# PROVIDER REIMBURSEMENT REVIEW BOARD HEARING DECISION

2000-D5

# **PROVIDER** -

St. Anthony's Memorial Hospital Effingham, Illinois

Provider No. 14-0032

vs.

# **INTERMEDIARY**-

Blue Cross and Blue Shield Association/Blue Cross and Blue Shield of Illinois

DATE OF HEARING-

January 8, 1999

Cost Reporting Period Ended - June 30, 1993

**CASE NO.** 94-0327

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# **ISSUE:**

Was the Health Care Financing Administration's ("HCFA") denial of the Provider's request for classification as a sole community hospital proper?

## STATEMENT OF THE CASE AND PROCEDURAL HISTORY:

St. Anthony's Memorial Hospital ("Provider") is a general, acute-care hospital located in Effingham, Illinois. The Provider is located in a rural area and is classified as a rural referral center. On March 10, 1993, the Provider filed a request for sole community hospital status pursuant to the regulatory provisions of 42 C.F.R. §412.92 et seq.. This regulation provides that a hospital qualifies as a sole community hospital if it is located between 25 and 35 miles from other like hospitals and no more than 25 percent of residents who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area. This test requires a two-step analysis. First, the hospital must define its service area. The regulation at 42 C.F.R. § 412.92(c)(3) states that the term service area means "the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital." Second, once a hospital has determined its service area, the next step of the test is whether the hospital has at least a 75 percent market share within that service area, i.e., no more than 25 percent of the hospital's patients in the service area seek care from other hospitals.

The dispute in this case focuses on the first step of the above test: defining the service area for the Provider. In filing its application for sole community hospital status, the Provider followed the instructions set forth in §2810.A.2.c of the Provider Reimbursement Manual ("HCFA Pub.15-1"). This manual section states that a hospital "may define its service area as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients." Following this methodology, the Provider defined its service area by using the lowest number of "contiguous" zip codes that identified 75 percent of its inpatients. The result of this analysis was a single contiguous service area comprising 18 zip codes. Having defined its service area in this manner, the Provider met the second part of the test and, thus, qualified for sole community hospital status.

The Provider's application was reviewed by Blue Cross and Blue Shield of Illinois ("Intermediary"), which in turn forwarded the application to the HCFA Regional Office with the recommendation that the

Provider Exhibit P-5.

Provider Exhibit P-2.

<sup>&</sup>lt;sup>3</sup> Provider Exhibit P-4.

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request be approved.<sup>4</sup> On May 24, 1993, the HCFA Regional Office denied the Provider's request based on its determination that the Provider did not meet the market share test within its service area.<sup>5</sup> Instead of defining the Provider's service area using the lowest number of "contiguous" zip codes, HCFA defined the Provider's service area using the lowest number of zip codes from which the Provider drew 75 percent of its inpatients. Under this approach, HCFA used 16 non-contiguous zip codes. On January 6, 1999, the parties entered into a joint stipulation which summarized the crux of their respective position as follows:<sup>6</sup>

- If the lowest number of "contiguous" zip codes is used to define the Provider's service area, which is 18 zip codes, then the Provider qualifies for sole community hospital status with a 75.77 percent market share in the service area.
- If the absolute lowest number of zip codes without regard to contiguity is used to define the Provider's service area, which is 16 zip codes, then the Provider represents 67.04 percent of the market share in the service area and does not qualify for sole community hospital status.

Accordingly, the question to be resolved in this case is whether the Provider should be required to use "contiguous" or "non-contiguous" zip codes to define its service area. The Provider appealed HCFA's determination to the Provider Reimbursement Review Board ("Board") pursuant to 42 C.F.R. §§405.1835-.1841, and has met the jurisdictional requirements of those regulations. The Provider estimates the reimbursement impact of HCFA's determination is approximately \$2,000,000 for the year beginning June 23, 1993 (30 days after the date of HCFA's denial), and lesser amounts in subsequent years.

The Provider was represented by Carel T. Hedlund, Esquire, of Ober, Kaler, Grimes & Shriver. The Intermediary's representative was Bernard M. Talbert, Esquire, of the Blue Cross and Blue Shield Association.

