C-0165

§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 designated 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 as of January 1, 2006, will maintain its necessary provider designation after January 1, 2006.*

Interpretive Guidelines §485.610(c)

Mountainous Terrain. *There are many locations that are called mountains that are not considered mountainous terrain. These may be foothills or ancient worn down mountains that do not have the fundamental characteristics of mountainous terrain. It is not uncommon for roads through mountainous areas to travel through valleys, over areas of high elevation, over high plateaus and other areas that do not have the characteristics of "mountainous terrain." Being located at the foot of a mountain, or being able to view mountains from the CAH does not, in and of itself, mean the CAH is located in "mountainous terrain."*

Slope and ruggedness of terrain, together with absolute altitude determine many of the fundamental characteristics of mountainous terrain. For the purposes of this regulation, to be considered located in mountainous terrain the CAH must comply with all of the following criteria:

- *The CAH must be located in a mountain range (being located within a mountain range, in and of itself, does not mean a CAH is located in "mountainous terrain");*

- *The CAH, or portions of the road to the nearest hospital or CAH, must be located at an elevation above 3000 feet and the travel route is regularly or seasonally subjected to weather-related hazardous driving conditions, such as poor visibility, slippery roads, or snow-covered roads resulting in slow driving speeds, required use of snow chains, or road closures. (Being located at a high elevation, in and of itself, does not constitute "mountainous terrain.");*

- *The roads on the travel route must be considered as traveling through mountainous terrain by the State Department of Transportation;*

- *The travel roads consist of extensive sections of roads with grades greater than 5 percent, and/or consist of continuous abrupt and frequent changes in elevation or direction. (These roads typically have frequent areas of low speed limits (15-25 mph) and many warning signs denoting sharp curves, steep grades, and frequent changes in direction. Roads through mountainous terrain usually display frequent benching and side hill excavation); and*

- *The safe speed limit on the travel route to the nearest hospital/CAH is less than 45 mph.*

When calculating the mountainous terrain travel distance to the nearest hospital/CAH, subtract the total of the distances represented by those sections of the travel route that are not considered "mountainous terrain." Travel routes that are not considered mountainous terrain include:

- *Those sections of the travel route of at least 1 mile in length, where the safe driving speed limit is 45 mph or greater, do not count toward the 15- mile mountainous terrain distance; and*

- *Those sections of the travel route of at least 1 mile in length, where the roads on the travel route have grades less than 5 percent and/or do not have frequent, abrupt changes in direction or elevation are not considered mountainous terrain and do not count toward the 15-mile mountainous terrain distance.*

***Definition of a Primary Road**. A primary road is an interstate highway, a U.S. highway, an expressway, an intrastate highway, a State-divided highway with two or more lanes each way, or any road with at least two contiguous miles with a speed limit of 45 mph or greater.*

***Definition of a Secondary Road**. A secondary road is any state or local road, paved or unpaved, that does not meet the definition of "primary road" as herein stated.*

A CAH meets the 15- mile secondary road distance requirement when the CAH is located less than 35 miles, but more than 15 miles, from a hospital or another CAH and at least one section of the shortest route to the nearest hospital or CAH consists of more than 15 miles of continuous uninterrupted secondary roads.

Travel distance is measured using the driving distance on the shortest possible route on federal, state, or local roads. The distance requirement is not limited to the State boundaries. The distance requirement applies to ANY hospital or CAH, regardless of State boundary lines.

***Issuance of Necessary Provider Designations for the Location Requirement.** States will no longer be allowed to designate a CAH as a necessary provider after January 1, 2006. A CAH that has met all federal requirements as a CAH, has an effective date for Medicare participation as a CAH prior to January 1, 2006, has been certified as a CAH based on a necessary provider designation made prior to January 1, 2006, and that continues to provide services based on the same criteria that originally qualified the CAH to be a necessary provider, may continue to maintain their necessary provider status after January 1, 2006.*

The regulation that allows a CAH's necessary provider designation to be grandfathered after January 1, 2006, does not apply where the CAH is no longer the same facility due to relocation, voluntary or involuntary termination of the provider agreement, or cessation of business. The necessary provider designation automatically ends if the Medicare provider agreement with that CAH is terminated, either voluntarily or involuntarily.

***Maintenance of Necessary Provider Designation.** Any CAH that is designated as a necessary provider in its State rural health plan prior to January 1, 2006, and certified by Medicare with an effective date prior to January 1, 2006, can be grandfathered as long as the CAH continues to provide services based on the same criteria that originally qualified the CAH to be designated as a necessary provider. If the grandfathered CAH relocates the facility, the CAH must continue to meet the criteria that originally qualified them for designation as a necessary provider.*

The State Agencies and CMS Regional Offices will closely monitor any such relocation to ensure that the CAH continues to provide services based on the criteria that originally qualified the CAH to be designated as a necessary provider.

