic Data Committee (FGDC) Digital Cartographic Standard for Geologic Map Symbolization as a "primary highway, divided by median strip."

A CAH may qualify for application of the "secondary roads" criterion if there is a combination of primary and secondary roads between it and any hospital or other CAH, so long as more than 15 of the total miles from the hospital or other CAH consists of areas in which only secondary roads are available. To apply the secondary roads criterion, measure the total driving distance between the CAH and each hospital or CAH located within a 35-mile drive and subtract the portion of that drive in which primary roads are available. If the result is more than 15 miles for each drive to a hospital or CAH facility, the 15-mile criterion is met.

The RO *will review* Web-based map servers, *such as Google Maps, or NationalAtlas.gov for example*, to determine whether the provider meets the requirements of 42 CFR 485.610(c). *The RO will also review any documentation the provider may submit to demonstrate that it meets either the mountainous terrain or secondary roads criterion of §485.610(c), but such documentation must satisfy the requirements discussed above. For example, CMS does not consider any issues raised by CAH applicants or other parties concerning the physical features of any specific US highway, or portion thereof, when making a CAH location determination. Therefore, documentation submitted by the applicant indicating that a particular portion of a US highway has numerous curves, or a weight limitation, or narrow shoulders, etc. would not affect the RO's determination that the highway is a primary road.*

2256H – Off-Campus CAH Facilities

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.”

“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 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 CAH must also review and comply with all applicable requirements at 42 CFR 413.65. If the CAH voluntarily seeks a determination that it meets the requirements of §413.65, 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 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.

State Operations Manual

Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev.143, Issued: 07-31-15)

C-0160

(Rev.143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

§485.610 Condition of Participation: Status and Location

Interpretive Guidelines §485.610

The CAH must meet the location requirements of §485.610(b) and §485.610(c) at the time of the initial survey. Compliance with these location requirements must be reconfirmed at the time of every subsequent *recertification (including the recertification of a deemed status CAH whose accreditation has been renewed)*. If the CAH moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and (c). *If a CAH that has been certified on the basis of having been designated by the State as a necessary provider moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and §485.610(d).*

C-0162

(Rev.143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

§485.610(b) Standard: Location in a Rural Area or Treatment as Rural

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of *paragraph (b)(3), (b)(4), or (b)(5)* of this section.

(1) The CAH meets the following requirements:

- (i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter;
- (ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter and is not among a group of hospitals have been redesignated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2010, was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

(5) Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most recent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as defined by OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, is located in an urban area.

Interpretive Guidelines §485.610(b)

Among other requirements, pursuant to 42 CFR 485.610(b), all CAH *applicants and existing CAHs, including necessary provider CAHs*, must either be:

- located in a rural area; or
- treated as rural in accordance with 42 CFR 412.103

in order to be eligible for CAH designation *and certification*. (The temporary provisions at 42 CFR 485.610(b)(3) and (4) have expired and no longer apply.)

Only the CMS Regional Office makes the determination whether a CAH applicant or existing CAH meets the rural location requirement, following the instructions below. However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey, following the guidance provided in Section 2256A of the SOM. If

the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

Survey Procedures §485.610(b)

*Conduct an informal assessment of the CAH's rural status, following the procedures in Section 2256A of the SOM, and if it appears the CAH no longer has rural status, confer with the CMS RO prior to scheduling the *initial* or *recertification* survey.*

C-0165

(Rev.143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

[§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification]

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guidelines §485.610(c)

A CAH that has not been designated by a State as a necessary provider prior to December 31, 2005 must be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from any other CAH or hospital. An exception is made for Indian Health Service (IHS) or Tribal CAHs and hospitals that are located less than the 35 or 15 miles from another hospital or CAH. Given that IHS and Tribal CAHs and hospitals serve distinctly different populations, IHS CAHs and hospitals are excluded from consideration when determining the proximity of non-IHS hospitals seeking CAH certification to other CAHs or hospitals. For the same reason, when an IHS or Tribal hospital applies for certification to participate in Medicare as a CAH, CMS will consider only its proximity to other IHS and Tribal CAHs and hospitals in determining whether it meets the location requirement under section 485.610(c).

If a CAH is located on an island and the location meets the following characteristics, the CAH is considered to be in compliance with the distance requirements relative to other hospitals and CAHs under §485.610(c):

- *The island is entirely surrounded by water;*
- *The CAH is the only hospital or CAH on the island; and*
- *The island is not accessible by any roads.*

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006, States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate (see the discussion related to §485.610(d)). ROs and SAs should have the documentation related to a CAH's original designation as a necessary provider in the file on each CAH. If they do not, they should ask the CAH to supply copies of the original necessary provider designation documents.

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination. Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive, as applicable, from the CAH. In the event that an existing CAH that is not a grandfathered necessary provider no longer meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.

C-0168

(Rev.143, Issued: 07-31-15, Effective: 07-31-15, Implementation: 07-31-15)

[§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:]

- (2) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.**

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State [does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, or] creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

Interpretive Guidelines §485.610(e)(2) & (3)

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 at §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 15 miles in the case of mountainous terrain or an area with only secondary roads) from *any other CAH or hospital*. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement.

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 assessing compliance with the requirements of this section. 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 assessing compliance.

The drive to another hospital or CAH is to be calculated from the provider-based facility's location to the main campus of the other hospital or CAH. The distance to another hospital or CAH requirement does not apply to the following types of facilities/services, because such facilities or services 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, 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 the 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.

Those CAHs seeking a provider-based determination for newly created or acquired provider-based departments, remote locations and/or psychiatric or rehabilitation units located off-campus must submit an attestation to the Regional Office (RO), as specified in §2254H of the SOM, who makes the determination of whether it satisfies the CAH provider-based criteria at §485.610(e)(2), and the provider-based rules at §413.65. At the conclusion of its review, the RO will notify the CAH and the SA (and accreditation organization (AO), if applicable) of its determination.

If the SA or AO becomes aware of a provider-based off-campus facility that appears not to comply with the provider-based location requirements, the SA or AO must notify the RO. The RO will utilize the guidance in §2254H of the SOM to determine if the CAH satisfies the provider-based location requirements at §485.610(e)(2). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

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 of the SOM. If the CAH corrects the situation, by terminating the off-campus provider-based arrangement that led to the non-compliance during this 90 day period, 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.