DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

**Ref: S&C-09-15**

**DATE:** **November 21, 2008**

**TO:** State Survey Agency Directors

**FROM:** Director
Survey and Certification Group

**SUBJECT:** New Critical Access Hospital (CAH) requirements under 42 CFR 485.610(e) related to CAH Co-location and CAH provider-based locations.

**Memorandum Summary**

The Centers for Medicare & Medicaid Services (CMS) has adopted regulations clarifying the Medicare requirements governing CAH location relative to other facilities. Effective January 1, 2008:

1. Necessary provider CAHs (NPCAHs) are prohibited from co-locating with other hospitals or CAHs. Existing co-located NPCAHs may retain their CAH designation only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of the services offered by the facility co-located with the NPCAH do not change.

2. CAH off-campus provider-based facilities, excluding rural health clinics (RHCs) but including CAH psychiatric/rehabilitation distinct part units (DPUs), that are created or acquired on or after January 1, 2008, must comply with the CAH location requirements.

3. CAHs with arrangements that do not meet these requirements will have their provider agreement terminated, unless the CAH terminates the non-complying arrangement.

CMS published a final rule in the November 27, 2007 *Federal Register* (72 Fed. Reg. 66934) amending 42 CFR Part 485 Subpart F, adding a new standard at §485.610(e), governing a CAH's location relative to other hospitals or CAHs with respect to co-location and off-campus provider-based arrangements. These amendments became effective January 1, 2008.

**Background**

Among other requirements, under section 1820(c)(2)(B)(i)(1) of the Social Security Act (the Act) and 42 C.F.R. 483.610(c), CAHs are required to be located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads, a 15- mile drive) from the nearest hospital or other CAH. Prior to January 1, 2006, States were permitted to override the statutory CAH minimum distance requirement by designating the CAH as a "necessary provider," under criteria established by each State's Medicare Rural Hospital Flexibility Program (MRHFP). Amendments to the Act that eliminated this provision also included a grandfathering provision for CAHs designated as necessary providers (NPCAHs) by a State prior to that date.

CMS has encountered situations where CAHs have established off-campus provider-based facilities that do not themselves satisfy the regulations for a CAH location relative to other hospitals or CAHs. Likewise, CMS learned that some CAHs operating with necessary provider designations are co-located with other hospitals, particularly specialty psychiatric and/or rehabilitation hospitals. Through amendments to the Act, Congress addressed the potential need for these services in rural areas by permitting CAHs to establish their own psychiatric or rehabilitation units, up to 10 beds each, in addition to their permitted 25 inpatient beds. This was done in the same legislation that eliminated States' ability to designate NPCAHs.

**Provisions of the Amended Regulation**

The new 42 C.F.R. 485.610(e)(1) permits NPCAH co-location arrangements only in those cases where the arrangement was in effect prior to January 1, 2008. Grandfathered arrangements may continue in effect only so long as the type and scope of services offered by the co-located facility do not change. (The regulation pertains only to NPCAHs, because it has always been clear that a regular CAH may not co-locate with another hospital or CAH.) Additionally, any changes of ownership of any NPCAHs with co-location arrangements in effect before January 1, 2008 will not be considered to be a new co-located arrangement.

The new 42 C.F.R. 485.610(e)(2) provides that a CAH or NPCAH that creates or acquires on or after January 1, 2008 an off-campus, provider-based location, excluding an RHC but including an off-campus distinct part psychiatric or rehabilitation unit, must meet the minimum distance from another hospital or CAH requirement of §485.610(c) at the off-campus location. Off-campus provider-based arrangements established prior to that date are grandfathered.

Finally, new section 485.610(e)(3) provides for the termination of a CAH that does not meet the requirements of 485.610(e)(1) and (2), unless the CAH terminates the co-location or off-campus arrangement, as applicable.

**Process**

The determination of whether or not a CAH applicant has met the requirements of §485.610(e) will be made by the Regional Office (RO), generally prior to a State Survey Agency or accreditation survey. The RO will utilize the guidance provided in Chapter 2 of the State Operations Manual (SOM), Section 2256G for issues related to co-location and Section 2254H for issues relating to off-campus locations of the CAH, in making this determination.

