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Center for Clinical Standards and Quality

Ref: QSO-26-15-CAH

DATE: August 21, 2026

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Critical Access Hospital (CAH) Evaluation of Compliance with the Rural and Distance Requirements

Memorandum Summary

To promote national consistency in evaluating compliance with the status and location requirements at 42 CFR 485.610 for currently certified CAHs and initial CAH determinations, the Centers for Medicare & Medicaid Services (CMS) is issuing updated guidance for use by CMS Location staff. This guidance addresses the following areas:

CAH Eligibility Verification

- Updates and clarifies the circumstances that trigger a CAH eligibility review, including proximal ACH identification, new CAH certification or conversion, and decennial reviews beginning in CY 2033.

CAH Provider-Based Location Review

- Evaluating whether a CAH's proposed provider-based location (PBL) will adversely impact a CAH's status.

CAH Decennial Reviews

- CMS is also implementing procedures for decennial reviews of existing CAHs to ensure they continue to meet rural status and distance requirements, including proximity to new acute care hospitals constructed since the previous evaluation.

State Survey Agency and CMS-Approved Accrediting Organization recertification surveys may be performed based on the CAH's existing recertification schedule and no longer require confirmation from CMS of rural and distance eligibility to proceed.

This memo supersedes S&C-16-08-CAH, which is now expired.

Background

Congress established the Critical Access Hospital (CAH) program to provide essential health services in rural communities where services may not be available so that patients can access care for emergencies and short-term inpatient services without traveling long distances. Sections 1820 and 1861(mm) of the Social Security Act (the Act) and implementing regulations at 42 CFR part 485, subpart F outline key eligibility requirements for CAHs and provides cost-based reimbursement from Medicare which generally allows for greater financial support to maintain the hospitals in these communities. As communities urbanize, transportation routes change, and new hospitals expand care, CMS periodically re-evaluates the eligibility of existing CAHs.

Section 1820(c)(2)(B) of the Act requires a CAH to be located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or to be treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act; *and* to be more than a 35-mile drive (15 miles in areas with only secondary roads or mountainous terrain) from a hospital (as defined at Section 1861(e) of the Act) or another facility as described in section 1820(c) of the Act.

The Office of Inspector General (OIG) report entitled, *"Most Critical Access Hospitals Would Not Meet the Location Requirements if Required to Re-enroll in Medicare,"* released August 14, 2013 (OEI-05-12-00080) recommended that CMS periodically reassess CAHs' compliance with all location-related requirements at 42 CFR 485.610. CMS concurred with the recommendation. The OIG subsequently called on CMS to maintain evidence that it is routinely re-evaluating the compliance of currently Medicare-certified CAHs with these status and location requirements.

In order to facilitate this re-evaluation, CMS has updated the SOM to provide additional information to guide CMS Location staff in CAH eligibility determinations.

Effective 30 days after issuance of this memo, CMS will implement the following process for CAH eligibility reviews:

Triggers for a CAH eligibility review

- *Proximal CAH* — CMS receives notification that a new acute care hospital (ACH) is seeking initial Medicare certification in proximity to an existing CAH or identifies a proximal ACH that was not flagged during a prior eligibility review but has since come to light through updated data or reporting.
- *New CAH Certification or Conversion* — CMS receives notification that a hospital is requesting certification as, or conversion to, a CAH.
- *Decennial Review* — Beginning in CY 2033, CMS will evaluate all existing CAHs for compliance with rural status and distance eligibility requirements

on a ten-year cycle. See Decennial Evaluations of Rural and Distance Status for All Existing CAHs below for additional details.

Eligibility Verification

When a trigger event occurs, CMS Location staff will conduct a distance and rural status verification. This process involves two components:

1. **Distance Verification Process**
   - CMS Location staff will determine whether any CAH or ACH is located within the statutory distance thresholds of the CAH under review. Specifically:
     - If any CAH or ACH is located within 35 miles by primary road, the CAH's distance eligibility is potentially impacted.
     - In areas served only by secondary roads or mountainous terrain, the applicable threshold is 15 miles.

For determinations of a CAH's eligibility with the statutory distance requirements, **Psychiatric hospitals, LTCHs, or Rehabilitation hospitals are not considered acute care hospitals and therefore will not factor into a CAH's distance eligibility calculation.**

2. **Rural Status Verification Process**
   - CMS will review the most current County-to-Core-Based Statistical Areas (CBSA) crosswalk files released annually in conjunction with the Fiscal Year Inpatient Prospective Payment System Final Rule, to identify any change in rural status since the previous evaluation.

Necessary Providers (NP)

CAHs that are designated by their state as a NP prior to January 1, 2006, are exempt from the distance requirement. To verify NP status, the CMS Location should:

- Review the CAH file to confirm there is evidence of NP CAH status (for example, an NP Designation letter issued by the State prior to January 1, 2006).
- If there is no documentation in the CAH's file, the CMS Location may ask the State for documentation of State NP designation performed prior to January 1, 2006.

If CMS is unable to confirm that CAH is a NP, within 60 days of the date of a CMS letter communicating a determination that the CAH distance requirements have not been met, the CAH may provide supplementary evidence to the CMS Location for further consideration. The burden is on the CAH to provide qualifying evidence demonstrating that NP designation was made by the state prior to January 1, 2006, and that the designation is applicable to the specific facility in question.

If a CAH retains its eligibility status following a statutory distance evaluation, the CMS Location will update the CAH's provider file to document the review and reflect continued CAH eligibility.

