XVIII. Proposed Changes Affecting Critical Access Hospitals (CAHs) and Hospital Conditions of Participation (CoPs)

A. Proposed Changes Affecting CAHs

(If you choose to comment on the issues in this section, please include the caption "Necessary Provider CAHs" at the beginning of your comment.)

1. Background

CAHs are subject to different participation requirements than are hospitals. Among other requirements, a CAH must be located in a rural area (or an area treated as rural), and, under §485.610(c), must meet an additional distance-related location requirement. Under this requirement, a CAH must be located at least 35-miles (or, in the case of mountainous terrain or in areas with only secondary roads, 15-miles) from the nearest hospital or other CAH. In addition, CAHs receive payment for services furnished to Medicare beneficiaries differently. CAHs receive cost-based payment for 101 percent of their reasonable costs.

Prior to January 1, 2006, States were permitted to waive the CAH minimum distance eligibility requirement by certifying that a CAH was a necessary provider. Approximately 850 current CAHs entered the program on the basis of a necessary provider designation. The criteria used to qualify a CAH as a necessary provider were established by each State in its Medicare Rural Hospital Flexibility Program (MRHFP). The State's MRHFP rural health care plan contains the necessary assurances that the plan was developed to further the goals of the statute and regulations to ensure access to essential health care services for rural residents. The statute and regulations give some discretion and flexibility within a Federal framework for a State to designate CAHs. States, in consultation with their hospital associations and Offices of Rural Health, have defined those CAHs that provide necessary services to a particular patient community in the event that the facility did not meet the required 35-mile (or, in the case of mountainous terrain or in areas with only secondary roads, 15-mile) distance requirement from the nearest hospital or CAH. Each State's criteria are different, but the criteria share certain similarities and all define a necessary provider related to the facility location.

However, section 405(h)(1) of Pub. L. 108-173 amended section 1820(c)(2)(B)(i)(II) of the Act by adding language that ended States' authority to waive the location requirement for a CAH by certifying the CAH as a necessary provider, effective January 1, 2006. In addition, section 405(h)(2) of Pub. L. 108-173 amended section 1820(h) of the Act to include a grandfathering provision for CAHs that were certified as necessary providers prior to January 1, 2006. We incorporated these amendments in §485.610(c) of our regulations in the FY 2005 IPPS final rule (69 FR 49220). Because those regulations did not address the situation where the grandfathered CAH is no longer the same facility due to relocation, in the FY 2006 IPPS final rule (70 FR 47490), we amended §485.610 of our regulations to add a new §485.610(d) that addressed the relocation criteria a necessary provider CAH has to meet to retain its necessary provider designation.

Additional circumstances concerning CAHs with existing necessary provider designations have come to our attention that we believe also need to be addressed. Specifically, we have learned that some CAHs with grandfathered necessary provider designations are co-located with other hospitals, which typically are PPS-excluded inpatient psychiatric facilities or inpatient rehabilitation facilities. We are also aware that there is interest in the creation or acquisition by CAHs with necessary provider designation of off-campus facilities that they do not believe would be subject to CAH location requirements.

For the reasons noted below, we are taking a proactive approach by proposing a change in the regulation to be consistent with our belief that the intent of the CAH program is to maintain hospital-level services in rural communities while ensuring access to care. We believe that this proposed change to the regulations will help to maintain the integrity of the MRHFP within the statutory requirements.

2. Co-Location of Necessary Provider CAHs

Some necessary provider CAHs are co-located with other hospitals, particularly specialty psychiatric and or rehabilitation hospitals. Prior to the enactment of section 405(g) of Pub. L. 108-173, it is understandable that a State MRHFP might have allowed co-location of a CAH with a necessary provider designation with the specialized services of a psychiatric and/or an inpatient rehabilitation hospital. The State may have believed that beneficiary access to care would be enhanced through the provision of both CAH and these specialized services at the same location, and the CAH itself might have had difficulty in providing such services within its permitted bed limits. However, section 405 of Pub. L. 108 173 included several provisions that permit CAHs themselves to address such access to care issues.

Specifically, section 405(e) of Pub. L. 108-173 amended sections 1820(c)(2)(B)(iii) and 1820(f) of the Act to increase the permitted number of CAH inpatient beds from 15 to 25. In addition, section 405(g) of Pub. L. 108-173 added section 1820(c)(2)(E) to the Act, which permits a CAH to operate distinct part inpatient psychiatric and/or rehabilitation units, each subject to a 10-bed limit that is not included as part of the CAH's 25-bed limit. Therefore, a CAH can operate a 45-bed facility addressing a wide range of needs in the rural community it serves. We believe that CAHs seeking to provide access to specialized services should avail themselves of the statutory provisions governing distinct part units in CAHs rather than making arrangements with other hospital providers to share space at the CAH location.

In light of these changes to the statute, we are proposing to no longer allow a necessary provider CAH to enter into co-location arrangements between CAHs and hospitals unless such arrangements were in effect on or 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. We believe that this restriction will help to ensure that the current necessary services will remain in the community. Further, we are proposing to clarify that a change of ownership of the CAH, when the new owners assume the original provider agreement, does not constitute a new co-location arrangement and, thereby, under our proposal, a necessary provider CAH would be permitted to continue under an existing co-location arrangement.