An advance copy of the revised sections of the SOM is attached to this memorandum. Although the final version, expected to be published in the on-line SOM in FY 2009, may differ slightly from this advance copy, the provisions found in this advance copy are now in effect.

**Effective Date:** Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

**Training:** This information contained in this memorandum should be shared with all appropriate survey and certification staff, their managers, and the State/RO training coordinators.

If you have any questions concerning this memorandum, please call Cindy Melanson at (410) 786-0310 or via e-mail at cindy.melanson@cms.hhs.gov.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

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

**Transmittal - Advance Copy** **Date:**

**SUBJECT: New Critical Access Hospital (CAH) requirements under 42 CFR 485.610(e) related to CAH Co-location and CAH provider-based locations.**

**I. SUMMARY OF CHANGES:** Changes were made to Chapter Two of the State Operations Manual (SOM) and Appendix W, "Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs)" in response to a final rule published in the November 27, 2007 Federal Register (72 FR 66934) amending 42 CFR Part 485, Subpart F, adding a new standard at §485.610(e).

Revisions to the SOM include:

- New Section 2256G- Co-Location of Critical Access Hospitals
- New Section 2256H- Off-Campus CAH Facilities
- Revised Appendix W Index
- New Appendix W Tags- C-0167 & C-0168 were added to provide guidance for regulations at 42 CFR 485.610(e)

**NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Publication**
**IMPLEMENTATION DATE: Upon Publication**

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

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

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|---|---|
| N | 2256G/Co-Location of Critical Access Hospitals |
| N | 2256H/Off-Campus CAH Facilities |
| R | Appendix W/Index |
| N | Appendix W/Tag C-0167 |
| N | Appendix W/Tag C-0168 |

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

**IV. ATTACHMENTS:**

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

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

**Revisions to Chapter 2 of the State Operations Manual – ADVANCE COPY**

**Index**

## *2256G - Co-Location of Critical Access Hospital*

*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 Section 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 in 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital and be assigned a new CCN number accordingly.*

---

## *2256H – Off-Campus CAH Facilities*

*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 15 miles 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.*

*Definitions related to provider-based status are found in 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 an 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 in §485.647, and departments that are off-campus and remote locations of CAHs, as defined in §413.65(a)(2). 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, 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.*
- *Ambulances*

*In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based, 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 are eligible for 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 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.*

***CAH Provider-based Locations "Under Development"***

*CAHs that were in the process prior to January 1, 2008 of building or acquiring off-campus facilities for which they intend to seek provider-based status are evaluated on a case-by-case basis by the RO to determine if the project was "under development" prior to January 1, 2008. In determining whether a provider-based location was "under development" prior to January 1, 2008, the RO considers whether the following (among other factors) had occurred as of that date:*

- *Architectural plans were completed;*
- *Letting of bids for construction;*
- *Purchase of land and building supplies;*
- *Expenditure of funds for construction'*
- *Financing commitments were secured;*

- *Zoning approvals were received;*
- *Application for certificate of need received; and*
- *Necessary approvals from appropriate State agencies were received.*

*In some cases, all of these steps may not have been completed, but the specific facts of the case provide ample evidence that the project was in an advanced stage of development. For example, construction of a facility might have been completed in December, but the State might not have completed processing the CAH's application to add the facility to the CAH's license before January 1, 2008. Thus, while all of the factors will be considered, the RO will make case-by-case determinations. In addition, the RO may consider any other evidence that it believes would indicate whether an off-campus provider-based location was under development as of January 1, 2008. If the RO determines that an entity was not under development as of January 1, 2008, then the off-campus facility will not be considered a grandfathered provider- based location (72 FR 66879).*

***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 of §485.610(c) only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or 15 mile drive in the case of mountainous terrain or in areas where only secondary roads are available) from a hospital or another CAH. Therefore, a CAH must seek an advance determination of compliance with the location requirements for any off-campus provider-based facility established on or after January 1, 2008.*

*A facility that seeks such a determination must submit an attestation to the RO documenting how the facility complies with the CAH provider-based location requirements at §485.610(e)(2).*