## PROVIDER'S CONTENTIONS:

The Provider contends that HCFA's use of non-contiguous zip codes is contrary to the statutory provisions of 42 U.S.C. § 1395ww(d)(5)(D)(iii). When Congress granted HCFA authority to determine which factors it deemed germaine in classifying a hospital as the only reasonably available

<sup>&</sup>lt;sup>4</sup> Provider Exhibit P-7.

<sup>&</sup>lt;sup>5</sup> Provider Exhibit P-9.

<sup>&</sup>lt;sup>6</sup> Provider Exhibit P-32.

Provider Exhibit P-1.

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inpatient facility in a geographic area, Congress did not authorize HCFA to consider reasonable inpatient alternatives for persons outside the hospital's geographic area. Yet, that is precisely what HCFA does by using the lowest number of zip codes rather that the lowest number of contiguous zip codes. Instead of determining the hospital's geographic area and then determining where 75 percent of the people in that area are admitted for inpatient care, HCFA reverses the analysis. Under HCFA's methodology, zip codes with the highest number of admissions in the hospital's service area are added together until 75 percent of the hospital's inpatient admissions are placed in the service area. Then HCFA determines whether inpatients from this collection of zip codes are admitted to like hospitals. This method leads HCFA to ask an entirely different question from the question that Congress mandated. Instead of determining whether people who live relatively close to a hospital have access to other hospitals, HCFA's methodology looks at whether people who live potentially at great distances from the hospital also have other hospitals from which to choose. Under HCFA's analysis, two zip codes located some 30 miles from Effingham are included in the Provider's service area, while immediately adjacent zip codes are excluded. This result is clearly at odds with the question Congress asked, i.e. do patients in the isolated area of the hospital in question have access to other hospitals.

The Provider further contends that HCFA's use of non-contiguous zip codes is also contrary to the governing regulation at 42 C.F.R. §412.92(a)(1)(i), which requires a single cohesive geographic service area. When this regulation was first published in 1983, the accompanying preamble indicated that the hospital's service area "would be defined as the geographical area from which the hospital draws or expects to draw its patients. Optimally, the boundaries of the service area would be defined by a statewide planning agency. If not, the hospital would determine its service area based on where it draws at least 75 percent of its admissions." By the use of the singular form of the word "geographical area," HCFA acknowledged at that time that the regulation requires providers to define a single cohesive geographic area. This is further supported by the fact that statewide planning agencies, HCFA's preferred method of defining service areas, define service areas as contiguous areas.

In 1988, HCFA amended the sole community hospital regulation to incorporate for the first time a definition of service area. The regulation itself makes no mention of zip codes or any particular method to be used to determine the single area from which the hospital draws its inpatients. The plain language of the regulation also makes clear that the service area must consist of a single bounded area. Not only does it use the singular term "service area" as opposed to "service areas," it also provides that the hospital must determine whether patients are admitted to other like hospitals located "within a 35-mile radius of the hospital, or, if larger, within its service area." The Provider argues that it would be impossible to determine whether the service area was larger than a 35-mile radius of the hospital if the service area were permitted to consist of scattered, non-contiguous areas, as HCFA proposes here. To determine the radius of an area requires a single bounded area, not scatter-shot areas that do not touch.

<sup>&</sup>lt;sup>8</sup> Provider Exhibit P-12.

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The Provider further notes that the 1988 preamble discussion accompanying the regulation indicated that HCFA was incorporating its prior process for making sole community hospital determinations into the regulations:

...[T]he Secretary's current criteria, as set forth in the regulation at 42 C.F.R. §412.92, and the process for making sole community hospital determinations are the result of long experience with various criteria as well as centralized and decentralized procedures.... Based on our experience with sole community hospital criteria and the decision making process, we believe the criteria and process for making sole community hospital determinations are appropriate and provide the proper balance between uniform standards and recognition of local conditions.

53 Fed. Reg. 38510 (September 30, 1988)<sup>9</sup>

The Provider points out that HCFA has acknowledged that its policy in pre-1988 determinations was to use contiguous zip codes to make service area determinations. The 1988 preamble discussion also stated that it was defining service area as an area comprising the "lowest number of zip codes." However, because the preamble indicated HCFA was incorporating prior criteria into this definition, the term "lowest number of zip codes" must be interpreted consistent with prior HCFA determinations, i.e., to use contiguous zip codes. In any event, the 1988 preamble's use of the term "lowest number of zip codes" is ambiguous. It could either be construed to mean the absolute lowest number of zip codes, or the lowest number of contiguous zip codes. In light of the Provider's arguments above that the plain language of the statute and regulation requires the service area to be a single bounded geographic area, the Provider contends that the 1988 preamble language must be read to mean the lowest number of contiguous zip codes.

