B. Revised OMB Definitions for Geographical Statistical Areas

1. Current Labor Market Areas Based on MSAs

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. In accordance with the broad discretion under section 1886(d)(3)(E) of the Act, we currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) issued by OMB. OMB also designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprising two or more PMSAs (identified by their separate economic and social character). For purposes of the hospital wage index, we use the PMSAs rather than CMSAs because they allow a more precise breakdown of labor costs. If a metropolitan area is not designated as part of a PMSA, we use the applicable MSA.

These different designations use counties as the building blocks upon which they are based. Therefore, hospitals are assigned to either an MSA, PMSA, or NECMA based on whether the county in which the hospital is located is part of that area. For purposes of the IPPS wage index, we combine all of the counties in a State outside a designated MSA, PMSA, or NECMA together to calculate a statewide rural wage index.

2. Core-Based Statistical Areas

OMB reviews its Metropolitan Area (MA) definitions preceding each decennial census. In the fall of 1998, OMB chartered the Metropolitan Area Standards Review Committee to examine the MA standards and develop recommendations for possible

changes to those standards. Three notices related to the review of the standards were published on the following dates in the **Federal Register**, providing an opportunity for public comment on the recommendations of the Committee: December 21, 1998 (63 FR 70526); October 20, 1999 (64 FR 56628), and August 22, 2000 (65 FR 51060).

In the December 27, 2000 **Federal Register** (65 FR 82228 through 82238), OMB announced its new standards. According to that notice, OMB defines a Core-Based Statistical Area (CBSA), beginning in 2003, as "a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. The standards designate and define two categories of CBSAs: Metropolitan Statistical Areas and Micropolitan Statistical Areas." (65 FR 82235)

According to OMB, MSAs are based on urbanized areas of 50,000 or more population, and Micropolitan Statistical Areas (referred to in this discussion as Micropolitan Areas) are based on urban clusters of at least 10,000 population but less than 50,000 population. Counties that do not fall within CBSAs are deemed ``Outside CBSAs." In the past, OMB defined MSAs around areas with a minimum core population of 50,000, and smaller areas were "Outside MSAs."

The general concept of the CBSAs is that of an area containing a recognized population nucleus and adjacent communities that have a high degree of integration with that nucleus. The purpose of the standards is to provide nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas. CBSAs include adjacent counties that have a minimum of 25 percent commuting to the

central counties of the area. This is an increase over the minimum commuting threshold for outlying counties applied in the previous MSA definition of 15 percent.

On June 6, 2003, OMB announced the new CBSAs, comprised of MSAs and the new Micropolitan Areas based on Census 2000 data. (A copy of the announcement may be obtained at the following Internet address: **http://www.whitehouse.gov/omb/bulletins/fy04/b04-03.html.)** The new definitions recognize 49 new MSAs and 565 new Micropolitan Areas, and extensively revise the composition of many of the existing MSAs. There are 1,090 counties in MSAs under these new definitions (previously, there were 848 counties in MSAs). Of these 1,090 counties, 737 are in the same MSA as they were prior to the changes, 65 are in a different MSA, and 288 were not previously designated to any MSA. There are 674 counties in Micropolitan Areas. Of these, 41 were previously in an MSA, while 633 were not previously designated to an MSA. There are five counties that previously were designated to an MSA but are no longer designated to either an MSA or a new Micropolitan Area: Carter County, KY; St. James Parish, LA; Kane County, UT; Culpepper County, VA; and King George County, VA.

3. Revised Labor Market Areas

In its June 6, 2003 announcement, OMB cautioned that these new definitions "should not be used to develop and implement Federal, State, and local nonstatistical programs and policies without full consideration of the effects of using these definitions for such purposes. These areas should not serve as a general-purpose geographic

framework for nonstatistical activities, and they may or may not be suitable for use in program funding formulas."

We have previously examined alternatives to the use of MSAs for the purpose of establishing labor market areas for the Medicare wage index. In the May 27, 1994, proposed rule (59 FR 27724), we presented our latest research concerning possible future refinements to the labor market areas. Specifically, we discussed and solicited comment on the proposal by the Prospective Payment Assessment Commission (ProPAC, a predecessor organization to the Medicare Payment Advisory Commission (MedPAC)) for hospital-specific labor market areas based on each hospital's nearest neighbors, and our research and analysis on alternative labor market areas. Even though we found that none of the alternative labor market areas that we studied provided a distinct improvement over the use of MSAs, we presented an option using the MSA-based wage index but generally giving a hospital's own wages a higher weight than under the current system. We also described for comment a State labor market option, under which hospitals would be allowed to design labor market areas within their own State boundaries.

We described the comments we received in the June 2, 1995 proposed rule (60 FR 29219). There was no consensus among the commenters on the choice for new labor market areas. Many individual hospitals that commented expressed dissatisfaction with all of the proposals. However, several State hospital associations commented that the options merited further study. Therefore, we contacted the association representatives that participated in our November 1993 meeting on labor market issues in which we

solicited ideas for additional types of labor market research to conduct. None of the individuals we contacted suggested any ideas for further research.

Consequently, we have continued to use MSAs to define labor market areas for purposes of the wage index. While we recognize MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose, and our analysis and discussion here are focused on issues related to adopting the new CBSAs to define labor market areas.

Comment: Many commenters recommended various revisions to the proposed labor market definitions. Many of these comments focused on specific situations, especially situations in which previously large MSAs were divided into smaller MSAs under the new definitions, and the converse situation in which MSAs expanded under the new definitions. One commenter, proposed an extensive reoconfiguration of CMS' labor market areas. Specifically, the commenter recommended that, instead of expanding certain MSAs, we create a system of overlapping markets, beginning with a core labor market, consisting of the original MSA and center city, and creating overlapping subdivisions, or "tiers," out of the areas outside the core. Furthermore, the commenter cites a U.S. Government Accountability Office (GAO) report that called for CMS to refine its MSA-based wage index areas so that they might better represent actual hospital labor markets, which could potentially entail reducing the size of some large urban markets because of the large disparities between the wage levels in central cities, large towns, and outlying counties.

The proposal begins with all counties associated with the urban area, either under the old or new MSAs, which are then subdivided based upon PMSAs or Metropolitan Divisions. These areas would be ranked according to wage level, assigning the highest wage area as the 'core.' Then overlapping labor markets would be formed as each subsequent ranked area is packaged with the center city, creating tiers of labor markets. A wage index would be developed for each tier, retaining a high wage value reflective of the center city, and successively lower wage levels for the surrounding areas. As the labor markets incorporate one another and build upon the central area, the system acknowledges the interaction between the given areas but fairly accounts for the wage level differences encompassed therein.

The commenter asserts that this system will adequately recognize the higher labor costs in the core area and moderate the funding differential between the central area and the outlying communities, who are undoubtedly linked to the core area. It would also afford more reclassification opportunities for hospitals within the greater metropolitan area and prevent the 'orphanization' of hospitals whose provider neighbors are reclassified into higher wage areas while they retain their geographic wage index.

Other commenters objected to the division of certain MSAs, and advocated restoring the larger MSAs that existed under the previous definitions. These commenters contended that the smaller MSAs do not adequately capture the regional nature of markets for hospital labor.

Other commenters, especially those that would benefit from specific changes, supported the changes previously cited. Hospitals in a high wage area supported the

proposal to split their area off from the lower wage areas around the fringe of the large MSA to which they had belonged under the old definitions. Hospitals that are included in a higher wage MSA under the new definitions also expressed strong support for the expansion of this MSA, and specifically requested that we make no changes in the proposal.

Response: We appreciate the detailed and substantive recommendations provided by these commenters. These recommendations merit further study and consideration. However, we do not believe that it would be prudent to proceed with any of these recommendations at this time, for several reasons. First, these recommendations are not entirely consistent, since some emphasize expanding existing MSAs or preserving large MSAs that existed under the old definitions, and others emphasize creating smaller units or at least distinguishing segments within larger MSAs. In addition, the range of comments on specific situations indicates the importance of taking into consideration all of the effects that these proposed revisions might have. Specifically, hospitals that stand to benefit from the new definitions might experience lesser gains from the proposed revisions. Finally, we believe that the 1-year transition that we have proposed will alleviate the concerns of many hospitals, by limiting the reductions that they might otherwise experience from the introduction of the new labor market areas. We will continue to study these issues.

