
CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 32

Date: January 18, 2008

Note: This instruction is being retransmitted due to an incorrect effective and implementation dates. The dates have been revised to September 7, 2007. The Transmittal number, date issued and all information will remain the same.

SUBJECT: Revisions to Chapter 2, “Critical Access Hospitals (CAHs)” and Appendix W, “Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs”

I. SUMMARY OF CHANGES: A summary of the changes is as follows:

- Revised Section 2256A of Chapter 2, the Certification Process, explains the criteria to be used by the CMS Regional Offices (ROs) in determining whether or not a CAH applicant satisfies the regulatory requirement to be located more than 35 miles from another CAH or hospital, and how to determine whether the CAH is eligible for application of the shorter, 15-mile standard due to mountainous terrain or lack of primary roads.
- New section 2256F of Chapter 2, the Certification Process, explains criteria to be used by ROs to determine whether a CAH with a necessary provider designation remains essentially the same provider, serving the same service area after relocation, thereby qualifying the CAH to retain its necessary provider designation and Medicare provider agreement.
- Appendix W, Tag C-0165 has been revised to reflect current regulatory language and to cross-reference Chapter 2, Section 2256A.
- Appendix W, new Tag C-0166 has been added reflecting regulations governing relocation of grandfathered necessary provider CAHs, and cross-references Chapter 2, Section 2256F.

NEW/REVISED MATERIAL -EFFECTIVE DATE: SEPTEMBER 7, 2007

IMPLEMENTATION DATE: SEPTEMBER7, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only.

NOTE: The SOM revisions in this instruction incorporate material previously issued as a Survey and Certification Memorandum

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	2/Table of Contents
R	2/2256A/Verification Criteria
N	2/2256F/Relocation of CAHs With a Grandfathered Necessary Provider Designation.
R	Appendix W/§485.610(c)/Standard: Location Relative to Other Facilities or Necessary Provider Certification/Tag C-165
N	Appendix /§485.610(d)/Standard/Relocation of CAHs With a Necessary Provider Designation/Tag C-166

III. ATTACHMENTS:

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

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

State Operations Manual

Chapter 2 - The Certification Process

Table of Contents

(Rev.32, 01-18-08)

Transmittals for Chapter 2

*2256F - Relocation of CAHs with a Grandfathered Necessary Provider
Designation*

2256A - Verification Criteria

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

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).

Location relative to other facilities or necessary provider certifications:

Pursuant to 42 CFR 485.610(b), all CAHs must be located in a rural area or area treated as rural under 42 CFR 412.232, and meet other rural requirements of 42 CFR 610(b). In addition, the regulations at 42 CFR 485.610(c) specify that one of the following 3 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: Before January 1, 2006, the CAH was designated by the State as being a necessary provider of health care services to residents in the area.*

In demonstrating that it meets the more than a 35-mile drive standard, 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.

To be eligible for the lesser 15-mile distance standard due to mountainous terrain under §485.610(c), between the CAH and any other hospital or CAH, it must be necessary to traverse more than 15 miles of roads located in mountainous terrain identified as such on any official maps or other documents prepared for and issued to the public by the State agency responsible for highways in the State (typically a Department of Transportation or Highways), or by the U.S. Geological Survey (USGS).

A CAH would qualify for application of the mountainous terrain criterion if there is a combination of mountainous and non-mountainous terrain between it and any other hospital or CAH, so long as there is no route to any hospital or other CAH with 15 or fewer miles of roads in mountainous terrain. 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 yields 16 total miles of mountainous terrain).

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

- A numbered federal highway, including interstates, intrastates, expressways or any other numbered federal highway; or*
- A numbered State highway with 2 or more lanes each way; or*
- 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 only" 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 this criterion, measure the total driving distance, and subtract the portion of that distance in which primary roads are available. If the result is more than 15 miles, then the 15-mile criterion is met.

The RO will review documentation submitted by the provider, as well as consult State transportation or highway department maps and/or maps of the U.S. Geological Survey to determine whether the provider meets the requirements of 42 CFR 485.610(c).

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:

<u>Zip Code</u>	<u>Current Patients</u>	<u>Patients in New Location</u>		
		<u>Example # 1</u>	<u>Example #2</u>	<u>Example #3</u>
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.....	<u>9 patients (4.5%)</u>	<u>30...</u>	<u>0 (Dropped #2)</u>	<u>9</u>
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:*

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

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

Retained:

Outpatient

Emergency department
Primary care
Pre & postnatal care
Outpatient Surgery
Well-baby clinic
Pediatric outpatient services
Counseling services
Ultrasound
Mammography

Inpatient

General medical/surgical services
General obstetrics/gynecology
Orthopedics

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
Chemotherapy

Distinct Part Unit – Rehabilitation*
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.

State Operations Manual

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

(Rev. 32, 01-18-08)

[Transmittals for Appendix W](#)

INDEX

§485.610(d) Standard: Relocation of CAHs With a Necessary Provider Designation

C-0165

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

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

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

Interpretive Guidelines §485.610(c)

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

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination.

C-0166

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

§485.610(d) Standard: Relocation of CAHs With 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 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).*

Interpretive Guidelines §485.610(d)

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. However, as discussed in the adoption of this regulation (70 FR 47472), all newly-constructed, necessary provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, are considered relocated facilities. The determination of whether or not CAHs with a necessary provider designation have met the requirements at §485.610(d) will be made by the RO, generally prior to an SA or accreditation survey. The RO will utilize the evaluation criteria set forth in the SOM, Chapter 2, §2256F to make this determination. At the conclusion of its review, the RO will notify the SA of its results.