The Provider contends that the requirement for contiguous zip codes set forth in HCFA Pub.15-1 §2810.A.2.c is a valid interpretation of the regulations and is binding on HCFA. When regulatory provisions need further clarification, or additional instructions to providers are needed, HCFA routinely issues provisions in the "Provider Reimbursement Manual" to provide its further interpretation of the provisions. Here, HCFA issued HCFA Pub.15-1 §2810 in March of 1990 to further explain how applications for sole community hospital status should be made. The manual expressly indicated how a service area should be calculated for sole community hospital purposes:

<sup>&</sup>lt;sup>9</sup> Intermediary Exhibit I-E.

<sup>61</sup> Fed. Reg. 46203 (August 30, 1996)-Provider Exhibit P-15.

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A hospital may define its service area as the <u>lowest number of</u> <u>contiguous zip codes</u> from which the hospital draws at least 75 percent of its inpatients. Alternatively, the boundaries of a hospital's service area as defined by a statewide planning agency may be used as long as the hospital can demonstrate that at least 75 percent of its inpatients are drawn from that area.

## HCFA Pub 15-1 §2810.A.2.c (emphasis added).

Since the Provider could not use the alternative of a service area defined by the statewide planning agency, it was required to use the lowest number of contiguous zip codes to define its service area. The Provider further notes that the contiguity requirement is also addressed in HCFA Pub.15-1 §2810.B.3.a, which sets forth the requirements on a hospital's utilization and service area. In this manual provision, HCFA expressly states:

The geographic boundaries of the hospital's service area (include a map for this purpose) and a description of how the service area is determined must be submitted. The service area must consist of <a href="mailto:contiguous">contiguous</a> areas. For example, if town A is located between towns B and C, the service area of the hospital could not include both towns B and C but not town A.

## HCFA Pub. 15-1 §2810.B.3.a (emphasis added).

Accordingly, the Provider argues that HCFA informed the public in 1990 through its interpretation in two subsections of the manual that a hospital's service area must be a single contiguous area. The Provider insists that this interpretation is consistent with the plain language of both the statute and regulation, unlike HCFA's interpretation of the lowest number of zip codes which results in multiple, unconnected service areas.

The Provider believes it is significant that, to this date, the Provider Reimbursement Manual continues to contain these requirements that providers must use the lowest number of contiguous zip codes to define their service areas. The Provider asserts that Medicare providers are clearly bound by the provisions of the manual, and that providers risk being accused of Medicare fraud for failure to follow its dictates in certain circumstances. Moreover, the Provider notes that the preamble to the Provider Reimbursement Manual affirms that the manual "provides guidance and policies to implement Medicare regulations," and assures providers that "the provisions of the law and the regulations are accurately reflected in this manual." Thus the manual is binding on HCFA as well.

<sup>&</sup>lt;sup>1</sup> Provider Exhibit P-3.

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In further support of its position, the Provider refers to the testimony of a high-ranking HCFA official who testified at a hearing in the <u>Howard Young Medical Center</u> case concerning the sole community hospital provisions.<sup>12</sup> This witness had been in charge of policy governing sole community hospital determinations for 11 years, since 1984. (HYMC Tr. at 132).<sup>13</sup> The Provider cites the following pertinent testimony of this witness to show that HCFA intended to use the lowest number of contiguous zip codes to define a hospital's service area:

- C HCFA's policies for sole community hospital status are expressed in the regulations and in the Provider Reimbursement Manual, and that the criteria were put into the Provider Reimbursement Manual "so that providers would be aware of the rules, when they filed their applications." (HYMC Tr. at 136-137).
- Agreed with the statement that a service area is defined as the lowest number of contiguous zip codes, and expressly confirmed that "contiguity has not been removed from the analysis." (HYMC Tr. at 147-149).
- C Testified that the requirement of the lowest number of contiguous zip codes is binding on HCFA when analyzing service areas, and testified that he hoped the regional offices would use the same criteria. (HYMC Tr. at 153).
- C Testified that zip codes must touch each other to be contiguous (HYMC Tr. at 162).
- The witness responded "yes" to the following question from the Intermediary's counsel: "So, isn't this manual section saying that your service area must be contiguous and if you come up with a service area that is not contiguous at all and jumps over areas that are contiguous, that is what you can't do? Isn't that, when you take a close look at it, isn't that really the prohibition that is expressed in [the manual]?" (HYMC Tr. at 164).
- In response to a question from a Board member, the witness testified, "the manual says that the lowest number of contiguous zip codes is the requirement." (HYMC Tr. at 164).

Howard Young Medical Center v. Blue Cross and Blue Shield Association/Blue Cross of Wisconsin, PRRB Dec. No. 98-D37, March 26, 1998, Medicare and Medicaid Guide (CCH) ¶46,171, rev'd, HCFA Administrator, May 27, 1998, Medicare and Medicaid Guide (CCH) ¶80,063.

<sup>&</sup>quot;HYMC Tr.\$" refers to pages from the transcript in the <u>Howard Young Medical</u> <u>Center</u> case. (Provider Exhibit P-30).

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Despite this witness' official statements before the Board that HCFA is required to use the lowest number of contiguous zip codes to define a hospital's service area, HCFA has come up with a service area in this case that is not contiguous at all and jumps over areas that are contiguous. Accordingly, it is the Provider's conclusion that, allowing HCFA to publish and encourage reliance on the standards set forth in HCFA Pub. 15-1, yet to apply a different standard in evaluating the Provider's application, is the essence of arbitrary and capricious action.

As to the Intermediary's and HCFA's reliance on the statement in the August 30, 1996 Federal Register that the contiguous zip code requirement in HCFA Pub.15-1 § 2810.A.2.c was inadvertent, the Provider contends that this position is not supportable for the following reasons:

- (1) The testimony of a high-ranking HCFA official in the <u>Howard</u> <u>Young Medical Center</u> case confirmed that the manual provision was binding on HCFA, and that "contiguity has not been removed from the analysis." (HYMC Tr. at 153).
- (2) The preamble accompanying the 1988 revisions to the sole community hospital regulations indicate that HCFA was continuing to apply its prior criteria for sole community hospital status. In light of this context, the 1988 preamble statement that the "lowest number of zip codes" be used to determine a hospital's service area meant the lowest number of contiguous zip codes, for that was HCFA's prior policy
- (3) Given the extensive review of manual issuances by HCFA staff, it is inconceivable that the contiguity requirement merely "slipped through" in the review process.
- (4) The 1996 preamble only states that subsection A.2.c was inadvertently placed in the manual. It makes no reference to subsection B.3.a, the section that states a service area must be contiguous and cannot skip over towns. Thus, that section of the manual, which also requires contiguity, has never been publicly disavowed by HCFA, and is still in place.
- (5) HCFA stated in the 1996 preamble that it intended to revise the manual "accordingly" (i.e. to delete the contiguity requirement) "at our earliest opportunity." Yet, as of the date of the post-hearing submission for this case (March, 1999), the manual has yet to be revised.

The Provider believes that all of the foregoing undermine HCFA's 1996 assertion that the inclusion of the contiguity requirement in HCFA Pub. 15-1 § 2810.A.2.c. was "inadvertent." Rather, the more

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plausible explanation is that HCFA may have been discussing the issue internally, but never reached consensus so as to be able to state its change in policy until 1996.

The Provider concludes that the application of the 1996 preamble to this case constitutes retroactive rulemaking and is, therefore, invalid. The contiguity requirement in HCFA Pub 15-1 §2810 was issued to providers as HCFA's interpretation of the regulation at that time, and there was no public or official statement by HCFA to the provider community to indicate otherwise until the August 30, 1996 Federal Register. Such a rulemaking process cannot be applied retroactively to the Provider's 1993 request for sole community hospital status, when the only valid published interpretation at that time required the use of contiguous zip codes and reflected HCFA's longstanding policy that had been in effect since before 1988. Nor can the 1996 preamble statement be classified as "clarification" of policy that might have retrospective effect. A clarification cannot convert the "lowest number of contiguous zip codes" to the "lowest number of zip codes," a totally different meaning. At the most, HCFA's 1996 announced change in policy can only be applied prospectively to applications filed after August 30, 1996. It cannot be applied to an application filed in 1993, when the governing manual provision required use of the lowest number of contiguous zip codes.