Comment: Several commenters have suggested that the implementation of the new MSAs be delayed at least another year so that alternative solutions may be reviewed.

Response: The new MSA designations were released June 6, 2003. We stated in our August 1, 2003 final rule that CMS was unable to implement the new MSAs immediately but intended to evaluate the impact of the changes for the FY 2005 proposed rule. In essence, we have already delayed the implementation of the new Census information.

Comment: One commenter mentioned the need to closely monitor the population changes in the large Micropolitan areas, as crossing the threshold to 50,000 would create a new MSA. The commenter cited the case of Eagle Pass, TX, which, according to July 1, 2003 population estimates, now exceeds the 50,000 threshold. The commenter states that failure to recognize such areas will unnecessarily cripple growing areas.

Response: In the past, CMS has updated its MSA database annually before the publication of the proposed rule based on OMB's listing of MSAs. While an area may have an estimated population exceeding the threshold, we can only update once OMB recognizes this change. At this time, OMB still recognizes Eagle Pass, TX as a Micropolitan Area.

Comment: Many commenters believe that the large MSA should not be divided into the Metropolitan Divisions as outlined by the new OMB definitions.

Response: In previous years we have utilized PMSAs, a division of the larger CMSA. We believe the usage of Metropolitan Divisions represent the closest approximation to PMSAs, the building block of our current Labor Market Definitions. Therefore, we do not believe that we should abandon the use of these new definitions since they most accurately retain our current structuring of labor market areas. However,

given the scope and drastic implications of these new boundaries and to buffer the subsequent negative impact on numerous hospitals, we have decided to provide, during FY 2005, a blend of wage indexes to those hospitals that would experience a drop in their wage indexes because of the adoption of the new labor market areas. Any hospital experiencing a decrease in their wage index relative to its FY 2005 wage index because of the labor market area changes will receive 50 percent of the wage index using the new labor market definitions and 50 percent of the wage index that the provider would have received under the old MSA standards. This blend will apply to any provider experiencing a decrease due to the new definitions, including providers who are reclassifying under MCGRB requirements, section 1886(d)(8)(B) of the Act or section 508 of Pub.L.108-173. We describe the determination of this blend in detail below. It is important to note that this blend will not protect hospitals from the effects of a drop in wage index due to any reason other than the usage of the new MSAs. For example, the blend will not apply to changes due to the use of new wage data in calculating the FY 2005 wage index. In other words, the two wage indexes (one wage index reflecting the labor market definitions employed in FY 2004, the other wage index reflecting the new CBSA definitions) used in determining the blended wage index both reflect the new FY 2005 wage data. Both these wage indexes also reflect the 10 percent occupational mix adjustment that we discuss in section III.G of this final rule.

a. New England MSAs

As stated above, we currently use NECMAs to define labor market areas in New England, because these are county-based designations rather than the 1990 MSA

definitions for New England, which used minor civil divisions such as cities and towns. Under the previous MSA definitions, NECMAs provided more consistency in labor market definitions for New England compared with the rest of the country, where MSAs are county-based. Under the new CBSAs, OMB has defined the MSAs and Micropolitan Areas in New England on the basis of counties. OMB also established New England City and Town Areas, which are similar to the previous New England MSAs. Therefore, to maintain consistency in the definition of labor market areas between New England and the rest of the country, in the May 18, 2004 proposed rule (69 FR 28250), we proposed to use the New England MSAs under the new CBSA definition.

Comment: Some commenters have expressed concern regarding the adoption of a county-based system for the New England MSAs. They believe that abandoning the city- and town-based areas will inaccurately reflect the labor market areas in New England.

Response: In order to create consistency among all labor market areas and facilitate the maintenance of these areas, we will use the county-based areas for all MSAs in the nation. Census has now defined the New England area around counties, creating a city- and town-based system as an alternative. We believe that adopting county-based labor market areas for the entire country provides consistency and stability in program payment, and minimizes programmatic complexity. In addition, we have consistently employed a county-based system for New England for precisely that reason: to maintain consistency with the labor market definitions used throughout the country. Because we have never used cities and towns, employing a county-based system in New England maintains that consistent practice.

b. Metropolitan Divisions

A Metropolitan Division is a county or group of counties within a CBSA that contains a core population of at least 2.5 million, representing an employment center, plus adjacent counties associated with the main county or counties through commuting ties. A county qualifies as a main county if 65 percent or more of its employed residents work within the county and the ratio of the number of jobs located in the county to the number of employed residents is at least .75. A county qualifies as a secondary county if 50 percent or more, but less than 65 percent, of its employed residents work within the county and the ratio of the number of jobs located in the county to the number of employed residents is at least .75. After all the main and secondary counties are identified and grouped, each additional county that already has qualified for inclusion in the MSA falls within the Metropolitan Division associated with the main/secondary county or counties with which the county at issue has the highest employment interchange measure. Counties in a Metropolitan Division must be contiguous. (65 FR 82236)

As noted above, in the past, OMB designated CMSAs as Metropolitan Areas with a population of one million or more and comprising two or more PMSAs. We currently use the PMSAs rather than CMSAs to define labor market areas because they comprise a smaller geographic area with potentially varying labor costs due to different local economies. Similarly, in the May 18, 2004 proposed rule, we proposed to use the Metropolitan Divisions where applicable under the CBSA definitions.

Under the CBSA definitions, there are 11 MSAs containing Metropolitan Divisions: Boston; Chicago; Dallas; Detroit; Los Angeles; Miami; New York; Philadelphia; San Francisco; Seattle; and Washington, D.C. Although these MSAs were also CMSAs under the prior definitions, in some cases their areas have been significantly altered. Under the prior definitions, Boston was a single NECMA. It is now comprised of 4 Divisions. Los Angeles went from 4 PMSAs to 2 Divisions because 2 MSAs became separate MSAs. The New York CMSA went from 15 PMSAs down to only 4 Divisions. Five PMSAs in Connecticut now become separate MSAs, and the number of PMSAs in New Jersey goes from 5 to 2, with the consolidation of 2 New Jersey PMSAs (Bergen-Passaic and Jersey City) into the New York-Wayne-White Plains, NY-NJ Division. In San Francisco, only 2 Divisions remain where there were once 6 PMSAs, some of which are now separate MSAs.

Previously, Cincinnati, Cleveland, Denver, Houston, Milwaukee, Portland, Sacramento, and San Juan were all designated as CMSAs, but are not any longer. As noted previously, the population threshold to be designated a CMSA was one million. In most of these cases, counties formerly in a PMSA have become a separate, independent MSA, leaving only the MSA for the core area under the new CBSA definitions.

Comment: Many commenters have expressed their concern regarding the division of large MSAs of 2.5 million population or greater. They are concerned that this dividing of previously larger areas will result in dramatic disparities in wage indexes in what once was a congruous area. Additionally, many hospitals are concerned they did

not have the opportunity to reclassify given the dramatic effect of this division of previously consolidated areas.

Response: As indicated above, Metropolitan Divisions represent the closest approximation to PMSAs, the building block of our current labor market definitions. Therefore, we do not believe that we should abandon the use of these new definitions since they most accurately retain our current structuring of labor market areas. However, given the scope and drastic implications of these new boundaries and to buffer the subsequent negative impact on numerous hospitals, we have decided to provide, during FY 2005, a blend of wage indexes to those hospitals that would experience a drop in their wage indexes because of the adoption of the new labor market areas. Any hospital experiencing a decrease in their wage index relative to its FY 2005 wage index because of the labor market area changes will receive 50 percent of the wage index using the new labor market definitions and 50 percent of the wage index that the provider would have received under the old MSA standards. This blend will apply to any provider experiencing a decrease due to the new definitions, including providers who are reclassifying under MCGRB requirements, section 1886(d)(8)(B) of the Act or section 508 of Pub.L.108-173. We describe the determination of this blend in detail below. It is important to note that this blend will not protect hospitals from the effects of a drop in wage index due to any reason other than the usage of the new MSAs. For example, the blend will not apply to changes due to the use of new wage data in calculating the FY 2005 wage index. In other words, the two wage indexes (one wage index reflecting the labor market definitions employed in FY 2004, the other wage index reflecting the

new CBSA definitions) used in determining the blended wage index both reflect the new FY 2005 wage data.

c. Micropolitan Areas

One of the major issues with respect to the new definitions is whether to use Micropolitan Areas to define labor market areas for the purpose of the IPPS wage index. Because the new Micropolitan Areas are essentially a third area definition made up mostly of currently rural areas, but also some or all of current MSAs, how these areas are treated will have significant impacts on the calculation and application of the wage index. Treating Micropolitan Areas as separate and distinct labor market areas would affect both the wage indexes of the hospitals in the Micropolitan Areas and the hospitals in the labor market areas where those hospitals are currently located (both positively and negatively).

