American Hospital Association

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Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. McClellan:

On behalf of the American Hospital Association (AHA) and our 4,800 member hospitals, health care systems and other health care organizations, and our 35,000 individual members, we submit the following comments on the Centers for Medicare & Medicaid Services' (CMS) Survey and Certification interpretive guidelines regarding the location of Critical Access Hospitals (CAHs) relative to other facilities and Necessary Provider certification.

We believe these guidelines go well beyond the regulations included in the fiscal year (FY) 2006 inpatient prospective payment system (PPS) that allow necessary provider CAHs to relocate as long as they continue to serve 75 percent of the same population, provide 75 percent of the same services and employ 75 percent of the same staff (commonly referred to as the "75 percent test"). These guidelines provoked numerous critical responses from individual CAHs, associations and federal lawmakers. The guidelines do not provide reasonable flexibility based on natural variation in patient needs and disbursement patterns, normal employee and board attrition and necessary changes in services to meet the community's needs. Rural hospitals that move just a few miles are clearly the same providers serving the same communities.

These guidelines will not only impose a great, unnecessary burden on some CAHs, but will preclude many from securing financing for needed capital improvements. According to a recent AHA survey of CAHs, 32 of them plan to relocate within a year and already have purchased land. The survey also found that almost 50 more CAHs plan to move in one to three years. Thus, these guidelines will negatively affect a significant number of CAHs and their continued ability to care for their communities. We urge CMS to make important changes to these guidelines based on survey feedback from CAHs around the nation, detailed below.

Mountainous Terrain and Secondary Roads

Despite the fact that the final FY 2006 inpatient PPS rule did not mention revising the mountainous terrain and secondary road definitions, the guidelines make extensive changes that, if implemented, may revoke the status of some CAHs. These changes seem to affect CAHs, even if they are not rebuilding or relocating.

Mountainous Terrain

We believe that the state definition of mountainous terrain, determined by individual state departments of transportation, should be sufficient for a CAH to qualify under the mountainous terrain exception. Requiring that the elevation of a hospital or portions of the road on the route to the hospital exceed 3,000 feet and that sections of the roads have grades greater than 5 percent is overly prescriptive. The guidelines should be just that – general recommendations. CMS cannot anticipate every combination of circumstances that may justifiably deserve an exception to the 35-mile requirement, thus some allowance for reasonable judgment should be incorporated. At minimum we would suggest the following changes to this section:

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~~ one or more *of the following criteria:*

- *The CAH must be located in a mountain range* that is generally considered high altitude *~~(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* on a *~~at an elevation above 3000 feet and the~~ travel route* that *is regularly or seasonally subjected to weather-related hazardous driving conditions, such as poor visibility,* flooding, *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.*~~

Secondary Roads

The AHA believes that the guidelines, such as specifying strict speed limits, are overly prescriptive. In addition, the requirement for survey agencies to measure the distance to hospitals in other states is new. CAHs that were approved without consideration of hospitals across borders should be allowed to continue in the program, since CMS should have determined their status at the time of application. These hospitals have invested in their facilities and communities, developed budgets, etc., based on the assumption that they would remain CAHs, and to revoke their status at this point would be unfair. Furthermore, these hospitals should be allowed to move a reasonable distance if necessary to build a new facility. At a minimum, we suggest the following changes to this section:

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 a substantial portion *of ~~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, or the route that Emergency Medical Services would use if different. ~~*The distance requirement is not limited to the State boundaries. The distance requirement applies to ANY hospital or CAH, regardless of State boundary lines.*~~

75 Percent Test

While CAHs generally were comfortable with the 75 percent test, CMS' further delineation of the requirements in the guidelines go too far. For instance, changes in demographics and the practice of medicine will occur over time that may necessitate a change in services when a hospital is rebuilt. Or a greater reliance on new technology may limit the number or change the type of staff needed at a newly built facility. Flexibility is needed to allow for such expected changes in the needs of the community.

According to the recent AHA survey of CAHs, approximately 94 percent of the 350 respondents cited a deteriorating facility as their primary reason for relocating. Many CAHs are planning to rebuild at some point to improve the safety and quality of patient care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or making other essential upgrades. Many facilities expect to relocate when they rebuild to be closer to a highway, connect to municipal water and sewer, respond to seismic safety concerns, or other similar reasons. Such improvements undoubtedly will result in higher quality care, better patient outcomes and more efficient service, yet the CMS guidelines discourage these improvements.

<u>Staffing</u>

CMS should make allowances within the guidelines for assessing compliance with the requirement that 75 percent of staff remain the same when relocating. Some employees will leave during the transition for unrelated reasons, such as the expiration of a visa, birth of a child, death, etc. In such small facilities, the loss of even a few staff members may jeopardize compliance with a strict interpretation of the test.