In addition to meeting the service area requirements, the Provider argues that it also meets the alternative test for qualifying for sole community hospital status under the regulation at 42 C.F.R. §412.92(a)(3) which provides:

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

42 C.F.R. §412.92(a)(3).

The Provider attests that the nearest hospital to its facility is Shelby Memorial Hospital, 32 miles away. <sup>14</sup> According to the Affidavit of the Sheriff of Effingham County, Shelby Memorial Hospital is a 45 minute drive from the Provider using the shortest driving route. Thus, the Provider qualifies under this test for sole community hospital status. The Provider acknowledges that it did not originally apply under this test because it met the other test using the lowest number of contiguous zip codes. Therefore, even if it is not entitled to sole community hospital status under 42 C.F.R. §412.92(a)(1)(i), the Provider has demonstrated that it meets all of the criteria under 42 C.F.R. § 412.92(a)(3), and is entitled to this status under this provision.

See Provider Exhibit P-29 (Sheriff's Affidavit) and Provider Exhibit P-31, p.2 (Provider's Original Application).

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#### INTERMEDIARY'S CONTENTIONS:

The Intermediary contends that HCFA correctly denied the Provider's application for sole community hospital status under the provisions of 42 C.F.R. §412.92 (a)(1)(i), and the preamble to the regulation which sets forth specific instructions in making this determination. Based on its analysis of the Provider's request, HCFA determined that the Provider's service area would consist of 16 zip codes, and that 32.96 percent of the residents of the service area were admitted to like hospitals. Since the maximum criterion to qualify is 25 percent, the Provider's request was denied. <sup>15</sup> The Intermediary points out that the issue in this case arises from a conflict between the manual and the regulation in defining a hospital's service area. The Provider determined its service area using the "lowest number of contiguous zip codes" based on the definition published in the manual in March of 1990 which states:

A hospital's service area is the area from which the hospital draws at least 75 percent of its inpatients during the most recently completed cost reporting period ending before it files for SCH status. A hospital may define its service area as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. Alternatively, the boundaries of a hospital's service area as defined by a statewide planning agency may be used as long as the hospital can demonstrate that at least 75 percent of its inpatients are drawn from that area.

HCFA Pub. 15-1 §2810.A.2.c.

The regulation at 42 C.F.R. §412.92(c)(3) defines a hospital's service area as follows:

The term "service area" means the area from which a hospital draws at least 75 percent of its inpatients during the most recent cost reporting period ending before it applies for classification as a sole community hospital.

42 C.F.R. §412.92(c)(3).

While the regulation does not state the use of the "lowest number of zip codes," the Intermediary argues that the linchpin of HCFA's determination is derived from the preamble to the final regulation which became effective October 1, 1988.<sup>16</sup> In addressing the use of zip codes in the determination of sole community hospital status, the preamble states the following:

<sup>&</sup>lt;sup>15</sup> Intermediary Exhibit I-A.

Intermediary Exhibit I-E.

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[A] hospital that seeks to qualify as a sole community hospital under § 412.92 (a)(2)(i) or (a)(2)(ii), under which no more than 25 percent of the residents of the hospital's service area are admitted to other like hospitals for care, must submit to its intermediary admissions data documentating the boundaries of its service area. The term "service area" means the area from which a hospital draws at least 75 percent of its inpatients.

A hospital may delineate its service area by identifying the zip codes of all its inpatients for the cost reporting period ending before the date it applies for SCH status. The lowest number of zip codes accounting for at least 75 percent of its inpatients would then constitute its service area. Alternatively, the boundaries of a hospital's service area as established by a statewide health planning agency may be used as long as the hospital can demonstrate that 75 percent of its inpatients are drawn from that area for the cost reporting period ending before it applies for SCH status.