Because we currently use MSAs to define urban labor market areas and we group all the hospitals in counties within each State that are not assigned to an MSA together into a statewide rural labor market area, we have used the terms "urban" and "rural" wage indexes in the past for ease of reference. However, the introduction of Micropolitan Areas complicates this terminology because these areas include so many hospitals that are currently included in the statewide rural labor market areas. In order to facilitate the discussion below, we use the term "rural" hospitals to describe hospitals in counties that are not assigned to either an MSA or a Micropolitan Area. This should not be taken to indicate that hospitals in Micropolitan Areas are no longer "rural" hospitals. In fact, we proposed that hospitals in Micropolitan Areas are included in the statewide rural labor market areas, for the reasons outlined below. The reader is referred to section IV.B. of

the preamble of this final rule for a more specific discussion of the implications of these changes for defining urban and rural areas under §412.62(f).

Chart 1 below, which was included in the proposed rule, demonstrates the distributions of hospitals by their current and new designations. Approximately 50 percent of hospitals currently designated rural are now in either Micropolitan Areas (691 hospitals) or MSAs (197 hospitals). The vast majority of hospitals currently in MSAs remain in an MSA (2,478, although in some cases the MSAs have been reconfigured), while 2 are now in rural areas and 65 are now in Micropolitan Areas.

Chart 1.--Distribution of Hospitals by Current and New Designation

2005 Statistical Area	Currently Rural (2004)	Currently MSA (2004)
Rural	861	2
Micropolitan	691	65
MSA	197	2,478
TOTALS	1,749	2,545

In order to evaluate the impact of these changes, we grouped hospitals based on the county where they are located according to the new MSA and Micropolitan areas using the definitions on the Census Bureau's website: **http://www.census.gov/population/www/estimates/metrodef.html**. We then compared the FY 2004 wage indexes (using data from hospitals' FY 2001 cost reports) calculated based on the current MSAs, without any effects of hospital geographic reclassifications. Consistent with current policy, we applied the rural floor in the case where the statewide rural wage index is greater than the wage index for a particular urban area. We excluded Indian Health Service hospitals from the analysis due to the special characteristics of the

prospective payment system for these hospitals. Hospitals in Maryland were excluded from the analysis because they remain excluded from the IPPS under the waiver at section 1814(b)(3) of the Act. Our analysis also did not reflect any changes to the Puerto Rico-specific wage index, which is applicable only to the Puerto Rico standardized amounts (the analysis does include the national wage index values for Puerto Rico hospitals).

Chart 2 below, which was included in the proposed rule, shows the impact on hospitals' wage indexes of recalculating new wage indexes based on the new MSAs, and treating the new Micropolitan Areas as separate labor market areas. Specifically, the table shows the impact of treating the new MSA and Micropolitan Areas as labor market areas and calculating a wage index for each one. The most dramatic impact of this change would be on hospitals that are currently classified as rural. Only 10 currently rural hospitals would experience no changes in their wage indexes after applying the new MSA definitions. Five of these hospitals are in Delaware and Connecticut (three and two hospitals respectively), where the only counties in the State currently considered rural are now part of Micropolitan Areas.

Approximately 62 percent (1,092 out of 1,749) of currently rural hospitals experience decreases in their wage indexes under this change. Among hospitals that remain rural after separately recognizing Micropolitan Areas (those hospitals in counties "outside CBSAs"), rural hospitals in six States (Arizona, Florida, Idaho, Indiana, Minnesota, and Missouri) experience a positive impact after applying the new MSA definitions. These hospitals benefit because the net effect on their wage index of other

hospitals moving into Micropolitan Areas is positive. The majority of the currently rural hospitals (762 out of 1,092) that experience decreases in their wage indexes are hospitals that would remain rural under the new definitions. Moreover, among the 646 rural hospitals whose wage indexes would increase under the new definitions, 547 would now be in an MSA or Micropolitan Area.

Furthermore, in many cases, the magnitude of the changes is quite large. Nearly one-half of all rural hospitals would experience payment changes of at least 5.0 percent, either negatively or positively, if we were to adopt labor market areas based in part on the new Micropolitan Areas.

In contrast, there are 938 currently urban hospitals (37 percent) with wage indexes that are unaffected by the new MSA definitions. These hospitals are in MSAs or PMSAs that are either unchanged (for example, the Austin, Buffalo, Milwaukee, Oakland, Phoenix, San Diego, and Tampa-St. Petersburg MSAs are all unchanged) or include new counties without any hospitals in those counties that are now part of the existing MSA (for example, counties were added to the Atlanta, Denver, Little Rock, Omaha, Portland, Richmond, Toledo, Virginia Beach-Norfolk MSAs but hospitals were not added).

The most significant negative impact (more than a 20-percent decrease) among hospitals currently in an MSA is on those located in counties that become Micropolitan areas or rural areas. Among hospitals with the largest positive impacts (more than a 20-percent increase), the changes appear to be largely due to changes in the counties that are now included (under the CBSAs) in the MSA labor market area.

Chart 2.--Impact on Wage Indexes of New MSA, Micropolitan Areas, and Rural Labor Market Areas

Percent Change in Area Wage Index	Number of Currently Rural Hospitals	Number of Currently MSA Hospitals	Total Number of Hospitals
Decrease Greater Than 10.0	99	36	135
Decrease Between 5.0 and 10.0	420	77	497
Decrease Between 2.0 and 5.0	238	95	333
Decrease Between 0 and 02.0	335	585	920
No Change	10	938	948
Increase Between 0 and 2.0	168	495	663
Increase Between 2.0 and 5.0	138	145	283
Increase Between 5.0 and 10.0	203	139	342
Increase Greater Than 10.0	138	35	173
Total	1,749	2,545	4,294

One of the reasons Micropolitan Areas have such a dramatic impact on the wage index is, because Micropolitan Areas encompass smaller populations than MSAs, they tend to include fewer hospitals per Micropolitan Area. Currently, there are only 25 MSAs with one hospital in the MSA. However, under the new definitions, there are 373 Micropolitan Areas with one hospital, and 49 MSAs with only one hospital.

This large number of labor market areas with only one hospital and the increased potential for dramatic shifts in the wage indexes from 1 year to the next is a problem for several reasons. First, it creates instability in the wage index from year to year for a large number of hospitals. Second, it reduces the averaging effect of the wage index, lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals. In labor market areas with a single hospital, high wage

costs are passed directly into the wage index with no counterbalancing averaging with lower wages paid at nearby competing hospitals. Third, it creates an arguably inequitable system when so many hospitals have wage indexes based solely on their own wages, while other hospitals' wage indexes are based on an average hourly wage across many hospitals.

For these reasons, in the May 18, 2004 proposed rule, we proposed not to adopt Micropolitan Areas as independent labor market areas. Although we considered alternative approaches that would aggregate Micropolitan Areas in order to reduce the number of one-hospital labor market areas, these approaches created geographically disconnected labor market areas, an undesirable outcome. Therefore, we proposed to maintain our current policy of defining labor market areas based on the new MSAs (and Divisions, where they exist) using OMB's new criteria and the 2000 Census data.