Decennial Evaluations of Rural and Distance Status for All Existing CAHs

To ensure consistency and predictability of CMS' re-evaluation of the location requirements for existing CAHs, beginning in CY 2033, all existing CAHs will be evaluated for compliance with rural status and distance eligibility requirements. This status review will then be performed every ten years hence.

Transitioning to a 10-year review cycle for CAH location requirements better aligns oversight resources with program risk. Changes that affect CAH eligibility due to proximity—such as the construction and certification of a new acute care hospital nearby—occur infrequently. Given the limited number of newly certified acute care hospitals each year, a decennial review of location requirements represents a reasonable and efficient approach. This policy would maintain program integrity while allowing survey efforts to remain concentrated on patient safety and quality of care.

CMS may perform a distance or rural eligibility review of a CAH at any time. However, barring new hospital certifications, the expected process will be for these reviews to be performed generally on a decennial basis.

If rural status or distance requirements are not met, the CMS Location will send the CAH a letter notifying the CAH of its options to address the ineligibility. The CAH will generally be allowed two years to attempt to reclassify as rural, convert to acute care hospital or rural emergency hospital status, or have its Medicare participation terminated.

Adverse Determinations

If a CAH is found to no longer meet distance or rural requirements, the CMS Location will send a letter notifying the CAH of its options to address the ineligibility. The CAH will be allowed generally two years to attempt to reclassify as rural (as applicable), convert to acute care hospital or rural emergency hospital status if eligible, or have its Medicare participation terminated.

Evaluation of Rural and Distance Requirements for New Applicants Seeking CAH Status

Nothing in this memo changes the initial eligibility determination for new CAH status. New applicants must meet the statutory and regulatory requirements to enroll and be approved for participation in Medicare as a CAH provider.

CAHs Adding a Provider-Based Location (PBL)

CMS recommends a CAH seek an advance determination of compliance with CAH location requirements prior to adding a PBL. This allows the CMS Location to determine whether a PBL is within the statutory distance exclusions from another acute care hospital or CAH, potentially impacting the CAH's status.

Contact: Questions concerning this memorandum should be addressed to *CAHReviewTeam@cms.hhs.gov.*

Effective Date: 30 days after issuance. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz Director Survey & Operations Group	Melissa C. Daly Acting Director Quality, Safety & Oversight Group

Attachment(s):

- Attachment 1: Summary of Changes to the SOM, Chapter 2: The Certification Process
- Attachment 2: Advanced copy of SOM Chapter 2: The Certification Process, which includes only those sections that are new or revised.

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.

***Receive email notification for memos**:*

Get guidance memos issued by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

Summary of Revisions to the State Operations Manual (SOM)
Chapter 2: The Certification Process

Condition	Tag / Topic/ Guidance	Status	Link to the Code of Federal Regulations	Reason for the update	Summary of Revisions/Updates
§ 485.610 Condition of participation: Status and location	Necessary Provider Status and Rural Reclassification	Revised	42 CFR 485.610	Clarification	Added information regarding demonstrating that the state designated it as a necessary provider before January 1, 2006. If CMS cannot independently verify the designation, the CAH has 60 days from CMS's notification to submit supporting documentation for further review. The guidance also clarifies the circumstances that trigger a CAH eligibility review, including proximal ACH identification, new CAH certification or conversion, and the move to decennial evaluations beginning in CY 2033. Additionally, examples of CAH evaluation were added.

Advance Copy of SOM: Chapter 2: The Certification Process

***NOTE**: This attachment contains an advance copy of the selected revisions to the State Operations Manual (SOM). It includes only those sections that are new or revised, with new and revised language shown in red italics. This attachment should be read in conjunction with the current version of the SOM available on the CMS website. Once these revisions are incorporated into the official SOM, users should refer to the updated online version for the complete and current manual.*

Critical Access Hospitals (CAHS)

2254 - CAHS (Critical Access Hospitals)

(Rev. 1, 05-21-04)

2254A - Statutory Citation

(Rev. 1, 05-21-04)

Section 4201 of the Balanced Budget Act of 1997, Public Law 105-33, amended §1820 of the Social Security Act and created the Medicare Rural Hospital Flexibility Program (MRHFP). The program allows for the creation of critical access hospitals and is designed to promote rural health planning, network development, and improve access to health services for rural residents of the State. The program is available in any State having rural facilities and which chooses to set up such a program and submits an acceptable State plan to CMS.

2254B - Regulatory Citation

(Rev. 1, 05-21-04)

The Conditions of Participation (CoPs) for Critical Access Hospitals are found in the Code of Federal Regulations at 42 CFR Part 485 subpart F.

2254C - Submission of a State Plan

(Rev. 1, 05-21-04)

States who are interested in establishing CAHS must submit an application to the Regional Administrator of the CMS Regional Office responsible for oversight of Medicare and Medicaid in the State. An official of the State must sign the application. The application must express the State's interest in developing a MRHFP. There are no Federal forms and no set format for the submission of the State plan. The State plan should designate facilities in the State that qualify for critical access hospital status. There is no statutory or

regulatory requirement for CMS to review changes or updates to any State plan subsequent to the initial review and acceptance by CMS.