53 Fed. Reg. 38510, 38511 (September 30, 1988).

In addition, the preamble includes the following HCFA comment relating to this particular requirement in the regulation:

Comment: One commenter protested our proposal to use zip codes to define service area in determining whether a hospital draws at least 75 percent of its inpatients from its service area. The commenter stated that defining a service area consisting of the lowest number of zip codes from which a hospital draws at least 75 percent of its inpatients is inequitable because it does not address differences in zip code, population, size or geographic considerations.

HCFA responded to the above noted concern as follows:

Response: We agree that the zip code method of defining a service area has limitations and, for this reason, suggested it only as one alternative methodology. We noted in the proposed rule at 53 FR 19518 that, "Alternatively, the boundaries of a hospital's service area as established by a statewide health planning agency may be used as long as the hospital can demonstrate that 75 percent of its inpatients are drawn from that area for the cost reporting period ending before it applies for SCH status." Thus, a hospital may use either method to define its service area. Since not all States have health planning agencies that

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define each hospital's service area, we offered the zip code methodology as one means available to every hospital. The important consideration is that a hospital be able to define its service area as the area from which it draws 75 percent of its inpatient admissions, as stated in the regulation's text at §412.92(c)(3).

53 Fed. Reg. 38,511 (September 30, 1988).

The Intermediary argues that the Federal Register presents a clear statement of HCFA's intent, and that the preamble is the definitive interpretation of the regulation that it introduced. The use of the term "lowest number of zip codes" is unambiguous, and this is exactly how HCFA made its calculation. The use of the term "contiguous" in the manual provision published in 1990 was simply wrong, and cannot hold up against the definitive interpretation of the regulatory preamble. <sup>17</sup>

Based on the above regulatory citations, the Intermediary contends that:

- 1. Defining the services area by the use of zip codes is the election of the provider when applying for sole community status. The regulation and the manual both spell out an alternative method if the use of zip codes does not reflect the geographic service area as defined by the statewide planning agency.
- 2. Once zip codes are selected as a method of determining the service area, the regulation is clear in defining the zip codes to be used "the lowest number of zip codes accounting for at least 75 percent of its inpatients would then constitute its service area." Contiguous zip codes may be included under the above definition. If these zip codes in question represent significant inpatient utilization, they will be included in the lowest number of zip codes that account for 75 percent of the hospital's inpatients. This methodology automatically recognizes areas that are significant, those from which the hospital will admit the greatest number of inpatients. Therefore, the Intermediary argues that the determining factor, according to the regulation, is identifying those zip codes which would account for 75 percent of the inpatients of the hospital.
- 3. The manual contains comments and examples that are not necessarily a part of the regulation. If a conflict occurs between the regulation and the manual, the regulation is the determining authority.

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The Intermediary notes that HCFA issued a subsequent Federal Register in 1996<sup>18</sup> which pointed out the error of using contiguous zip codes, and advised that HCFA had not applied or used a contiguous zip code test after 1988. HCFA further advised that the manual issuance in 1990 inadvertently reflected policy prior to October 1, 1988. The Intermediary acknowledges that the manual's use of the term "contiguous" was an unfortunate error. However, it cannot supplant the mandated interpretation set forth in the preamble to the rule that the manual purported to interpret.<sup>19</sup>

At the hearing before the Board, a witness from HCFA testified in support of HCFA's determination in the instant case. This witness testified that, while the regulation does not specifically state the use of the lowest number of zip codes, the preamble to the regulation is specific and is part of the administrative rule making process which describes the changes being made to the Code of Federal Regulations. The witness further testified that the preamble to the regulation is part of the directive which instructs HCFA staff as to how to write policies that implement regulations. Accordingly, the manual provision written after the preamble in the 1988 Federal Register was a mistake because it is not consistent with the regulatory directive which requires the use of the lowest number of zip codes in making sole community hospital determinations.<sup>21</sup>

With respect to the <u>Howard Young Medical Center</u> case, the Intermediary contends that there were many variations and variables in that case, and that the use of contiguous zip codes was not the definitive or determining factors which exists in the present case. The Intermediary believes the stance taken in the <u>Howard Young Medical Center</u> case was not correct, and that HCFA's position in the instant case correctly focuses on the preamble to the regulation which provides the definitive interpretation applicable in determining sole community hospital status.<sup>22</sup>

As to the Provider's alternative position that it met the travel time test under 42 C.F.R. §412.92(a)(3), the Intermediary argues that this criteria was never part of the Provider's original request and is incomplete on its face.<sup>23</sup> The Provider did include distances to neighboring hospitals in its request, which showed that Shelby Memorial Hospital is located 31.2 miles from the Provider's facility. While the Provider contends that Shelby Memorial Hospital is a 45 minute drive from its facility, the

<sup>61</sup> Fed. Reg. 46,203 (August 30, 1996).