Chart 3, which was included in the proposed rule, displays the impacts of using this approach on hospital wage indexes. The most apparent difference comparing this chart to Chart 2 is the reduction in the numbers of currently rural hospitals impacted by more than 2.0 percent. Recognizing Micropolitan Areas as independent labor market areas results in negative impacts of more than 2.0 percent for 757 currently rural hospitals, while the comparative number, when recognizing only MSAs, is 256. Conversely, the number of currently rural hospitals positively impacted by more than 2.0 percent declines from 479 to 154.

The greatest negative impacts among hospitals currently designated rural are in Idaho, where the statewide rural wage index falls 6.7 percent as a result of 6 formerly

rural hospitals now being included in either new or redefined MSAs. The wage index for rural Utah hospitals declines by 5.7 percent, for similar reasons. Conversely, formerly rural hospitals that are not part of an MSA generally experience positive impacts.

Among hospitals that are currently in MSAs, the number of hospitals with decreases in their wage indexes of at least 10 percent increases from 36 to 45. These are primarily hospitals that are now located in Micropolitan Areas that are included in the statewide labor market area. There are 46 counties with 72 hospitals that are currently in an MSA that would be treated as rural.

Chart 3.--Impact on Wage Indexes of New MSA and Rural Labor Market Areas

Percent Change in Area Wage Index	Number of Currently Rural Hospitals	Number of Currently MSA Hospitals	Total Number of Hospitals
Decrease Greater Than 10.0	0	45	45
Decrease Between 5.0 and 10.0	122	60	182
Decrease Between 2.0 and 5.0	134	73	207
Decrease Between 0 and 2.0	588	615	1,203
No Change	160	1,015	1,175
Increase Between 0 and 2.0	591	574	1,165
Increase Between 2.0 and 5.0	32	103	135
Increase Between 5.0 and 10.0	64	25	89
Increase Greater Than 10.0	58	35	93
Total	1,749	2,545	4,294

Comment: Many commenters addressed the usage of Micropolitan Areas. Some commenters believe that we should adopt a policy recognizing each of the individual

Micropolitan Areas. These commenters pointed out that some hospitals would benefit from the adoption of Micropolitan Areas as in the case of higher wage hospitals in currently rural areas that would receive a wage index more closely reflecting their own wage level. However, other commenters endorsed our proposal to treat Micropolitan Areas as part of the statewide rural areas. Many hospitals and several national hospital associations supported our decision not to employ Micropolitan Areas for the reasons that we presented. MedPAC also expressed support for the proposal to include Micropolitan Areas in the statewide rural areas.

Response: We continue to believe that the reasons we presented in the proposed rule for including Micropoplitan Areas in the statewide rural areas are compelling. We are therefore finalizing our proposal to treat the Micropolitan Areas as "rural."

d. Transition Period

We have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. When we recently removed the wage costs of teaching physicians and residents from the wage index data of teaching hospitals, we spread out the impact over 3 years by blending the hospitals' average hourly wages with and without the data. Similarly, the regulations at §412.102 provide for a 3-year transition to the DSH adjustment payments to a hospital redesignated from urban to rural.

Given the significant payment impacts upon some hospitals because of these changes, we considered options to transition from the current MSAs to the new MSAs. As noted above, the most dramatic negative impacts are among hospitals currently

located in an MSA but would become rural under the new definitions. Some negative impacts also occur among urban hospitals that remain in MSAs that have been reconfigured. However, these impacts are generally smaller than those among currently urban hospitals that would become rural. To help alleviate the decreased payments for currently urban hospitals that would become rural, in the May 18, 2004 proposed rule, we proposed to allow them to maintain their assignment to the MSA where they are currently located for the 3-year period FY 2005, FY 2006, and FY 2007.Specifically, we will assign these hospitals, as we did in the proposed rule, the prereclassified wage index of the urban area to which they currently belong. (For purposes of wage index computation, the wage data of these hospitals will remain assigned to the statewide rural area in which they are located.) We are finalizing this policy in the final rule. We are using the wage data from these hospitals as part of setting the rural wage index. The higher wage indexes these hospitals are receiving is being taken into consideration in determining whether they qualify for the out-commuting adjustment and the amount of any adjustment. Beginning in FY 2008, these hospitals would receive their statewide rural wage index, although they will be eligible to apply for reclassification by the MGCRB, both during this transition period as well as subsequent years.

We also considered the option of allowing a transition to the new MSAs for all hospitals, such as a blend of wage indexes based on the old and new MSAs for some specified period of time. We noted that, although this would help some hospitals that are negatively impacted by the changes to the MSAs, it would dampen the payment increases for those hospitals that are positively impacted by the changes. Therefore, although we

notified the public that a blended rate was a viable option, we did not propose this in the proposed rule. We also noted that OMB in the past has announced MSA changes on an annual basis due to population changes, and we have not transitioned these changes.

Comment: Many commenters urged CMS to adopt broader protections for hospitals against changes in the wage index due to the adoption of the new labor market areas. Many of these commenters advocated extending hold harmless protection to other categories of providers beyond those that we provided for in the proposed rule. Commenters offered various recommendations about how to provide such protection. Most commenters advocated transition mechanisms such as hold harmless or blending only for those hospitals that would experience a wage index decrease from the effects of the labor market area changes. MedPAC recommended providing a transition to all hospitals that experience large decreases in their wage indexes due to these changes and phasing in the changes for these hospitals over three years. MedPAC also recommended that the threshold for large decreases be set so that the cost of this provision over the transition period would equal the cost of our proposal to implement the new market definitions with a hold harmless for urban hospitals that become rural under the new definitions.

Response: We recognize that many hospitals will experience decreases in wage index as a result of the labor market area changes. At the same time, significant numbers of hospitals will benefit from these changes. In addition, as of September 1, 2004, hospitals will be able to seek reclassification for FY 2006 using the new labor market areas, if they believe another area's wage index is more appropriate and if they meet the

requirements for reclassification by the MGCRB. Therefore, we have decided to provide a 1-year transition blend for hospitals that, due solely to the changes in the labor market definitions, experience a decrease in their FY 2005 wage index compared to the wage index they would have received using the labor market areas included in calculating their FY 2004 wage index. Each hospital experiencing a decrease in its wage index due to the labor market changes will receive 50 percent of its wage index based upon the new CBSA configurations and 50 percent based upon FY 2004 MSA boundaries (in both cases using the FY 2001 wage data). This blend will not apply to any hospital that experiences a drop for any reason other than the new MSA definitions, nor will it apply to hospitals that benefit from a higher wage index due to the labor market definition changes.

Specifically, we will determine for each hospital a new wage index employing the FY 2001 wage index data and the old labor market definitions, and a wage index employing FY 2001 wage index data and the new labor market definitions. Any hospital experiencing a decrease in its wage index under the new labor market definitions will receive a blended wage index consisting of 50 percent of each of these wage indexes (that is, 50 percent of the wage index using the FY 2001 wage index data and the old labor market definitions, and 50 percent of the wage index using FY 2004 wage index data and the new labor market definitions). Both the comparison and the blending will employ post reclassification wage indexes; that is, wage indexes computed after applying the established rules for assigning the wage data for reclassifying hospitals to one or more wage areas.

As part of this transition, as we proposed in the proposed rule, we will also allow currently urban hospitals that become rural under the new definitions to maintain their assignment to the MSA where they are currently located for the 3-year period FY 2005, FY 2006, and FY 2007. Specifically, we will assign these hospitals, as we did in the proposed rule, the prereclassified wage index of the urban area to which they currently belong. (For purposes of wage index computation, the wage data of these hospitals will remain assigned to the statewide rural area in which they are located.) Beginning in FY 2008, these formerly urban hospitals will receive their statewide rural wage index, although they would be eligible to apply for reclassification by the MGCRB, both during this transition period as well as subsequent years. The hospitals receiving this transition will not be considered urban hospitals but rather they will maintain their status as rural hospitals. Thus, the hospital would not be eligible, for example, for a large urban add-on under capital PPS. Thus, it is the wage index, but not the urban or rural status, of these hospitals that is being affected by this transition.

Comment: One commenter asked us to clarify whether the special provisions of §412.102 of the regulations apply to these hospitals, that is, hospitals that were classified as urban under the previous labor market definitions, but are rural under the new labor market definitions. The commenter pointed out that this section of the regulations provides special protections for hospitals against abrupt reductions in DSH payments resulting from transitions from urban to rural status.