2254D - Requirements for Critical Access Hospitals

(Rev. 1, 05-21-04)

A critical access hospital is a facility that is designated as a CAH by the State in which it is located and meets the following criteria:

- Meets the Conditions of Participation found at 42 CFR Part 485 subpart F;
- Is a rural public, non-profit or for-profit hospital; or is a hospital that was closed within the previous ten years; or is a rural health clinic that was downsized from a hospital;
- Is a facility located in a State that has established a State plan with CMS for the Medicare Rural Hospital Flexibility Program;
- Is located more than a 35-mile drive from any other hospital or CAH (in mountainous terrain or in areas with only secondary roads available, the mileage criterion is 15 miles); **or** is certified by the State in the State plan as being a **necessary provider** of health care services to residents in the area;
- Makes available 24-hour emergency care services 7 days per week;
- Provides not more than 15 beds for acute (hospital level) inpatient care. An exception to the 15-bed requirement is made for swing-bed facilities, which are allowed to have up to 25 inpatient beds that can be used interchangeably for acute or SNF-level care, provided that not more than 15 beds are used at any one time for acute care;
- Provides an annual average length of stay of 96 hours per patient for acute care patients;

NOTE: An exception has been made by CMS for hospice admissions to a CAH. The hospice may contract with a CAH to provide the hospice hospital benefit. Reimbursement from Medicare is made to the hospice. The CAH may dedicate beds to the hospice but the beds must be counted as part of the allowable number of CAH beds. The hospice patient does not contribute to the 96-hour annual average length of stay computation. The hospice patient can be admitted to the CAH for any care involved in their treatment plan or for respite care. The CAH negotiates reimbursement through an agreement with the hospice.

2255 - SA Procedures for CAH Approval

(Rev. 1, 05-21-04)

A CAH must be surveyed for compliance with the CoPs in 42 CFR Part 485 subpart F, and compliance with the specific CAH SNF requirements specified by 42 CFR 485.645(d) if it has or is requesting swing-bed approval.

2255A - CAH Applications

(Rev. 1, 05-21-04)

When a facility contacts the SA to apply for Medicare participation as a CAH, the SA sends a letter to the CAH, see (Exhibit 134) "Transmitting Materials to Critical Access Hospitals."

A current Medicare provider who is requesting a change of status to a CAH sends an amended Form CMS-855A to the FI with specific information required by the FI.

Within 30 days, the intermediary will notify the SA indicating if the Form CMS-855A was approved or not approved. The State survey agency verifies that the facility has been properly designated as a CAH by the State government entity responsible for CAH designation prior to forwarding the application to the RO.

2255B - Pre-Survey Activity

(Rev. 1, 05-21-04)

The SA follows the procedures outlines in Appendix W, Survey Protocol for CAH Providers. The SA verifies requirements in the CAH CoPs in 42 CFR 485.608, 485.610, and 485.612 from facility files and any other documentation available at its office. If the prospective CAH has swing-bed approval, the SA determines that the swing-bed approval is current.

2255C - Arranging a CAH Survey

(Rev. 1, 05-21-04)

After the RO has authorized a survey, the SA follows the procedures outlined in Appendix W, Survey Protocol for CAH Providers. All CAH surveys are unannounced surveys.

2255D - Onsite Survey Activity

(Rev. 1, 05-21-04)

The SA follows the guidelines for the survey process in Appendix W.

2255E - Preparing a Statement of Deficiencies

(Rev. 1, 05-21-04)

The SA uses the "Statement of Deficiencies and Plan of Correction," Form CMS-2567, when citing deficiencies, and refers to Exhibit 7A, "Principles of Documentation," for procedural guidance. The SA sends the completed Form CMS-2567 to the facility. If there are deficiencies cited, the SA sends a letter, see Exhibit 151, "Request for a Plan of Correction Following an Initial CAH Survey." If there are swing-bed deficiencies, a separate Form CMS-2567 must be prepared.

2256 - RO Procedures for CAH Approval

(Rev. 1, 05-21-04)

A prospective CAH must be surveyed by the SA and be in compliance with the CoPs for CAHS at 42 CFR Part 485 subpart F, before it can be approved for participation in Medicare as a CAH provider. The change from hospital to CAH is considered a change in status. A new provider agreement is not needed unless there is a change in ownership (CHOW) without the assumption of debt.

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 Core-Based Statistical Areas (CBSA)**

Under 42 CFR 485.610(b)(1)(i), a rural area is any area that is outside a Core-Based Statistical Areas (CBSA), as defined by the Office of Management and Budget (OMB)[1]. In making a determination regarding the rural status of a CAH, the CMS RO first consults the latest IPPS Final Rule OMB CBSA delineations that have been adopted by CMS.

OMB conducts a comprehensive review of its CBSA delineation 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 CBSA 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 CBSA 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 CBSA 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

[1] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates (69 FR 48916)

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 *CBSA* and therefore is in a rural area, it is also necessary to determine that it is also <u>not</u>:**

    - 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 *Office of Program Operations and Local Engagement (OPOLE)* 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 a *CBSA*, but treated as rural**

    Even if the CAH applicant is located in a *CBSA*, 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 *CBSA* 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 *CBSA* 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 *CBSA*, using the OMB *CBSA* 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 *CBSA*, 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 *CBSA*, but is now in an *CBSA* 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 *CBSA* 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 *CBSA* 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 *CBSA* as a result of a change in the OMB *CBSA* 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.[2] 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

[2] 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/.

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:

- 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.[3] (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.[4,5] 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. [6]

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

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

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

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

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

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 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.[7]

  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

[7] *AASHTO Special Committee on U.S. Route Numbering. Retrieved June 17, 2014, from: http://route.transportation.org/Documents/HO1_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, 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.

If CMS is unable to confirm that a CAH is designated by its state as a necessary provider, within 60 days of the date of a CMS letter communicating a determination that the CAH distance requirements have not been met, the CAH may provide supplementary evidence to the CMS Location for further consideration. The burden is on the CAH to provide qualifying evidence demonstrating that necessary provider designation was made by the state prior to January 1, 2006, and that the designation is applicable to the specific facility in question.