<sup>&</sup>lt;sup>19</sup> Tr. at 23-24.

Acting Deputy Division Director, Division of Acute Care, Center for Health Plans and Providers, HCFA.

<sup>&</sup>lt;sup>21</sup> Tr. at 111-113.

<sup>&</sup>lt;sup>22</sup> Tr. at 23.

<sup>&</sup>lt;sup>23</sup> Tr. at 26.

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Intermediary notes that the Provider failed to consider the travel time to Sarah Bush Lincoln Health Center in Mattoon, Illinois. The Provider is located 32.6 miles from Sarah Bush Lincoln Health Center, of which approximately 31 miles is made up of Interstate 57 with a posted speed limit of 65 miles per hour. Sarah Bush Lincoln Medical Center is located within ½ mile of Interstate 57 at exit 190, and the Provider is located within 1/4 mile of Interstate 57/70 at exit 160. The travel time between these hospitals will not require a 45 minute trip. The Intermediary did not verify travel time since this was not a part of the original sole community hospital request. However, this trip should not exceed 35 minutes when traveling at the posted speed limits. Accordingly, even if the mileage criteria is granted consideration as an allowable argument in this appeal, the travel time to Sarah Bush Lincoln Health Center would not meet the requirements of 42 C.F.R. §412.92(a)(3).

# <u>CITATION OF LAW, REGULATIONS AND PROGRAM INSTRUCTIONS:</u>

1. <u>Law - 42 U.S.C</u>:

§1395ww(d)(5)(D)(iii) - Inpatient Hospital Service Payments on Basis of Prospective Rate - Sole Community Hospitals

2. Regulations - 42 C.F.R.:

§§ 405.1835 - .1841 - Board Jurisdiction

§ 412.92 <u>et seq.</u> - Special Treatment: Sole Community Hospitals

§ 412.92 (a)(1)(i) - Criteria for Classification as a Sole Community

Hospital - Service Area

§412.92(a)(3) - Criteria for Classification as a Sole Community

Hospital - Travel Time

§412.92 (c)(3) - Terminology -Service Area

3. <u>Program Instructions - Provider Reimbursement Manual, Part I (HCFA Pub.15-1)</u>:

§2810 - Special Treatment of Sole Community Hospital

**Under Prospective Payment System** 

§2810.A.2.c. - Criteria For Sole Community Hospital

Classification - All other Hospitals

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§2810.B.3.a

Requesting Sole Community Hospital Classification - Utilization Data

# 4. <u>Federal Register:</u>

53 Fed. Reg. 38,510, 38,511 (September 30, 1988).

61 Fed. Reg. 46,203 (August 30, 1996).

# 5. <u>Cases</u>:

Howard Young Medical Center v. Blue Cross and Blue Shield Association/Blue Cross of Wisconsin, PRRB Dec. No. 98-D37, March 26, 1998, Medicare and Medicaid Guide (CCH) ¶46,171, rev'd, HCFA Administrator, May 27, 1998, Medicare and Medicaid Guide (CCH) ¶80,063.

## FINDINGS OF FACT, CONCLUSIONS OF LAW AND DISCUSSION:

The Board, after consideration of the facts, parties' contentions, evidence presented, testimony elicited at the hearing and the Provider's post-hearing brief, finds and concludes that the Provider correctly defined its service area by using the lowest number of contiguous zip codes. HCFA's denial of the Provider's request for sole community hospital status was inconsistent with the explicit manual provisions that were issued to implement the statutory and regulatory requirements.

The Board finds that, when the Provider filed its request for classification as a sole community hospital in March of 1993, the Provider correctly defined its service area in accordance with the specific instructions set forth in HCFA Pub. 15-1 §§2810.A.2.c and 2810.B.3.a. These controlling manual instructions were issued in 1990 to provide additional guidance to hospitals applying for sole community status pursuant to the authorizing regulatory provisions of 42 C.F.R. § 412.92 et seq., published in 1983. The regulations contained the requirements for classification as a sole community hospital, and provided general procedures which hospitals must follow for requesting such classification. In 1988, HCFA amended the regulations to incorporate the definition of a hospital's service area as follows:

The term service area means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12 month cost reporting period ending before it applies for classification as a sole community hospital.