Response: We agree with the commenter that the provisions of §412.102 apply in this case. Specifically, as described in §412.102, in the first year after a hospital loses

urban status, the hospital will receive an additional payment that equals two thirds of the difference between the urban disproportionate share payments applicable to the hospital before its redesignation from urban to rural and the rural disproportionate share payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one third of the difference between the urban disproportionate share payments applicable to the hospital before its redesignation from urban to rural and the rural disproportionate share payments applicable to the hospital subsequent to its redesignation from urban to rural.

We decided not to provide for a longer transition, as recommended by MedPAC and other commenters, because we have already, in effect, provided one year at a higher wage index level for these hospitals by retaining the previous labor market definitions for one year after the new labor market definitions became available. However, we are still allowing a longer, 3-year hold-harmless transition for the group of hospitals that were previously urban, and are now rural under the new definitions. We are continuing to provide for a longer transition for these hospitals because, as a group they have experienced a steeper and more abrupt reduction in their wage index due to the labor market revisions.

We will apply this blended transition in a budget neutral manner. Specifically, we will make an adjustment to the rates to ensure that total payments, including the effects of the transition provisions, will equal what payments would have been if we had fully implemented the new labor market areas. We believe that doing so is most consistent

with the requirement of section 1886(d)(3)(E) of the Act that any "adjustments or updates [to the adjustment for different area wage levels]... shall be made in a manner that assures that aggregate payments… are not greater or less then those that would have been made in the year without such adjustment." In addition, as a policy matter, it would not be feasible for us to allow for a transition only for hospitals that experience a decrease as a result of the new labor market definitions, were we not to implement such a transition in a budget neutral manner. Because we have adopted a policy of allowing for a transition only when it would benefit the hospital, we believe it is appropriate to ensure that such a transition does not increase Medicare payments beyond the payments that would be made had we simply adopted the new labor market definitions without any transition provisions. We note that, consistent with past practice, we are not adopting the new labor market definitions themselves in a budget neutral manner. We do not believe that the revision to the labor market areas in and of itself constitutes and "adjustment or update" to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

C. Occupational Mix Adjustment to FY 2005 Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose

to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Development of Data for the Occupational Mix Adjustment

In the September 19, 2003 **Federal Register** (68 FR 54905), we published a final notice of intent to collect occupational mix data from hospitals using the Medicare Wage Index Occupational Mix Survey, Form CMS-10079. (The survey and instructions may be accessed at the website: **http://cms.hhs.gov/providers/hipps/ippswage.asp**.) The survey requires hospitals to report the number of total paid hours for directly hired and contract employees in occupations that provide the following services: nursing, physical therapy, occupational therapy, respiratory therapy, medical and clinical laboratory, dietary, and pharmacy. These services each include several standard occupational classifications (SOCs), as defined by the Bureau of Labor Statistics (BLS) on its Occupational Employment Statistics (OES) survey **(http://ww.bls.gov/oes/2001/oes_tec.htm)**, that may be used by hospitals in different mixes to provide specific aspects of patient care. CMS decided to use BLS's SOCs to categorize employees for the occupational mix survey in an effort to ease hospitals' reporting burden; most hospitals have had experience with collecting and reporting their employment data according to the SOC definitions. The survey includes a total of 19 SOCs that provide services for the above 7 categories and an "all other occupations" category. The hours collected on the survey would be used to determine the proportion

of a general service category total that is attributable to each of the category's SOCs, that is, the category's occupational mix.

In order to accurately reflect a hospital's employment, we initially planned to require all hospitals to provide occupational mix data collected from a 1-year period. Several hospitals and their representatives advised us that a 1-year reporting period was feasible because salary and wage data are maintained quarterly for revenue and tax reporting purposes. However, several hospitals expressed concern that their payroll and other personnel accounting systems are typically not set up to collect data on hours for contract employees. The hospitals and their representatives advised us that the approximately 2-month timeframe (see dates below) for collecting and submitting the occupational mix data to the fiscal intermediaries would not allow hospitals enough time to develop a year's worth of hours data for contract workers. Therefore, given the short timeframe for collecting the occupational mix data, and to reduce hospitals' reporting burden associated with the initial collection of the data, we decided to allow hospitals the option of providing their hours data for the 19 SOCs either prospectively for a 4-week period beginning on or between December 28, 2003 and January 11, 2004, and ending no later than February 7, 2004, or retrospectively for a 12-month period, that is, calendar year 2003. Although we recognize that using data from only a 4-week period increases our risk of obtaining results that reflect seasonal rather than normal employment trends, we believe that the 4-week prospective reporting period should enable hospitals to plan and provide more accurate data according to our survey instructions and definitions. (See

the discussion below on the verification and validity of our occupational mix survey results.)

An advance copy of the occupational mix survey was provided to hospitals in mid-December 2003 so that hospitals could begin gathering their data and documentation necessary to complete the survey. The official survey was published as a CMS One-Time Notification (Pub. 100-20, R47OTN) on January 23, 2004. We instructed our fiscal intermediaries to distribute and collect completed occupational mix surveys from any hospital that is subject to IPPS, or any hospital that would be subject to IPPS if not granted a waiver. If a hospital was not an IPPS provider during FY 2001 or, otherwise, did not submit a FY 2001 cost report, the hospital was not required to submit occupational mix data. Consistent with the wage data, CAHs were excluded from the occupational mix survey. In addition, the FY 2005 wage index does not include occupational mix data for hospitals that submitted FY 2001 wage data, but terminated participation in the Medicare program as IPPS providers before calendar year 2003. For such terminated hospitals, there would be no occupational mix data to collect for our survey period.

Hospitals had to submit their completed occupational mix surveys to their fiscal intermediaries by February 16, 2004. Our initial collection of these data was completed by March 1, 2004, the deadline for fiscal intermediaries to submit hospitals' survey data to CMS. We released a public use file containing the data on March 8, 2004 (through the Internet on our website at: **http://cms/hhs.gov/providers/hipps/ippswage.asp)**. In a memorandum also dated March 8, 2004, we instructed all fiscal intermediaries to inform

the IPPS hospitals they service of the availability of the occupational mix data file and the process and timeframe for requesting corrections and revisions. If a hospital wished to request a change to its data as shown in that file, the hospital had to submit the changes to its fiscal intermediary by March 22, 2004. In addition, as this was hospitals' first experience with the occupational mix survey, we provided hospitals another opportunity, if they missed the February 16 filing deadline, to submit their completed surveys. The deadline for this one-time, final opportunity to submit occupational mix data to fiscal intermediaries for the FY 2005 wage index was also March 22, 2004. The final deadline for fiscal intermediaries to submit hospitals' data to CMS was April 16, 2004. (From April 16 until the final rule is published, the process, criteria, and timetable for correcting occupational mix data was the same as for Worksheet S-3 wage data, under Section H.) Occupational mix survey data received by us through March 15, 2004, were used in computing the proposed wage index in the May 18, 2004 proposed rule. Data received from intermediaries after March 15 through April 16, 2004 are included in this final rule.

The final response rate for the occupational mix survey was 93.8 percent. We received occupational mix data from 3,768 hospitals. We expected to receive completed survey data from 4,018 hospitals that submitted cost report wage data for FY 2001 and were still IPPS hospitals during calendar year 2003 or on January 1, 2004. In the proposed rule, we said that for any hospital that was expected to provide occupational mix data but did not, we would consider using proxy occupational mix data to adjust the hospital's wage data in the final wage index. One option would be to assume that the hospital only has employees in the highest level SOC for each of the general service

categories included on the occupational mix survey. Another option would be to assume that such hospitals have the national SOC mix for each general service category. We invited public comment to this proposal. We noted that the wage index in the proposed rule did not include proxy data for hospitals that did not complete and submit the occupational mix survey.