NOTE: The CAH should submit the supplementary evidence at the time it submits its initial application for CAH designation and may do so before the CAH is due for a recertification survey or at any other prior time. Some examples of potentially qualifying evidence include:

a.) A letter, issued before January 1, 2006, from the appropriate State authority designating the CAH by name as a necessary provider.

b.) An edition of the State's Rural Health Plan, published in 2005 or earlier, identifying the CAH by name as a necessary provider.

c.) A State's Rural Health Plan, combined with supporting documented evidence that includes all of the following:

(i) An edition of the State's Rural Health Plan, published in 2005 or earlier, specifying the State's criteria for a CAH to qualify as a necessary provider;

(ii) At the time of its CAH certification, which must have been prior to January 1, 2006, the CAH met the State's criteria to qualify as a necessary provider in accordance with the applicable edition of the State's Rural Health Plan (published

in 2005 or earlier). Acceptable data sources used to support the documented evidence that the CAH met the necessary provider criteria in the State's Rural Health Plan includes, but are not limited to: Health Resources Services Administration (HRSA), U.S. Census Bureau, or data from the applicable State departments; and

(iii) A signed statement by the appropriate State authority that the State considers the CAH to have been designated as a necessary provider before January 1, 2006. This statement may be from a date before or after January 1, 2006, when combined with the documented evidence cited above.

d.) A State law or regulation with supporting documented evidence that includes all of the following:

(i) The law or regulation, enacted prior to January 1, 2006, specifically describes the requirements for necessary provider designation by the State in order to become a CAH,

(ii) At the time of its CAH certification, which must have been prior to January 1, 2006, the CAH met the criteria in the law or regulation to qualify as a necessary provider, and

(iii) A signed statement by the appropriate State authority that the State considers the CAH to have been designated as a necessary provider before January 1, 2006. This statement may be from a date before or after January 1, 2006.

If a CAH retains their eligibility status following a statutory distance evaluation, the CMS Location will update the CAH's provider file to document the review and reflect continued CAH eligibility.

For existing CAHs

Evaluation of the Location and Distance Requirements for Existing CAHs:
CMS Locations will review CAH compliance with location and distance requirements when there is a ***newly*** *certified acute-care hospital and determine if the new hospital impacts the CAH eligibility of any existing CAH located near the new hospital (i.e., if it is more than a 35-mile drive, or 15-miles in areas with only secondary roads or mountainous terrain, from another hospital or CAH).*

For determinations of a CAH's eligibility with the statutory distance requirements, Psychiatric hospitals, LTCHs, or Rehabilitation hospitals are not considered acute care hospitals and therefore will not factor into a CAH's distance eligibility calculation.

If the newly certified acute care hospital impacts the eligibility of existing CAHs:

- *The CMS Location will send the CAH a letter notifying the CAH of its options to address the ineligibility.*
- *The CAH will be allowed generally one-year to attempt to reclassify as rural (as applicable), convert to acute care hospital or rural emergency hospital status if eligible, or have its Medicare participation terminated.*

Decennial Evaluations of Rural and Distance Status for All Existing CAHs

Beginning in CY 2033, all existing CAHs will be evaluated for compliance with rural status and distance eligibility requirements. This status review will then be performed every ten years hence.

Note: CMS may perform a distance or rural eligibility review of a CAH at any time. However, barring new hospital certifications, the expected process will be for these reviews to be performed generally on a decennial basis.

If rural status or distance requirements are not met, the CMS Location will send the CAH a letter notifying the CAH of its options to address the ineligibility. The CAH will generally be allowed one year to attempt to reclassify as rural, convert to acute care hospital or rural emergency hospital status, or have its Medicare participation terminated.

CAH Evaluation Examples:

A. Examples of Compliance

A1. CAH Meeting Distance and Rural Requirements at Decennial Review
A CAH is located 42 miles from the nearest acute care hospital via primary roads and remains in a rural area. No new hospitals have been certified nearby since the prior review.
Interpretation: The CAH meets both rural and distance requirements.
Action: Document continued eligibility in the provider file. No further action required.

A2. CAH Meeting Secondary Road Distance Standard
A CAH is located 18 miles from the nearest acute care hospital in an area where only secondary roads are available.
Interpretation: The applicable threshold is 15 miles. Since the CAH exceeds this distance, it remains compliant.
Action: Confirm road classification and document the determination.
A3. Necessary Provider (NP) CAH Within Standard Distance
A CAH is located 10 miles from another acute care hospital but provides documentation of NP designation by the State prior to January 1, 2006.
Interpretation: The CAH is exempt from distance requirements.
Action: Verify and retain NP documentation in the provider file.
A4. Proximity to Non-Qualifying Facility
A rehabilitation hospital opens within 10 miles of a CAH.
Interpretation: Rehabilitation hospitals are not considered acute care hospitals; therefore, the CAH's distance compliance is unaffected.
Action: No impact on eligibility; document determination if reviewed.

B. Examples of Noncompliance

B1. New Acute Care Hospital Within 35 Miles
A newly certified acute care hospital is established 20 miles from an existing CAH that was previously compliant.
Interpretation: The CAH no longer meets the 35-mile distance requirement.
Action: CMS issues a notice of noncompliance. The CAH is generally afforded one year to:

- *Reclassify as rural (if applicable),*
- *Convert to another provider type, or*
- *Face termination of Medicare participation.*

B2. Loss of Rural Status
A CAH remains more than 35 miles from the nearest hospital but is redesignated as urban based on updated OMB delineations.
Interpretation: The CAH fails to meet the rural requirement.
Action: Notify the CAH of noncompliance and available corrective actions.