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We are concerned that, without this change, there may be situations where more necessary provider CAHs will co-locate with PPS hospitals. Currently, co-location arrangements seem to involve psychiatric or rehabilitation hospitals. We are concerned about co-location by a necessary provider CAHs with a short-term acute care hospital, including a physician-owned specialty hospital. We also cannot rule out a scenario where two necessary provider CAHs could co-locate after relocation. We believe the co-location of a necessary provider CAH with another hospital or necessary provider CAH is not consistent with the CAH statutory framework that establishes requirements for a CAH to be a certain minimum distance from other hospitals or CAHs. We believe that the elimination of States' authority to designate necessary provider CAHs and the ability for CAHs to operate psychiatric and rehabilitation units should provide sufficient flexibility for necessary provider CAHs to operate within the statutory framework without engaging in additional arrangements.

We also are clarifying in this proposed rule that under certain circumstances, a change of ownership of any of the facilities (either the CAH or the existing co-located facility) with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement. If a change of ownership should occur in a CAH with a grandfathered co-location arrangement on or after January 1, 2008, we note the provider agreement is generally automatically assigned to the new owner, unless the new owner rejects assignment of the provider agreement or assignment of the provider agreement is otherwise not made. If the new owner does not get assignment of the provider agreement, the new owner would have to go through the same enrollment process as any other new provider; that is, enrolling with the fiscal intermediary (or if applicable, the MAC), applying for participation, undergoing the Office of Civil Rights clearance and an initial certification survey that meets all the current Medicare conditions (see State Operations Manual 3210) to obtain CAH status. Thus, grandfathered necessary provider CAH status, including grandfathered co-location arrangements, would not transfer to a new CAH owner who does not assume the provider agreement from the previous owner. To obtain CAH designation, the new provider would have to comply with all the CAH designation requirements, including the location requirements relative to other providers, that is, more than a 35-mile drive (or 15 miles in areas of

mountainous terrain or secondary roads).

3. Provider-Based Facilities of CAHs

We have consistently taken the position that the intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care (FY 2006 IPPS final rule (70 FR 47469)). A CAH is permitted to create or acquire an off-campus location, including a distinct part unit that satisfies the location criteria for a CAH and operates under the CAH's provider agreement under the provider-based rules at 42 CFR 413.65. We note that, under section 1820(c)(2)(B)(i)(II) of the Act, a CAH does not have to meet the distance requirements relative to other hospitals or CAHs if it was certified prior to January 1, 2006, as a necessary provider by the State. We stated in the FY 2006 IPPS final rule (70 FR 47472), when addressing the relocation criteria for a necessary provider CAH, that the "necessary provider" designation is specific to the physical location(s) of the CAH in existence at the time of the designation. We believe the necessary provider CAH designation cannot be considered to extend to any new facilities not in existence when the CAH received its original necessary provider designation. Accordingly, we believe the creation of any new location that would cause any part of the CAH to be situated at a location not in compliance with the distance requirements at 42 CFR 485.610 would cause the entire CAH to violate the distance requirements.

Of the approximately 1,300 CAHs, 453 CAHs have health clinics, 81 have psychiatric units, and 20 have rehabilitation units. We do not know how many of the existing clinics and distinct part units are at off-site locations. However, we are concerned with CAHs creating or acquiring off-campus locations, including distinct part psychiatric and rehabilitation units, that do not comply with the CAH location requirement relative to other facilities. Therefore, when such off-campus facilities are created by a CAH with a necessary provider designation, there is no reason to assume that the distance exemption given to the CAH should be extended without qualification to any location for that CAH's off-campus facilities. Accordingly, any CAH off-campus locations must satisfy the current statutory CAH distance requirements, without exception and regardless of whether the main provider CAH is a necessary provider CAH.

Therefore, we are proposing to clarify that if a necessary provider CAH, or a CAH that does not have a necessary provider designation, operates a provider-based facility as defined in §413.65(a)(2), or a psychiatric or rehabilitation distinct part unit as defined in §485.647 that was created or acquired on or after January 1, 2008, it must comply with the distance requirement of a 35-mile drive to the nearest hospital or CAH (or 15 miles in the case of mountainous terrain or in areas with only secondary roads).

4. Termination of Provider Agreement

In the event that a CAH with a necessary provider designation enters into a co-location arrangement after January 1, 2008, or acquires or creates an off-campus facility after January 1, 2008, that does not satisfy the CAH distance requirements in §485.610(c), we are proposing to terminate that CAH's provider agreement, in accordance with the provisions of §489.53(a)(3). The necessary provider CAH could avoid termination by converting to a hospital that is paid under the IPPS, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions in 42 CFR Part 482. We also note that if the necessary provider CAH corrects the situation that led to the noncompliance, a termination action will not be triggered. A CAH that is not a necessary provider CAH could not have a co-location situation due to the distance requirements it is required to meet at 485.610 (c).

5. Proposed Regulation Changes

We are proposing to amend §485.610 by adding a new paragraph (e) to address situations under our proposal relating to off-campus and co-location requirements for CAHs with a necessary provider designation.