42 C.F.R. §412.92(c)(3).

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Consistent with the regulations, the requirements for sole community hospital status were also incorporated into the Provider Reimbursement Manual to provide further explanation and clarifying instructions as to how hospitals should apply for this classification. In describing how a provider's service area should be calculated and incorporated into a provider's request for sole community hospital status, the manual provisions expressly state:

A hospital may define its service area as the <u>lowest number of</u> <u>contiguous zip codes</u> from which the hospital draws at least 75 percent of its inpatients. Alternatively, the boundaries of a hospital's service area as defined by a statewide planning agency may be used as long as the hospital can demonstrate that at least 75 percent of its inpatients are drawn from that area.

HCFA Pub. 15-1 §2810.A.2.c (emphasis added).

The geographic boundaries of the hospital's service area (include a map for this purpose) and a description of how the service area is determined must be submitted. The service area must consist of <a href="mailto:contiguous">contiguous</a> areas. For example, if town A is located between towns B and C, the service area of the hospital could not include both towns B and C but town A.

HCFA Pub. 15-1 §2810.B.3.a (emphasis added).

It is the Board's conclusion that the manual provisions provide clear and explicit directions for the use of a single contiguous geographical area in determining a hospital's service area for sole community hospital purposes. The Board finds the manual interpretation to be compatible with the plain language of the regulation, and consistent with HCFA's prior policy for making sole community hospital determinations. The Board further notes that this position is supported by the testimony of a high-ranking HCFA official in the <a href="Howard Young Medical Center">Howard Young Medical Center</a> case, who testified in 1995 that the contiguity requirement was still part of the analysis for evaluating sole community hospital applications, and that it was binding on both HCFA and the providers.

The Board notes that HCFA's statement in the 1988 preamble discussion, that the "lowest number of zip codes" should be used to determine a hospital's service area, provides a more discerning characterization of a service area than the definition set forth in the regulation. However, the Board finds this declaration to be an ambiguous statement that could mean either the lowest absolute number or the lowest number of contiguous zip codes. In light of HCFA's prior policy on this matter, the Board concludes that the most reasonable and valid interpretation must be the specific instructions set forth in the manual revision issued two years after the regulatory pronouncement.

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With respect to HCFA's revelation in the August 30, 1996 Federal Register that the contiguous zip code requirement in HCFA Pub. 15-1 §2810.A.2.c was inadvertent, the Board finds that this recantation cannot be retroactively applied to the Provider's 1993 request for sole community hospital status. When the Provider filed its request for classification as a sole community hospital, it correctly relied on the current published interpretation set forth in the Provider Reimbursement Manual. This manual provides guidelines and policies for the implementation of Medicare regulations, and providers are bound by the provisions of the manual in seeking reimbursement under the Medicare program. It is the Board's conclusion that the provisions of HCFA Pub. 15-1 §2810.A.2.c established valid instructions that were consistent with the implementing regulations, and that this official publication cannot be negated after the fact by a subsequent proclamation issued in the preamble to the 1996 Federal Register. Moreover, the Board finds that HCFA's decision also violates the provisions of HCFA Pub. 15-1 §2810.B.3.a, which requires that a service area be contiguous and not skip over towns. The Board notes that the 1996 preamble did not disavow the validity of HCFA Pub. 15-1 §2810.B.3.a, which remains in effect and continues to be a valid requirement in defining a hospitals's service area.

# **DECISION AND ORDER:**

HCFA's denial of the Provider's request for classification as a sole community hospital was not proper. The Provider shall be granted sole community hospital status consistent with the provisions set forth in 42 C.F.R. §412.92 et seq..

## **Board Members Participating:**

Irvin W. Kues James G. Sleep Henry C. Wessman, Esquire Martin W. Hoover, Jr., Esquire Charles R. Barker

**Date of Decision**: October 20, 1999

## FOR THE BOARD:

Irvin W. Kues Chairman