B3. Failure to Meet 15-Mile Secondary Road Requirement
A CAH is located 12 miles from another acute care hospital in a mountainous area where the 15-mile standard applies.
Interpretation: The CAH does not meet the applicable distance requirement.
Action: Issue noncompliance notice and allow time for corrective action.

B4. Unsupported Necessary Provider Claim
A CAH within 35 miles of another hospital asserts NP status but cannot provide documentation.
Interpretation: NP exemption cannot be verified.
Action: Provide the CAH 60 days to submit documentation. If not provided, proceed with noncompliance determination.

C. Decennial Review Process Examples
C1. Standard Decennial Review
A CAH is evaluated in CY 2033 and found compliant. No new hospitals are introduced in the region.
Interpretation: The next routine review is conducted in CY 2043.
Action: Maintain documentation of the review and schedule subsequent evaluation accordingly.

C2. Off-Cycle Review Triggered by New Hospital
A new acute care hospital is certified within proximity to a CAH between decennial review cycles.
Interpretation: An immediate reassessment of distance compliance is required.
Action: Conduct off-cycle review; do not wait for the next decennial review.

C3. Survey Timing and Eligibility Verification
A State Survey Agency conducts a recertification survey of a CAH.
Interpretation: The survey may proceed without prior CMS confirmation of rural or distance eligibility.
Action: Conduct survey per standard recertification schedule.

2256B - Notification

(Rev. 1, 05-21-04)

When the facility is found to be in full compliance with the CoPs in 42 CFR Part 485, Subpart F, or has submitted an acceptable Plan of Correction, the RO notifies the facility in writing by sending letter, see Exhibit 150, "CAH Approval Notification," stating the facility has been approved for participation. A copy of the notice letter is sent to the FI and SA. Do not issue the letter until the facility is in compliance with all the CoPs.

2256C - Effective Dates

(Rev. 1, 05-21-04)

After the RO has reviewed and approved the SA recommendation for Medicare participation, the effective date for participation by a CAH will be one of the following:

- The last date of the initial survey by the SA, provided the prospective CAH is in full compliance with the CAH CoPs on that date; or

- The date that the prospective CAH submits an acceptable plan of correction to the SA.

2256D - RO Processing Complaints Against a CAH

(Rev. 1, 05-21-04)

When the RO or SA receives a complaint against a CAH regarding the CoPs in 42 CFR Part 485 subpart F, including the SNF requirements for a swing-bed CAH, the RO follows the normal complaint process for non-accredited hospitals.

2256E - RO Processing Denials or Terminations of a CAH

(Rev. 1, 05-21-04)

When the RO processes a denial or termination of a CAH, it follows the normal procedures that apply to Medicare-participating hospitals. For CAH denials, the RO uses a letter, see Exhibit 149, "CAH Denial for Medicare Participation Letter"; for CAH terminations use a letter, see Exhibit 152, "CAH Termination Letter."

2256F - Relocation of CAHs With a Grandfathered Necessary Provider Designation

(Rev. 32, Issued: 01-18-08, Effective: 09-07-07, Implementation: 09-07-07)

The intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care, through provision of reimbursement on a more favorable basis than that available to participating hospitals. Therefore, CAHs are required to satisfy

criteria designed to assure that they are located in rural areas and that there are no other hospitals or CAHs close by.

Prior to January 1, 2006, States were able to waive the distance requirement (the requirement that the facility be 35 miles from other hospitals or CAHs) by designating a facility as a necessary provider CAH. Section 405(h)(2)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 changed the statute. As of January 1, 2006, States are no longer permitted to designate a facility as a necessary provider CAH, but existing necessary provider CAHs were grandfathered. The regulations at 42 CFR 485.610(d) specify limits on the ability of a grandfathered CAH to relocate and still retain its grandfathered status. The regulation permits such CAHs to relocate, so long as the CAH remains essentially the same provider and continues to ensure access to care in the same rural service area. Specifically:

> **"§485.610(d) Standard: Relocation of CAHs that have a necessary provider designation.**

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

> (1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH is in its new location--
>
> (i) Serves at least 75 percent of the same service area that it served prior to its relocation;
>
> (ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and
>
> (iii)Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.
>
> (2 If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3)."

Apply the guidance below in determining whether the regulatory requirements have been met.

General Considerations in Any Relocation

- Burden of Proof: The CAH bears the burden of proof in demonstrating that its relocation satisfies the regulatory standards.

- Basis for Necessary Provider Designation: As explained when the regulation at 42 CFR 610(d) was first published, the CAH is expected to continue to provide services based on the criteria that the State used when initially determining that the CAH was a necessary provider. For example, if the determination was based on the CAH being located in a health professional shortage area (HPSA), then the relocated CAH must continue to be located in a HPSA. (See 70 FR 23453 and 70 FR 47472.) The CAH bears the burden of providing documentation from the State indicating what the original basis of the State's necessary provider determination was, and that the relocation will not have any impact on continued conformity of the CAH to the original decision criteria.

- Renovation or Expansion: Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation (unless a CAH previously undertook a relocation without receiving the necessary RO approval). There is no change to its CAH designation and, therefore, no need for the RO to make any determination on its continued CAH designation.

- All New Facilities: All newly constructed necessary provider CAH facilities are considered relocated facilities. This includes construction of a new facility that replaces the existing CAH main campus, even when on the same site as the original building. (See 70 FR 47472.) (See discussion at 70 FR 47472.)