Comment: Some commenters supported the intent of the occupational mix adjustment to the wage index. The commenter believed that an occupational mix adjusted wage index more accurately reflects hospitals' labor costs. Other commenters questioned whether there is a need for the occupational mix adjustment with the implementation of the provisions of Pub. L. 108-173 that has also increased payments to hospitals in rural areas. One commenter, an association representing hospitals in a large metropolitan area, stated that its members are concerned that any redistribution of monies from urban teaching hospitals to rural hospitals will result in further underpayment by Medicare to hospitals that utilize the most sophisticated and costly equipment, technology, and staff needed to treat the sickest patients. Further, the commenter believed that an occupational mix classification system is inherently flawed due to the diverse manner in which hospital services are rendered throughout the United States.

Several commenters expressed concern that the occupational mix adjustment is contrary to CMS' quality initiatives that place emphasis on improvement in quality outcomes and standards of care, which may require hospitals to employ more highly skilled caregivers. In addition, some commenters believed that the occupational mix adjustment opposes the direction that State governments are undertaking in mandating

registered nurse staffing ratios; the resulting adjustment may be negative for hospitals in these states. Two commenters opposed the occupational mix adjustment because the commenters believed that the adjustment is unnecessary, increases the information burden for hospitals, and adds to the data that CMS must regularly audit. A few commenters recommended that we request Congress to rescind the BIPA provision that requires the occupational mix adjustment because our proposed adjustment does not have the anticipated impact.

Response: We appreciate these and other comments and concerns we received regarding the proposed initial implementation of the occupational mix adjusted wage index. We acknowledge that a wage index adjusted for occupational mix could have a redistributive effect on Medicare payments to hospitals, and, combined with the provisions of Pub. L. 108-173, some hospitals may be significantly negatively impacted. However, we also agree with the theory that an occupational mix adjusted wage index should more accurately reflect relative labor costs among hospitals by removing the differences that result from hiring higher skilled or lower skilled workers. For hospitals that employ a higher skill mix because they treat more complicated cases, the DRG assignment of cases should reflect the extra cost. Therefore, we do not agree with the recommendation that we should approach Congress to rescind the law that requires the occupational mix adjustment.

While the law requires us to implement the adjustment with the FY 2005 wage index, we also intend to minimize the negative impact that this initial implementation of the occupational mix adjustment may have on some hospitals' wage index values. The

final FY 2005 wage index adjustment is only partially adjusted for occupational mix. A complete discussion of the blended wage index appears in section III.G. of the preamble to this final rule. We welcome input from MedPAC, hospitals, and associations in assessing the impact of the occupational mix adjustment on hospitals' wage index values and monitoring how current hospital staffing trends affect the expected outcome of the adjustment.

Comment: Several commenters addressed the issue of how we should handle the occupational mix adjustment for hospitals that did not complete the survey. The majority of commenters recommended that we use the unadjusted wage data or the national SOC mix so that other hospitals in the MSA are not adversely impacted by negative proxy data. One commenter requested us to adopt the first option, that, for any hospital that did not respond to the survey, CMS should assume that the hospital employs all of its workers in the highest level SOC for each category. The commenter believed that hospitals were provided enough time to ensure that their data collected for the occupational mix adjustment were accurate. One commenter suggested that we could achieve a 100 percent response rate to the survey if we make the survey mandatory. Another commenter recommended that we set the same consequences for failure to complete the occupational mix survey as those for not submitting a cost report and notify hospitals of these consequences in the survey instructions.

Response: We agree that other hospitals should not be harmed by a hospital's failure to respond to the occupational mix survey. If we were to apply the first option, the worst-case scenario, the wage index values for most of the areas that have hospitals

that did not complete the survey would decrease significantly compared to leaving such hospitals' wage data unadjusted for occupational mix. Therefore, for the final FY 2005 wage index, we decided to use the unadjusted wage data for hospitals that did not submit occupational mix survey data. For calculation purposes, this equates to applying the national SOC mix to the wage data for such hospitals, because hospitals having the same mix as the nation would have an occupational mix adjustment factor equaling 1.0000. We note that we will revisit this matter with subsequent collections of the occupational mix data. We will explore the possibilities of making it mandatory for all IPPS hospitals to complete the survey, as well as establishing penalties for hospitals that fail to submit occupational mix data.

Comment: Some commenters opposed our decision to allow hospitals to provide occupational mix data prospectively for a 4-week period. The commenters believed that the 4-week reporting period occurred during hospitals' peak season and is not representative of hospitals' annual staffing (about 30 percent of hospitals used this option). The commenter suggested that the next survey should be for a full year only.

Response: We believe that in the first year of the occupational mix adjustment, it was reasonable to use a 4-week period. A 4-week period represents a sampling of the occupational mix that occurs in a hospital during the year. We do not have available data to determine if the 4-week reporting period is a peak season for hospitals, as the commenter contends, or even whether a hospital's employment mix significantly changes during peak seasons. However based on the similarity of our results and the results found by the Bureau of Labor

Statistics, we believe use of the 4-week period did not significantly affect the data we received for the adjustment. Nevertheless, in order to further assure the accuracy of the adjustment, in future years, we will require data collected from a full year.

Comment: Several commenters reported that the short timeframe for hospitals to complete, review, and correct the survey data and lack of clarity by hospitals in determining the proper category to place certain employees (for example, a registered nurse who also conducts administrative duties) led to errors and inconsistencies in reporting that may have contributed to the unexpected outcomes. One commenter noted errors in the date fields of the survey, stating that about 8-percent of hospitals appear to have incorrect dates in the date fields and large variances in hours reported between Worksheet S-3 and the occupational mix survey. The commenter recommended that CMS clarify its definitions and notify hospitals of the next survey's design at least 60 days or, ideally, 6 months prior to the period the data collection will begin. This would allow hospitals more time to prepare their payroll and other systems to collect more accurate data. Some commenters suggested that, due to possible errors and inconsistencies in the initial data collection, CMS should gather new data next year, rather than waiting 3 years for the next collection of occupational mix data.

Response: We did not believe that the survey definitions would be problematic for hospitals because of hospitals' experience with the BLS OES survey. In fact, several hospitals and associations strongly recommended that we use the BLS definitions for the occupational mix survey. In future years, if

hospitals wish to receive further clarification of the definitions of the occupational categories then we welcome their assistance. We also plan in future years to provide the next survey to hospitals prior to the period that the data collection begins. The suggested 60-day preparation period appears reasonable, and we will consider such a schedule for future occupational mix data collections. With regard to administering another survey next year, we are reluctant to do so because of the additional reporting burden for hospitals. Further, we would have to issue the survey immediately for implementation with the FY 2006 index. However, we have not ruled out the possibility of revising the survey and administering another survey before 2007. According to section 1886(d)(3)(E) of the Act, the Secretary has the authority to administer the occupational mix survey more than once during a 3-year period.

Comment: Two commenters suggested changes to the categories that are included in the occupational mix survey. One commenter recommended that CMS exclude the dietary categories and medical assistants. The commenter noted significant variations among hospitals in these categories that may have been due to lack of clarity regarding the category definitions. The commenter further cautioned that, although only a small portion of hospital workers are in these occupational categories, misreporting in these categories could significantly distort the occupational mix data because the categories have low hourly rates. MedPAC recommended that CMS assess whether including subcategories of RNs would result in a more accurate occupational mix adjustment. MedPAC believed that including all RNs in a single category may obscure

significant wage differences among the subcategories of RNs, for example, the wages of surgical RNs and floor RNs may differ. To offset additional reporting burden for hospitals, MedPAC suggested that CMS could eliminate some of the general service categories that account for fewer hours, since most of the total occupational mix adjustment is correlated with the nursing general service category.

Response: We believe that it is appropriate to include the dietary and medical assistant occupations in the FY 2005 adjustment. Although these occupations represent a small portion of a hospital's total workforce, hospitals employ these occupations in different mixes, just as for the other survey categories. In the absence of data showing that there is minimum variation among hospitals in their employment of these occupations, we are not convinced, as the commenter suggests, that the variations reflected in the survey results are due to a lack of clarity regarding the category definitions. With regards to MedPAC's recommendation to expand the RN category, we would need to investigate this matter further to assess its impact on the occupational mix adjustment, hospital's reporting burden, and intermediary's review workload. We welcome any data or studies related to both of these issues.