It is also unreasonable to expect CAHs to retain exactly the same governing body. Many CAH governing boards have term limits. For instance, one CAH reports that its county appoints three members of a nine-member board every two years. If the three members are at their limits, the CAH would not have the same board even though they would be appointed in the same manner as before relocation. Thus, flexibility should allow for natural attrition and the customary appointment schedule. While this may have been the intent, it is not clear in the guidelines. The governing body provision also appears to preclude a change in ownership after relocation. We do not believe that CMS intended to interfere with business decisions of a CAH or its prospective owners, so long as the CAH continued to meet the requirements.

Contract employees should have similar flexibility, such as physicians who are temporarily employed by the hospital, employees rotated in from other facilities, or those connected to a

change in contractor. If a CAH has a limited number of contract employees, compliance could again be jeopardized through no fault of the CAH.

Policies and Procedures

It is not clear how maintaining the same policies and procedures is relevant to the 75 percent test. This not only dictates how a hospital conducts its business, but could unnecessarily endanger patient safety. There is no stated exception for changes in policies and procedures to improve quality. For instance, if a CAH takes part in the Surgical Care Improvement Project (SCIP) or the Institute for Healthcare Improvement's (IHI) 100,000 Lives Campaign, the facility would have to change their policies and procedures. If a hospital wants to install a physician order entry or bar-coding system, the case would be the same. We urge CMS to drop this requirement. Medical staff bylaws, policies and procedures are similarly inappropriate – what if a CAH wants to change its emergency department on-call policy due to changes in physician supply in the area?

Services and Billing Codes

Using the volume of services provided by a relocating CAH to determine whether it is essentially providing the same services to its community is problematic. The volume of services provided by a CAH can vary greatly from year-to-year for reasons out of its control, such as a heavy flu season. CMS should examine the cause for the change in volume if it exceeds the threshold. The CAH may still serve almost 100 percent of its original community but that makes up only 70 percent of its new volume. Being closer to a highway, for instance, may make it easier for patients from the other side of the county to go to the hospital. Additionally, a change in just one physician can alter the mix of services of a small hospital – adding a much needed service or creating an access to care issue for other services. Uncontrollable changes in physician supply should not negatively affect a CAH if that change affects the types of services provided at the hospital.

Using billing codes to determine if a relocating CAH is essentially providing the same services is too narrow, as it does not account for changes in billing instructions and the practice of medicine in general. In addition, a number of factors can impact the billing codes/volumes of an organization, beyond relocation, such as: increasing the size of the medical staff; closure of neighboring facilities; natural and/or man-made disasters; disease patterns; demographic changes; etc. Broader service categories should be considered instead of specific codes.

We believe that the services test should be applied to only inpatient and outpatient services. CAHs that have skilled-nursing facilities or home health agencies should not have to include these services in the 75 percent test.

Population

We believe that an analysis of zip codes in the service area would be the best measurement of the continuity of the population served. It would be inappropriate to look at specific patients as they may not have a need for treatment in a subsequent year.

Verifying that 75 percent of the population served has "equal or less travel distance to come to the new location" is difficult to prove. This cannot be done using billing addresses, as some patients may have their bills sent to an office or a caregiver's home. And it would take extensive analysis to map out each patient's drive time and distance from a relocated CAH. This criterion should be dropped from the guidelines.

The final rule did not specify the further breakdown of the "75 percent of the same population" test by payer type, income levels or demographics. This is unnecessarily prescriptive and burdensome for CAHs that may not capture this type of patient information. For instance, hospitals do not typically track patients' income levels unless the patient is applying for financial assistance. These criteria should be dropped.

This would hardly change access anymore than a mile or so would since driving to everything is a way of life in rural areas. This also ignores the need for some CAHs to move away from their current location to connect to public water and sewage services, or closer to a highway for emergency access, or out of a flood plain or seismically unsound piece of land. Additionally, many of these hospitals will be moving to a piece of land that was donated, thus lowering the cost to the community.

The guidelines' statement that 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" is disconcerting. The vast majority of CAHs that are moving believe that they can easily meet the spirit of the 75 percent test as articulated in the FY 2006 final rule; however, statements like this create concern and doubt. Hospitals and CMS need to clearly understand the requirements and have a reasonable way of demonstrating compliance. Blanket statements like this one introduce uncertainty into the process. CMS should ensure that regional offices do not abuse this broad discretion. Further, this type of discretion should be used only to allow a hospital that does not meet one of the 75 percent test criteria to provide additional information or application to show that the hospital is the same hospital.