*RO survey and certification staff review the attestation for evidence that the CAH's off-campus facility is more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH. The RO utilizes the same process employed for assessing the compliance of a CAH applicant's main campus with the minimum distance criteria.*

*RO financial management staff review the CAH's attestation for completeness and consistency with the provider-based rules. For purposes of this review, CMS considers issues such as the following. This list is provided for informational purposes only; it is not all-inclusive. CAHs must consult and comply with all applicable requirements of 42 CFR 413.65.*

- *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.*
    - *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.*
- *When Medicare beneficiaries are treated in CAH outpatient departments that are located off-campus, the treatment is not required to be provided by the anti-dumping rules in §489.2, unless the off-campus facility meets the EMTALA definition of a dedicated emergency department found at 42 CFR 489.24(b).*

***Termination for Noncompliance***

*A CAH found out of compliance with the off-campus location requirements of §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 Section 3012. If the CAH corrects the situation, by terminating during this 90 day period the off-campus provider-based arrangement that led to the non-compliance, then the provider agreement is not terminated.*

*A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions in 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.*

---

## Revisions to Appendix W of the State Operations Manual

**INDEX**

*** * ***

**Regulations and Interpretive Guidelines for CAHs**

§485.610 Condition of Participation: Status and Location
§485.610(a) Standard: Status
§485.610(b) Standard: Location in a Rural Area or Treatment as Rural
§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification
§485.610(d) Standard: Relocation of CAHs With a Necessary Provider Designation
*§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs*

* * *

---

***C-0167***

# *§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs.*

***Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:***

> ***(1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.***
>
> * * *
>
> ***(3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, [or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section,] the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.***

***Interpretive Guidelines §485.610(e)(1) & (3)***

*A CAH may not be co-located with another hospital or CAH, because this would violate the minimum distance requirement found at §485.610(c). However, some CAHs that were*

*designated as necessary providers prior to January 1, 2006, and therefore exempted from this distance requirement, also chose to co-locate with another hospital. Co-location occurs when a necessary provider CAH shares the same campus and/or building in which the CAH is currently located with another hospital or necessary provider CAH. For example, a necessary provider CAH shares the same campus with an unrelated psychiatric or rehabilitation hospital.*

*Effective January 1, 2008, grandfathered necessary provider CAHs may no longer enter into co-location arrangements with another CAH or hospital (72 FR 66878). However, necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008 are permitted to continue these arrangements, as long as the type and scope of services offered by the facility co-located with the CAHs 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 now decides to increase the number of beds to 30.*

*The determination of whether or not CAHs with a grandfathered necessary provider designation have met the requirements at §485.610(e)(1) is made by the RO. If the SA or accreditation organization (AO) becomes aware of a co-location arrangement, the SA or AO must notify the RO. The RO will utilize the co-location guidance in Section 2256G of the State Operations Manual (SOM) to determine if such CAHs satisfy the co-location requirements at §485.610(e)(1). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.*

*A CAH found out of compliance with the requirements 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 Section 3012 of the SOM. If the CAH corrects the 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 in 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.*

---

***C-0168***

# *§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs (con't.)*

***Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:***

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

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

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

*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 15 miles 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 to be calculated from the provider-based facility's location to the main campus of the other hospital or CAH.*

*The distance to another hospital or CAH requirement does not apply to the following types of facilities/services, because such facilities or services are not eligible for provider-based status in accordance with §413.65(a)(1)(ii):*

- *Ambulatory surgical centers (ASCs);*
- *Comprehensive outpatient rehabilitation facilities (CORFs);*
- *Home Health Agencies (HHAs);*
- *Skilled nursing facilities (SNFs);*
- *Hospices;*
- *Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services;*
- *ESRD facilities;*
- *Departments of providers that perform functions necessary for the successful operation of the CAH but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g., laundry, or medical records department.*
- *Ambulances.*

*In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based, 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 as well as facilities that participate as FQHCs by virtue of being tribally owned or operated that are eligible for provider-based status.*

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

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

*A CAH found out of compliance with the off-campus location requirements of §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 Section 3012 of the SOM. If the CAH corrects the*

*situation, by terminating the off-campus provider-based arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.*

---

*A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions in 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.*

---