***Collocation Issues Using a Necessary Provider Designation**. CMS does not view a CAH that is collocated with a hospital or another CAH as a "necessary provider" of services. A CAH with a necessary provider designation cannot become collocated with a hospital or another CAH and maintain its grandfathered status. The collocation of a CAH with a hospital or another CAH would void the state's previous designation of the CAH as a necessary provider.*

Survey Procedures §485.610(c)

- *The SA will determine that a CAH meets the basic location requirement prior to scheduling the survey in the new location. The appropriate RO will reverify the location requirement prior to approving the CAH in the new location.*

- *Use maps, Department of Transportation information, information from the United States Geodesic Service, and/or GIS programming in order to evaluate distances, types of roads, terrain, speed limits, and driving conditions.*

- *Determine the shortest driving route between the CAH and the nearest hospital or another CAH. Actually driving the road(s) on the shortest route may be used to document speed limits, terrain, curves, distances that can be excluded, driving conditions, and total distance.*

C-0166

§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)

These guidelines are meant to be applied to any relocated CAH, with or without a necessary provider designation. Any CAH may relocate at any time if the CAH continues to be essentially the same provider serving the same community, and meets all the Conditions of Participation at 42 CFR Part 485, Subpart F.

The relocation criteria include specific criteria for a CAH with a grandfathered necessary provider designation that plans to relocate and that wishes to maintain its necessary provider designation after the relocation. At its new location, a CAH with a necessary provider designation must continue to be essentially the same provider, must continue to meet the same criteria under which it was originally designated by its State as a necessary provider, must comply with the requirements at §485.610(d) as herein described, and must comply with all the Conditions of Participation at 42 CFR §485 subpart F.

CAHs that construct a new facility will be considered to have relocated. The CMS Regional Office will determine if the CAH meets the requirements for relocation on a case-by-case basis. In all cases of relocation, the CAH must meet all of the CoPs found at 42 CFR Part 485, Subpart F, including location in a rural area as required at §485.610. (Note: The CMS Regional Office can provide guidance on questions regarding rural vs urban status.

***Retention of the Medicare Provider Agreement after a Provider Relocation**. In order for any provider to relocate and maintain its provider agreement from the previous location, a provider must be essentially the same provider serving the same community at the new location.*

Criteria that are used by CMS to determine if any provider continues to be essentially the same provider at a new location as it was at its original location include:

- *The provider remains in the same State and complies with the same State licensure requirements;*
- *The provider remains the same type of Medicare provider after relocation;*
- *The provider maintains at least 75 percent of the same medical staff, nursing staff and other employees, and contracted personnel (contracted personnel includes all personnel who regularly work 20 or more hours a week at the provider, whether they are directly contracted by the provider or whether they are employees of a contractor.);*
- *The provider retains the same governing body, or person(s) legally responsible for the provider, after the relocation;*
- *The provider maintains essentially the same policies and procedures such as nursing, infection control, pharmacy, patient care, etc.;*

- *The provider maintains essentially the same Medical Staff bylaws, policies and procedures;*

- *At least 75 percent of the services offered by the provider during the last year at the original location continue to be offered at the new location;*

- *The distance the provider moves from the original site;*

- *The provider continues to serve at least 75 percent of the original community at its new location;*

- *The provider complies with all Federal requirements, including CMS requirements and regulations at the new location; and*

- *CMS may use any other information, determined by CMS to be necessary, to determine if a provider continues to be essentially the same provider, under the same provider agreement, after relocation.*

CAH Relocation in General. *In the event of relocation, any CAH, with or without a necessary provider designation, must ensure that it is functioning as essentially the same provider and continues to serve the same community in order to operate under the same provider agreement. A provider that is changing location is considered to have closed the old facility if the original community or service area can no longer be expected to be served at the new location. The intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care. CMS allows any CAH, including a CAH with a grandfathered necessary provider designation, to relocate its facility as long as the CAH remains essentially the same provider and continues to ensure access to care in the same community.*

The distance of the moved CAH from its old location will be considered, but will not be the sole determining factor in granting the relocation of a CAH under the same provider agreement. There may be situations where the CAH relocation is so far removed from the originally approved site that we would conclude that this is a different provider. If, for example, the CAH serves a different community, offers substantially different services to the community, or employs substantially different employees to provide those services, we would conclude that this is a different provider.