Comment: Several commenters noted that the occupational mix adjusted wage index in the proposed rule was based on data from the March 8, 2004 public use file. However, 263 surveys were added to the database in the May 13, 2004 public use file. The commenters urged CMS to recalculate its final analysis of the occupational mix adjustment using the data for all hospitals that submitted the survey data.

Response: As we stated in the proposed rule (69 FR 28253), and above, the occupational mix adjustment in the proposed rule was based on data we received by March 15, 2004. We further stated in the proposed rule, and above, that data received after March 15 and through April 16 would be included in the final wage index. The FY 2005 wage index in this final rule includes the most complete and updated set of occupational mix survey data that we received timely from hospitals, that is, by April 16, 2004.

Comment: Two commenters recommended that CMS collect data on hospitals' service mix to include as part of the occupational mix adjustment. The commenters believe that hospitals that provide more services requiring highly skilled workers, such as oncology services, should not be penalized in the wage index for providing those services. One of the commenters also suggested that the adjustment should account for productivity, because hospitals should not be penalized if they hire highly skilled workers who work effectively with minimum support staff.

Response: We are concerned that collecting data on service mix and productivity would substantially increase the reporting burden for hospitals and the complexity of the occupational mix adjustment. We are also uncertain as to what impact these additional factors would actually have on the occupational mix adjustment. If hospitals hire more highly skilled workers because they treat more complex cases, Medicare's DRG assignment already reflects the higher costs of providing these services. We note that the wage index under section 1886(d)(3)(E) is intended to account for geographic differences in labor costs–

not skill mix. We welcome the commenters to provide more details of the data and methodology that would be required to include these factors in the occupational mix adjustment, as well as any analysis of the impact of these factors on the occupational mix adjustment.

Comment: Several commenters expressed concern about CMS' use of unaudited occupational mix data and suggested that a review process is needed. Some commenters believed that CMS should not implement the occupational mix adjustment because the survey data were not verified by the fiscal intermediaries. One commenter added that CMS should provide the fiscal intermediaries ample time and resources to complete more thorough reviews of future occupational mix data.

Response: We plan to audit the occupational mix survey data in future years. However, given the short timeframe for collecting the occupational mix data and implementing the adjustment with the FY 2005 wage index, there was no time for fiscal intermediaries to conduct such reviews. Further, as this was the first time we collected data on hours for the 19 occupational categories, we had no baseline data to develop edit thresholds to incorporate in an intermediary review program. Thus, it would have been difficult to develop an audit program for use by fiscal intermediaries. We notified hospitals that they were responsible for submitting to us accurate data for Medicare payment purposes. Because hospitals will be affected by their own submission of data, we believe that hospitals had ample incentive to ensure that the data they submitted were correct and, therefore, self-audited their own data. Finally, we note that our policy of applying the occupational mix adjustment to only 10 percent of the wage index takes into

account that this is the first year for submitting, analyzing, and applying the occupational mix data.

Although the occupational mix data were not as extensively reviewed as may occur in future years, we are required by law to implement an occupational mix adjustment with the FY 2005 wage index. The next collection of occupational mix data will include an intermediary review period and an opportunity for hospitals to respond to any adjustments made by the intermediaries during the review.

As this was the first administration of the occupational mix survey, we did not provide fiscal intermediaries an extensive program for reviewing the hours of data collected. However, hospitals were required to be able to provide any documentation that could be used by the fiscal intermediaries to verify the survey data. In addition, after reviewing the compiled survey data, we contacted fiscal intermediaries to request corrections from a few hospitals that provided data for reporting periods that were out of range with our specified 12-month or 4-week data collection periods. As the wage index is a relative measure of labor costs across geographic areas, it is important that the data collected from hospitals reflect a common period. We also tested the validity of our occupational mix survey data by comparing our results to those of the 2001 BLS OES survey. As shown in Charts 4 and 5 below, the results of our survey are rather consistent with the findings of the BLS OES survey, especially for the nursing and physical therapy categories.

In addition, to compute the occupational mix adjustment, we collected data on the average hourly rates for the 19 SOCs so that we could derive a weighted average hourly

rate for each labor market area. (More details about the occupational mix calculation are included in section III.C.2. of this preamble.) To decrease hospital's reporting burden for this initial collection of the occupational mix data, and to facilitate the timely collection of the data, we did not require hospitals to report data on their total wages or average hourly rates associated with the 19 SOCs. Instead, we used national average hourly rates from the BLS OES 2001 National Industry-Specific Occupational Employment and Wage Estimates, SIC – Hospitals (accessible at website: **http://www.bls.gov/oes/2001/oesi3_806.htm**), as reflected in Chart 4 below.

Chart 4.-- BLS National Occupational Employment and Wage Estimates for Hospitals

General Service Categories	Number of Hospital Employees	Percent of Service Category	Percent of Total Employees	National Average Hourly Wage
Nursing Services and Medical Assistant Services				
Registered Nurses	1,307,960	68.8%	25.88%	$23.62
Licensed Practical Nurses	194,900	10.2%	3.86%	$14.65
Nursing Aides, Orderlies, & Attendants	351,910	18.5%	6.96%	$10.01
Medical Assistants	47,250	2.5%	0.93%	$11.79
Total	**1,902,020**	**100.0%**	**37.63%**	
Physical Therapy Services				
Physical Therapists	46,290	61.0%	0.92%	$27.80
Physical Therapist Assistants	17,610	23.2%	0.35%	$17.11
Physical Therapist Aides	12,020	15.8%	0.24%	$10.40
Total	**75,920**	**100.0%**	**1.50%**	
Occupational Therapy Services				
Occupation Therapists	24,110	75.3%	0.48%	$25.62

General Service Categories	Number of Hospital Employees	Percent of Service Category	Percent of Total Employees	National Average Hourly Wage
Occupation Therapist Assistants	5,690	17.8%	0.11%	$16.81
Occupation Therapist Aides	2,220	6.9%	0.04%	$11.60
Total	**32,020**	**100.0%**	**0.63%**	
Respiratory Therapy Services				
Respiratory Therapists	68,920	72.8%	1.36%	$19.26
Respiratory Therapy Technicians	25,710	27.2%	0.51%	$16.96
Total	**94,630**	**100.0%**	**1.87%**	
Pharmacy Services				
Pharmacists	48,630	48.8%	0.96%	$34.58
Pharmacy Technicians	44,270	44.4%	0.88%	$12.30
Pharmacy Assistants/Aides	6,810	6.8%	0.13%	$11.52
Total	**99,710**	**100.0%**	**1.97%**	
Dietary Services				
Dieticians	16,820	56.4%	0.33%	$20.02
Dietetic Technicians	13,020	43.6%	0.26%	$11.64
Total	**29,840**	**100.0%**	**0.59%**	
Medical & Clinical Lab Services				
Medical & Clinical Lab Technologists	87,380	57.8%	1.73%	$20.74
Medical & Clinical Lab Technicians	63,900	42.2%	1.26%	$14.90
Total	**151,280**	**100.0%**	**2.99%**	
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	**2,385,420**		**47.19%**	
All Other Occupations	**2,669,400**		**52.81%**	

General Service Categories	Number of Hospital Employees	Percent of Service Category	Percent of Total Employees	National Average Hourly Wage
Total Hospital Employees	**5,054,820**		**100.0%**	

Source: BLS, OES, 2001 National Industry-Specific Occupational Employment and Wage Estimates, **www.bls.gov/oes/2001**.