Below we provide our detailed suggestions on the 75 percent test portion of the guidelines.

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. CAHs that move within five miles of their existing location will be automatically considered compliant with the 75 percent test.

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 essentially *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 on a piece of land that is not contiguous to the current property *will be considered to have relocated.* Renovations or expansions of existing structures and rebuilding on the current campus will not be considered 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* essentially *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* retains ~~*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* (unless due to expiration of term or other natural attrition)*;*
- ~~*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* (although the provider can add services);

- *The distance the provider moves from the original site* if the CAH moves more than five miles.

- *The provider continues to serve 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.*~~

- A hospital that does not meet one or more of the 75 percent criteria may provide additional information to justify why it cannot meet the criteria and demonstrate that it remains the same provider. CMS can use its discretion to identify exceptions when appropriate.

Relocation of CAHs Without Necessary Provider Designation

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* only if it moves more than five miles*. 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.*

Necessary Providers

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 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 or relevant agency 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* who utilized the CAH's services *prior to the 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.~~* One way to demonstrate this would be to document that 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.

- ~~*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* and *75 percent of its direct employees, that were at the CAH during the previous year prior to relocation, remain on staff for the first year after the relocation.* Discretion for normal and reasonable attrition should be used.

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

Cessation of Business

The AHA believes that CMS has gone too far in trying to portray hospitals that are moving a few miles from their current location as "ceasing business" and then reopening as a *new provider*.

These CAHs are integral to their communities and often one of the largest employers. Moving down the road will not demonstrably change the population served.

We further believe it is unreasonable for CMS to immediately deem a CAH as having ceased business and become a new provider based on the review one year after the relocation without an opportunity to dispute the decision. The guidance states: *"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."* We do not believe this should be considered a voluntary termination. We believe that CAHs should be given the opportunity to explain and document legitimate reasons for not meeting the interpretive guidelines to their fullest extent. This is not an "appeal" but, rather, should be viewed as a corrective period before a final determination is made. Some flexibility must be introduced into this process to insure that CAHs with extenuating circumstances are fairly treated. The CMS regional offices, in cooperation with state survey agencies, should be able to work with a CAH to rectify aspects of its operations that are deemed to be in violation of the interpretive guidance. If need be, the central office should become involved.

Letter of Attestation

In the letter of attestation section of this guidance on whether or not a CAH move is approved, CMS notes that "*The final determination will not occur until after the CAH relocates.*" The uncertainty that this creates has been the single greatest concern for hospitals. This provision could sabotage CAH financing – as has been true in a few cases for CAHs currently in the process of trying to move. CMS should develop a preliminary approval letter that gives CAHs some indication of whether their move is acceptable. CMS cannot expect small, rural hospitals to put everything on the line, and lenders to put up funds toward the project, with absolutely no indication as to whether the move will be approved. We understand that under the current criteria CMS cannot give 100 percent approval before a move, as something may change in the interim, but some assurance should be provided. This is one key reason for creating a five-mile safe harbor that presumes any hospital moving five miles or less is the same hospital.

Instead, the AHA believes CMS should state: "The RO will issue preliminary approval of the relocation project, within 30 days from receipt of the hospital's Letter of Attestation and supporting documentation, and this decision will stand, provided the applicant continues to meet the guidelines for construction, relocation, and the 75 percent rules."

Furthermore, we believe that the following line should be struck: *"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."* The final approval should occur when the hospital completes its move. CAHs should not have to operate in limbo for another year. It is impractical and unfair.

CAHs are the sole providers of inpatient acute-care services in their communities, and often outpatient and long-term care services as well. Facilities that convert to CAH status do so because of their dire financial conditions under the prospective payment systems. Thus, it is

unlikely that they would be able to successfully convert back to the inpatient PPS. In addition to the lower reimbursement, they would face other hurdles, such as licensing for additional beds in certificate-of-need states or hiring additional staff to expand services when there are shortages in many areas would need to be surmounted to build volume and survive under the PPS. For many of these CAHs, loss of their status would force them to close. Given the role of these facilities in their communities, such closures would have devastating affects on rural health care access.

Other Issues

We also encourage CMS to consider special provisions for hospitals that are merging. Under these circumstances, the hospitals may not be able to meet the criteria. In these cases, CMS should make determinations on a case-by-case basis. If the merger meets the needs of the communities, then CMS should consider it an appropriate and allowable relocation.

Thank you for your consideration of these comments. Please contact me or Danielle Lloyd, AHA senior associate director for policy, at (202) 626-2340 if you have any questions.

Sincerely,

Rick Pollack
Executive Vice President

cc: Herb Kuhn
Thomas E. Hamilton