- Relocation Without Necessary Provider Designation: If a CAH relocates and meets, at the new location, all of the CoPs found at 42 CFR 485 Subpart F (including location in a rural area as required at §485.610(b) and distance from other hospitals or CAHs as required at §485.610(c)), it will qualify for CAH designation in the same way as would a new CAH. However, if it wishes to retain its grandfathered necessary provider status, then it must also satisfy the requirements at §485.610(d).

- 75 Percent Criteria: The relocated CAH must meet each of the three 75 percent criteria found at 42 CFR 485.610(d) (and explained below) in order to maintain its grandfathered necessary provider designation after relocation. We expect that CAHs will demonstrate in advance of their relocation the likelihood that they will satisfy the criteria. The discussion below focuses on the evaluation of this prospective data. After the relocation is completed, the CAH must submit evidence confirming that it satisfied the criteria.

Listed below are examples of methods necessary provider-designated CAHs could use to meet each of the 75 percent criteria at 42 CFR 485.610(d) (1). The CAHs are free to submit documentation employing different methodologies for each criterion, indicating how they think both the methodology and supporting evidence document comply with the

regulatory requirements. The RO will determine whether the methodology employed is supported by the evidence and if the CAH has met the burden of proof necessary to satisfy the regulation. The same methodology should be used by the CAH for both the pre-relocation attestation and the confirmation after relocation is completed.

Relocation Serves 75 Percent of the Same Service Area

The CAH must present documentation showing why the Service Area projected for the relocated CAH will include at least 75 percent of its original service area.

In the absence of special factors that indicate the need for an alternative methodology, in order to meet the statutory and regulatory intent of this provision, CMS will compare the zip code location of populations currently served by the CAH with the populations in the zip codes served by the CAH in its new or proposed new location. Examples of special factors are: (a) Statistical anomalies that may occur when each of one or more zip codes contains less than 5 percent of the total number of individuals served by the CAH, or (b) The presence of major demographic or geographical differences between the old and new location (such as an un-bridged river separating the two locations).

Example of adequate documentation:

Assume that the CAH identifies the zip codes of its patients from the past year, ranked from highest to lowest volume of patients per zip code, and found that it served 200 patients from the following zip codes:

		Patients in New Location		
Zip Code	Current Patients	Example # 1	Example #2	Example #3
Zip code A ……	80 patients ……	70 ……	70 ……	80
Zip code B…….	30 patients……	26…	26 …	30
Zip code C…….	29 patients……	9……	9…	29
Zip code D…….	28 patients …	15…	15	28
Zip code E…….	24 patients……	0……	24 …	24
Zip code F……..	9 patients (4.5%)	30…	0 (Dropped #2)	9
Subtotal (Ex. #1)…	**200**	**150 (75%)**	**144**	
Subtotal (Ex. #2) …	191		144 (75% of 191)	
Subtotal (Ex. #3)	**200**			
Zip code G	20	26	40	
Zip code H	30	30	60	
GRAND TOTAL	200	200	200	300

In example #2, zip code “F” has been dropped at the CAH’s request because its percent of the current service area is less than 5 percent.

In example #3, the CAH meets the 75 percent requirement. Even though the number of people served from the original location is only 67 percent of the total to be served in the new location (200/300), 100% of the volume from the zip codes served in the original location will be served in the new location (200/200). The regulation focuses on whether the people in the original location will continue to be served, not whether the CAH services are being expanded.

After the CAH has been in operation at the new location for a reasonable period of time (e.g., 6 months to 1 year), the CAH must submit evidence to confirm that the 75 percent requirement is met as a matter of fact rather than projection.

CMS may lessen the amount of supporting information required in some cases where the circumstances and extent of relocation are very simple. For example, if the CAH documents that the new facility is being built on or adjacent to the current facility's campus, then it would be reasonable for the CAH to argue that the relocated CAH by virtue of its very close proximity to the original CAH could be assumed to serve the same community. For almost all other cases, more evidence will be required. Depending on the characteristics of the community served by the CAH and the availability of other CAHs or hospitals in the region, it is possible that relocations of even a few miles might significantly change the CAH's service area.

Seventy-five Percent of the Same Services

In order to meet the "75 percent of the same services standard," the CAH must demonstrate that at least 75 percent of the total service lines provided by the CAH at its original location will continue to be offered at its new location, under generally similar terms.

The same services standard under 42 CFR 485.610(d)(ii) does not preclude the CAH from adding additional, new services at the new location. It merely states that the CAH must retain 75 percent of the original services offered at its original location prior to relocation.

CMS examines two dimensions to the "same services" requirement:

- The services lines themselves (e.g., lines of business such as obstetrics), in which we compare the number of such lines retained after relocation compared to the pre-relocation service array; and

- The scope and availability of such services, in which we seek to understand if there are to be any significant reductions in the new location compared to the pre-location services.

There are a variety of ways in which health care services can be categorized. The regulation does not prescribe a particular service classification taxonomy. However, the CAH must present a breakdown of its services that is sufficiently detailed to enable a pre- and post-relocation analysis. For example, a listing that consisted only of "inpatient" and "outpatient" services would be too general to permit meaningful analysis. It would be

acceptable for a CAH to use the service categories found in the American Hospital Association annual hospital survey data, but the CAH can also submit an alternative list of services. In the latter case, the RO will determine whether there is sufficient information about the services to make a determination of regulatory compliance. Whatever service classification system the CAH uses to describe the services offered prior to relocation must also be used for the services after relocation.