Relocation of a CAH with a Grandfathered Necessary Provider Designation*. The necessary provider designation does not automatically follow the provider if the facility relocates to a different location. In order to maintain its necessary provider designation after relocation, a CAH with a grandfathered necessary provider designation must have an effective date for Medicare participation as a CAH prior to January 1, 2006, and continue to meet the same criteria it originally met to be designated as a necessary provider by the State and must meet the requirements of §485.610(d).*

Those criteria used to qualify a CAH as a necessary provider were established by each State in the State Medicare Rural Hospital Flexibility Plan (MRHFP). The State plan identified those CAHs that provided essential services to a particular patient community in the event that the facility did not meet the required distance requirement from the nearest hospital or CAH. All the State criteria are different but share similarities and all define a necessary provider relative to

the facility location. It therefore becomes crucial to define whether the necessary provider designation remains pertinent in defining the facility in a different location in the event the CAH moves. In order to assess the impact on its necessary provider designation status and to obtain a letter of assurance regarding its continued compliance with State necessary provider criteria, a CAH with a necessary provider designation should inform and consult with their State Office of Rural Health early in the planning stages of a proposed relocation. Prior to a CAH with a grandfathered necessary provider designation relocating, its State Office of Rural Health must confirm whether the CAH's necessary provider designation remains pertinent and provide a letter of assurance to CMS.

***75 Percent Criteria**. CMS may allow a CAH with necessary provider certification to replace its facility at any time and to maintain its necessary provider designation provided it complies with each of the 75 percent criteria. The 75 percent criteria will assist in ensuring continued access to care in the community for which any CAH was originally certified. The relocated CAH must meet all the defining criteria listed under each 75 percent criteria in order to maintain its necessary provider designation after a relocation.*

***75 percent Community Served.** The relocated CAH must comply with all of the following defining criteria in order to meet "75 percent community served."*

- *At least 75 percent of the community prior to the CAH's relocation must continue to utilize the CAH after the relocation. One factor to consider is the number of people in the original community that will seek healthcare at a different provider after the CAH relocates.*

- *At least 75 percent of the same people in various demographic groups within the community must continue to be served at the new location. At a minimum this includes at least 75 percent of the original Medicaid and Medicare beneficiaries, and at least 75 percent of the original families with incomes at less than 100 percent of the Federal poverty level.*

- *At least 75 percent of the patients served at the new location reside in the same zip code areas served at the CAH's previous location.*

- *Taken as a whole, 75 percent of the people in the CAH's original service area continue to have the same access to care at the CAH as measured by whether they have equal or less travel distance to come to the CAH at the new location.*

- *CMS will use any other criteria or information it deems appropriate to evaluate whether the CAH continues to serve at least 75 percent of the original population.*

***Providing at Least 75 percent of the Same Services**. The relocated CAH must meet all the following defining criteria in order to meet "providing at least 75 percent of the same services."*

- *At least 75 percent of the total services provided by the CAH during the last year at its original location must continue to be offered at its new location for at least one year. For example, the CAH offered 10 services during the previous year. After relocation the CAH offers all 10 services and adds 3 new services. They have retained 100 percent of their services and added new services. If they drop 3 services, even though they add 3 new and different services, they have not maintained 75 percent.*

- *At least 75 percent of the billing codes and the volume for inpatient and outpatient services provided by the CAH during the last year prior to the relocation must remain the same for at least one year after the move. CMS will evaluate both the type of services offered and the volume of each type of service offered, as appropriate.*

Providing Services Using 75 percent of the Same Staff (including medical staff, contracted staff and direct employees). *The relocated CAH must meet all of the following defining criteria in order to meet "providing services using 75 percent of the same staff."*

- *75 percent of the members of the CAH's medical staff, 75 percent of its direct employees, and 75 percent of its contract staff that were at the CAH during the previous year prior to relocation, remain on staff for the first year after the relocation. Contracted staff includes all personnel who regularly work 20 or more hours a week at the CAH, whether they are directly contracted by the CAH or whether they are employees of a contractor.*

- *To address the employee criterion, the CAH must provide a list of medical staff, contract staff, and employees before and after the move.*

Cessation of Business.

Under existing CMS policy, if the CAH relocation results in the CAH not remaining essentially the same provider or in the cessation of furnishing services to the same community, we would not consider this to be a relocation, but instead would consider such a scenario to be a cessation of business at one location and establishment of a new business at another location. Cessation of business is a basis for voluntary termination of the provider agreement under 42 CFR Part 489. If the proposed move constitutes a cessation of business, the RO may assist the provider in obtaining an agreement to participate under a new provider agreement.