Example 1:

- The CAH originally offered 14 services:

Outpatient	Inpatient
Emergency department	General medical/surgical services
Primary care	Pediatric medical/surgical services
Pre- & postnatal care	General obstetrics/gynecology
Outpatient surgery	Orthopedics
Counseling services	Distinct Part Unit – Psychiatric*
Well-baby clinic	
Pediatric outpatient services	
Ultrasound	
Mammography	

- After relocation the CAH attests that it will retain 12 of those services

Retained:

Outpatient	Inpatient
Emergency department	General medical/surgical services
Primary care	
Pre & postnatal care	General obstetrics/gynecology
Outpatient Surgery	Orthopedics
Well-baby clinic	
Pediatric outpatient services	
Counseling services	
Ultrasound	
Mammography	

Eliminated:

Outpatient	Inpatient
	Pediatric medical/surgical services
	Distinct Part Unit – Psychiatric*

- The CAH also proposes to add 7 services:

Added:

Outpatient	Inpatient
MRI	
CT Scanner	
Dietician	
Physical rehabilitation	Distinct Part Unit – Rehabilitation*
Chemotherapy	Oncology

- Additionally, the retained services are planned and actually are generally available under the same terms, e.g., the number of inpatient beds or service hours for outpatient clinics are generally the same, etc. In this scenario the CAH demonstrates it will retain over 85 percent of its original services, exceeding the 75 percent regulatory requirement.

  ***NOTE**: Although CAH distinct part units are subject to hospital rather than CAH Conditions of Participation, for purposes of determining compliance with the 75 percent same services standard they must be included in the list of services.

Example 2:

- The CAH originally offered 20 different services. If the CAH attests it will drop 6 services, while adding 6 new and different services, it has not demonstrated it will retain 75 percent of the same services and would not meet the regulatory same service requirement.

Regardless of the number of original services, if the CAH attests it will retain a service, but make it available only 20 percent of the time that it was available at the original location, then that is not the same service. If it is available 50 percent or more of the time than it was available at the original location, then that service can count toward its 75 percent of the same services compliance.

In its attestation the CAH should list all the services offered at the CAH at its original location at the time of the attestation, including an indication of the quantity or hours the outpatient services are available. It should also list the services and their availability planned for the new location.

After the relocation is complete, the CAH must submit confirming evidence that it meets the 75 percent same services standard. The CAH should provide the list of its actual services and their availability.

Seventy five percent of the Same Staff (including medical staff, contracted staff, and direct employees):

In order to meet the "75 percent of the same staff" standard, the CAH must demonstrate

that 75 percent of the CAH's staff that were at the CAH prior to relocation remains on staff after the relocation takes place. This includes contracted personnel. For purposes of this requirement, contracted staff includes all personnel who regularly work onsite at the CAH, whether they are directly contracted by the CAH or whether they are employees of a contractor. At the CAH's option, the CAH may exclude from these calculations all contracted employees who work less than halftime on average (or any lesser threshold of time the CAH elects (such as 10 hours per week on average). However, the CAH must consistently apply such a threshold in all calculations.

It is not necessary to calculate the 75 percent for each of the 3 types of staff – medical, contracted, and direct employees – separately. For example, a CAH could retain 50 percent of its medical staff, 40 percent of its contracted staff, but 80 percent of its direct employees, and meet the regulatory standard, so long as the retention rate for these 3 groups combined is 75 percent.

In its attestation, the CAH should provide a list of all staff at the time of the attestation. It must demonstrate how it plans to retain at least 75 percent of its current staff. Staff who are working on a J-1 Visa Waiver Program, National Health Service Corps Federal Loan Repayment Program, or National Health Service Corps State Loan Repayment Program and whose service limits under the terms of those programs will have expired at the time of relocation should not be included when comparing the staff at the old and new locations.

Examples of how a CAH could demonstrate in its attestation that it will meet the 75 percent of the same staff criteria include:

- Attestation from staff that they expect to continue their current employment or contractual relationship with the CAH at the new location; or

- Evidence demonstrating how staff commutes to the CAH would not change significantly from the original location to the new location for at least 75 percent of staff; or

- Evidence of employment arrangements/contracts continuing with at least 75 percent of the same staff.

Those CAHs that have difficulty meeting the 75 percent same staff criterion due to historically high staff turnover and/or vacancy rates, can provide additional documentation explaining the effect of such factors on their ability to satisfy the standard, and whether they could meet the standard if the original staff list is adjusted to reflect historical turnover. The CAH must provide evidence, however, that it is actively attempting to recruit replacements for the same type of staff as those who have left. The documentation must provide evidence that circumstances beyond the CAH's control rather than the relocation of the CAH accounts for the expected greater than 25 percent change in the staff roster. It might not be reasonable to expect a CAH to meet the 75 percent same staff standard if it can provide sufficient evidence that it has, for example, a 25 percent historic rate of staff turnover. In addition, to documenting an historically high turnover rate the

CAH should also provide documentation of efforts it is making to reduce turnover, such as evidence of active recruitment efforts, i.e., posting of vacancies, participating in job fairs, and evidence of outreach to professional schools and universities. The CAHs might also indicate whether they believe relocation will benefit the facility by decreasing the staff turnover rate, including evidence to support this assumption.

Letter of Attestation

Prior to the relocation of a CAH with a necessary provider designation, the CAH should submit a letter of intent to the RO. The CAH would be well-advised to send the letter early in the planning stage of its relocation, prior to spending or obligating significant funds and resources. The letter should state that the CAH plans to relocate, i.e., that it plans to build a new replacement facility, and must attest that it will continue to be essentially the same provider serving the same service area, but in a new facility. It is recommended that the CAH administration contact CMS RO Survey and Certification staff prior to preparing the letter of attestation, in order to facilitate communications about the standards that a relocated CAH with a necessary provider designation must meet.

To facilitate efficient review by the RO, the Letter of Attestation should include:

- A copy of the CAH's original necessary provider determination from its State Office of Rural Health;
- Documentation from the State of how the CAH at the relocation site will continue to satisfy the criteria used by the State in the original necessary provider determination;
- Addresses of both the present location and the future location;
- Documentation that demonstrates how the new facility/location meets the rural location requirement at §485.610(b);
- Documentation showing how the CAH will continue to be essentially the same provider at the new facility/location, in accordance with 485.610(d); and
- Timetable for the relocation.

The RO will evaluate the letter of attestation and documentation provided by the CAH to determine if the planned relocation appears likely to meet the requirements under §485.610. The RO will advise the CAH in writing of any additional information that may be needed. The RO will assess the information provided in the attestation letter and notify the CAH of its preliminary determination. The RO will provide preliminary approval of the relocation if the information provided by the applicant demonstrates that the proposed relocation complies with the regulatory standards at 42 CFR 485.610(b) and (d). A final determination can only be made after the relocation is completed.

Implementation Phase

During the implementation phase, the CAH should notify the RO of any changes to the information submitted in its letter of attestation. The purpose is for the RO to be kept apprised of any changes so that the CAH can be informed if the changes do not comply with the requirements at §485.610(b) and (d).

After the relocation is completed, if the RO determines the CAH meets all of the following criteria:

- Received a preliminary approval for its relocation from the RO;
- No changes have occurred that materially affect its preliminary attestation;
- Holds any required State license at the new location;
- Meets all CoP requirements as determined by an accreditation or SA survey; and
- Submits confirming evidence of compliance with the 75 percent criteria (in the case of same service area criterion, as noted below, the submission of this evidence will need to be submitted at a later point in time as the CAH must see patients to conclusively show compliance with the same service area requirement, but this should not delay continuation of the provider agreement at the new location upon satisfaction of all the other listed criteria);

then the RO makes a final determination that the relocated necessary provider CAH will be permitted to continue Medicare participation under its original provider agreement as a necessary provider CAH.

If the RO determines that the relocated necessary provider CAH does not satisfy the regulatory requirements under §485.610(b) and (d), the CAH will be considered to have ceased business in accordance with §489.52(b)(3) as of the date that it relocated. The RO will take action to terminate the CAH's provider agreement.

2256G - Co-Location of Critical Access Hospital

(Rev. 49, Issued: 06-12-09, Effective/Implementation: 06-12-09)

It is never permissible for a CAH that is not designated as a necessary provider to be co-located with another hospital or CAH because of distance requirements it is required to meet at 42 CFR 485.610(c). However, since States had the ability, up until January 1, 2006, to waive the minimum distance from other hospitals or CAHs requirement for CAHs designated as necessary providers, it was technically possible for a necessary provider CAH (NPCAH) to be co-located with another hospital or CAH, i.e., share the same building or campus as the other facility. Moreover, prior to the enactment of Section 405(g) of Pub. L. 108-173, which permits CAHs to operate distinct part inpatient psychiatric and/or rehabilitation distinct part units, it was understandable that a State

Medicare Rural Hospital Flexibility Program (MRHFP) might have allowed co-location of a CAH with a necessary provider designation with the specialized services of a psychiatric and/or a rehabilitation hospital.

However, as of January 1, 2008, CAHs with a necessary provider designation can no longer enter into co-location arrangements with another CAH and/or hospital (72 FR 66878). Necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008, may continue these arrangements, as long as the type and scope of services offered by the facility co-located with the CAH do not change. An example of a change in type of services would be when a hospital that provides only rehabilitation services chooses to provide general hospital acute care services. An example of a change in scope of services would be when a grandfathered necessary provider CAH is currently co-located with a 20-bed psychiatric hospital and the psychiatric hospital decides to increase the number of beds to 30.

A change of ownership of a CAH participating in a grandfathered co-location arrangement will not be considered to create a new, and therefore prohibited, co-location arrangement, if, and only if, assignment of the existing provider agreement is accepted by the new owner. In all cases where there is a change of ownership of a grandfathered necessary provider CAH and the new owner does not accept assignment of the provider agreement, both the CAH's provider agreement and necessary provider designation are terminated as part of the former owner's provider agreement. If a grandfathered necessary provider CAH's provider agreement is terminated, and the facility seeks a new CAH designation, it would be required to meet all CAH requirements, including the minimum distance from other hospitals or CAHs. It would also be prohibited from entering into any co-location arrangement with a hospital or another CAH.

A change of ownership by a hospital that is co-located with a necessary provider CAH does not affect the grandfathered co-location arrangement, regardless of whether the hospital's provider agreement is assumed by the new owner or not.

Termination for Noncompliance

Compliance with the co-location requirements of §485.610(e)(1) is determined by the RO. A CAH found out of compliance with the requirement is subject to termination of its Medicare provider agreement under §489.53(a)(3). In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. During this period, the CAH will have the opportunity to come back into compliance and meet all conditions of participation (CoPs). If the CAH corrects the noncompliance situation, by terminating the co-location 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 designation as a result of non-compliance with §485.610(e)(1) 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 and be assigned a new CMS Certification

Number (CCN) accordingly.

2256H – Off-Campus CAH Facilities

(Rev. 193, Issued: 09-20-19, Effective: 09-20-19, Implementation: 09-20-19)

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 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 the 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 applies to convert back to a hospital and meets the hospital CoPs, the effective date of the CAH's hospital certification would coincide 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.