There is no appeals process for a voluntary termination. Under CMS policies, the cessation of business by a CAH automatically terminates the CAH provider agreement regardless of whether the designation was obtained through a necessary provider determination or not.

Letter of Attestation*.*

Prior to any relocation of a CAH, the CAH must send a letter of intent to the SA and to the RO. The CAH should send the letter early in the planning stage of its relocation and prior to spending or obligating significant funds and resources. The letter should state that the CAH plans to relocate and must attest that it will continue to be essentially the same provider serving the same community but at a new location.

The Letter of Attestation must:

- *Include addresses, both the present location and the future location;*
- *Provide documentation that supports that it will continue to be essentially the same provider at the new location as herein described;*
- *Include the travel distance from the current location to the future location;*
- *Provide the names, addresses, and travel distances to all hospitals and CAHs that share and surround the community at the current and future locations;*
- *Provide documentation to address all criteria previously discussed in "Retention of the Medicare Provider Agreement after Provider Relocation";*
- *Provide a time table for the relocation;*
- *Any CAH with a grandfathered necessary provider designation that is planning to relocate and that wishes to maintain its designation as a necessary provider must provide documentation to support the CAH attestation that it will meet the requirements in §485.610(d)(1) in every area as herein stated (75 percent community served, services provided, and staff. The documentation must include references and sources for numbers and statistics used);*
- *Any grandfathered CAH planning to relocate that wishes to maintain its designation as a necessary provider must provide documentation that demonstrates that the CAH will continue to meet the same criteria that was originally used by the State for its designation as a necessary provider. Additionally, the CAH must include a letter of assurance from the State Office of Rural Health (or the agency in the State that is authorized to designate CAHs) that it has made a preliminary determination that the CAH will continue to meet the original criteria for its designation as a necessary provider at its new location.*
- *All documentation must identify source(s) and references used by the CAH to develop statistics, numbers, and other attestation requirements;*

The RO will evaluate the letter of attestation and documentation provided by the CAH including any other information that the RO deems appropriate in its comparison of the CAH at its current and future locations. The RO will advise the CAH of any additional information that may be needed for evaluation. The RO will advise the CAH of the results of its preliminary evaluation. ***The final determination will not occur until after the CAH relocates****.*

Construction and Relocation Phase*. During the construction and relocation the CAH must notify the SA and the RO of any changes, other than minor changes, that are identified by the CAH that change its letter of self attestation that it will be essentially the same provider serving the same community at the identified location and that it will be in compliance with §485.610(d).*

After Relocation*. Once the relocation is complete the CAH must attest that it remains essentially the same provider serving the same community in its new location and whether the information provided with its earlier attestation remain the same. The CAH must address any changes in its*

previous attestation letter and must provide documentation to demonstrate that it is essentially the same provider serving the same community at the new location and, for a CAH with a necessary provider designation, that it meets all the requirements in §485.610(d) at its new location. Additionally, a CAH with a grandfathered necessary provider designation must provide a letter of determination from its State Office of Rural Health (dated after the relocation is complete) advising CMS as to whether or not the relocated CAH continues to meet the original criteria for its designation as a necessary provider now that the CAH has completed its move to the new location.

Once the CAH has completed its relocation and has forwarded all required and requested documentation to the RO, the RO will make its determination of the CAH's status. The RO will advise the CAH of any additional information that is needed to make the determination. After completing its evaluation and making its determination, the RO will notify the CAH in a letter as to whether the CAH will retain the same provider agreement and, as applicable, whether the CAH can retain its necessary provider designation.

In addition to the determination made immediately after a CAH's relocation, and at the RO's discretion, the RO may conduct a review one year after a CAH's relocation to determine that a relocated CAH meets the relocation criteria.

Survey Procedures §485.610(d)

- *The RO will evaluate the letter of attestation and documentation provided by the CAH including any other information that the RO deems appropriate in its comparison of the CAH at the old and new sites. The RO will determine whether the CAH remains essentially the same provider serving the same community after relocation and may continue to operate under the same Medicare provider agreement. The RO will communicate with the CAH, the State Office of Rural Health, and the SA, as it deems necessary, to conduct its determination.*

- *Additionally, for the relocation of a CAH with a necessary provider designation, theRO will determine whether the CAH complies with §485.610(d) after a relocation.*

- *In order to determine if a relocated CAH with a grandfathered necessary provider designation continues to meet the original criteria for its designation as a necessary provider at its new location, the RO must receive a letter of assurance from the CAH's State Office of Rural Health.*

- *A survey of the CAH should be conducted in the new location to determine compliance with all CoPs, including Life Safety Code requirements, and to verify the information in the letter of attestation.*