Chart 5.--Medicare Occupational Mix Survey Results

General Service Categories	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours
Nursing Services and Medical Assistant Services			
Registered Nurses	1,429,939,708.87	70.51%	26.77%
Licensed Practical Nurses	152,076,000.02	7.50%	2.85%
Nursing Aides, Orderlies, & Attendants	373,013,761.93	18.39%	6.98%
Medical Assistants	72,930,628.98	3.60%	1.37%
Total	**2,027,960,099.80**	**100.00%**	**37.97%**
Physical Therapy Services			
Physical Therapists	45,536,940.56	61.15%	0.85%
Physical Therapist Assistants	17,235,657.69	23.15%	0.32%
Physical Therapist Aides	11,691,298.12	15.70%	0.22%
Total	**74,463,896.37**	**100.00%**	**1.39%**
Occupational Therapy Services			
Occupation Therapists	19,165,885.91	79.13%	0.36%
Occupation Therapist Assistants	4,082,490.26	16.86%	0.08%
Occupation Therapist Aides	972,594.68	4.02%	0.02%
Total	**24,220,970.86**	**100.00%**	**0.45%**
Respiratory Therapy Services			
Respiratory Therapists	84,719,095.59	80.16%	1.59%
Respiratory Therapy Technicians	20,965,596.00	19.84%	0.39%
Total	**105,684,691.58**	**100.00%**	**1.98%**
Pharmacy Services			
Pharmacists	55,307,036.23	48.08%	1.04%
Pharmacy Technicians	55,248,144.37	48.03%	1.03%
Pharmacy Assistants/Aides	4,480,980.40	3.90%	0.08%
Total	**115,036,161.00**	**100.00%**	**2.15%**
Dietary Services			
Dieticians	19,056,751.23	42.10%	0.36%

General Service Categories	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours
Dietetic Technicians	26,209,576.38	57.90%	0.49%
Total	**45,266,327.61**	**100.00%**	**0.85%**
Medical & Clinical Lab Services			
Medical & Clinical Lab Technologists	116,177,701.08	58.79%	2.17%
Medical & Clinical Lab Technicians	81,437,014.90	41.21%	1.52%
Total	**197,614,715.98**	**100.00%**	**3.70%**
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	**2,590,246,863.19**		**48.49%**
All Other Occupations	**2,751,434,492.48**		**51.51%**
Total Hospital Employees	**5,341,681,355.67**		**100.00%**

Source: Medicare Wage Index Occupational Mix Survey, Form CMS-10079.

2. Calculation of the Occupational Mix Adjustment Factor and the Occupational Mix Adjusted Wage Index

The method used to calculate the occupational mix adjusted wage index follows:

Step 1--For each hospital, the percentage of the general service category attributable to an SOC is determined by dividing the SOC hours by the general service category's total hours. Repeat this calculation for each of the 19 SOCs.

Step 2--For each hospital, the weighted average hourly rate for an SOC is determined by multiplying the percentage of the general service category (from Step 1)

by the national average hourly rate for that SOC from the 2001 BLS OES survey (see Chart 4 above). Repeat this calculation for each of the 19 SOCs.

Step 3--For each hospital, the hospital's adjusted average hourly rate for a general service category is computed by summing the weighted hourly rate for each SOC within the general category. Repeat this calculation for each of the 7 general service categories.

Step 4--For each hospital, the occupational mix adjustment factor for a general service category is calculated by dividing the national adjusted average hourly rate for the category by the hospital's adjusted average hourly rate for the category. (The national adjusted average hourly rate is computed in the same manner as Steps 1 through 3, using instead, the total SOC and general service category hours for all hospitals in the occupational mix survey database.) Repeat this calculation for each of the 7 general service categories. If the hospital's adjusted rate is less than the national adjusted rate (indicating the hospital employs a less costly mix of employees within the category), the occupational mix adjustment factor will be greater than 1.0000. If the hospital's adjusted rate is greater than the national adjusted rate, the occupational mix adjustment factor will be less than 1.0000.

Step 5--For each hospital, the occupational mix adjusted salaries and wage-related costs for a general service category is calculated by multiplying the hospital's total salaries and wage-related costs (from Step 5 of the unadjusted wage index calculation in section F) by the percentage of the hospital's total workers attributable to the general service category (this is corrected from the proposed rule, in which we applied, instead, the national percentages to all hospitals) and by the general service category's

occupational mix adjustment factor (from Step 4 above). Repeat this calculation for each of the 7 general service categories. The remaining portion of the hospital's total salaries and wage-related costs that is attributable to all other employees of the hospital is not adjusted for occupational mix.

Step 6--For each hospital, the total occupational mix adjusted salaries and wage-related costs for a hospital are calculated by summing the occupational mix adjusted salaries and wage-related costs for the 7 general service categories (from Step 5) and the unadjusted portion of the hospital's salaries and wage-related costs for all other employees. To compute a hospital's occupational mix adjusted average hourly wage, divide the hospital's total occupational mix adjusted salaries and wage-related costs by the hospital's total hours (from Step 4 of the unadjusted wage index calculation in Section F).

Step 7--To compute the occupational mix adjusted average hourly wage for an urban or rural area, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the area, then sum the total hours for all hospitals in the area. Next, divide the area's occupational mix adjusted salaries and wage-related costs by the area's hours.

Step 8--To compute the national occupational mix adjusted average hourly wage, sum the total occupational mix adjusted salaries and wage-related costs for all hospitals in the nation, then sum the total hours for all hospitals in the nation. Next, divide the national occupational mix adjusted salaries and wage-related costs by the national hours. The national occupational mix adjusted average hourly wage is 26.4114.

Step 9--To compute the occupational mix adjusted wage index, divide each area's occupational mix adjusted average hourly wage (Step 7) by the national occupational mix adjusted average hourly wage (Step 8).

Step 10—To compute the Puerto Rico specific occupational mix adjusted wage index, follow the Steps 1 through 9 above. The Puerto Rico occupational mix adjusted average hourly wage is 12.2577.

Example of Occupational Mix Adjustment

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
NATIONAL				
Nursing and Medical Assistant Services				
Registered Nurses	1,429,939,708.87	70.51%	26.77%	$23.62
Licensed Practical Nurses	152,076,000.02	7.50%	2.85%	$14.65
Nursing Aides, Orderlies, & Attendants	373,013,761.93	18.39%	6.98%	$10.01
Medical Assistants	72,930,628.98	3.60%	1.37%	$11.79
Total	**2,027,960,100**	**100.00%**	**37.97%**	**$20.02**
HOSPITAL A				
Registered Nurses	1,642,116	79.84%		$18.86
Licensed Practical Nurses	67,860	3.30%		$0.48
Nursing Aides, Orderlies, & Attendants	259,177	12.60%		$1.26
Medical Assistants	87,622	4.26%		$0.50
Total	**2,056,774**	**100.00%**		**21.11**
Occupational Mix Adjustment				0.9485
HOSPITAL B				
Registered Nurses	1,510,724	64.44%		$0.31
Licensed Practical Nurses	159,795	6.82%		$0.09
Nursing Aides, Orderlies, & Attendants	391,201	16.69%		$0.08

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Medical Assistants	282,728	12.06%		$2.55
Total	**2,344,449**	**100.00%**		**19.31**
Occupational Mix Adjustment				1.0366
NATIONAL				
Physical Therapy Services				
Physical Therapists	45,536,940.56	61.15%	0.85%	$27.80
Physical Therapist Assistants	17,235,657.69	23.15%	0.32%	$17.11
Physical Therapist Aides	11,691,298.12	15.70%	0.22%	$10.40
Total	**74,463,896**	**100.00%**	**1.39%**	**$22.59**
HOSPITAL A				
Physical Therapists	94,987	61.40%		$17.07
Physical Therapist Assistants	36,254	23.43%		$4.01
Physical Therapist Aides	23,460	15.16%		$1.58
Total	**154,701**	**100.00%**		**$22.66**
Occupational Mix Adjustment				0.9971
HOSPITAL B				
Physical Therapists	60,337	57.37%		$15.95
Physical Therapist Assistants	22,391	21.29%		$3.64
Physical Therapist Aides	22,444	21.34%		$2.22
Total	**105,173**	**100.00%**		**$21.81**
Occupational Mix Adjustment				1.0359
NATIONAL				
Occupational Therapy Services				
Occupation Therapists	19,165,885.91	79.13%	0.36%	$25.62
Occupation Therapist Assistants	4,082,490.26	16.86%	0.08%	$16.81
Occupation Therapist Aides	972,594.68	4.02%	0.02%	$11.60
Total	**24,220,971**	**100.00%**	**0.45%**	**$23.57**
HOSPITAL A				
Occupation Therapists	40,366	90.06%		$23.07
Occupation Therapist Assistants	0	0.00%		$0.00
Occupation Therapist Aides	4,454	9.94%		$1.15
Total	**44,820**	**100.00%**		**$24.23**

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Occupational Mix Adjustment				0.9728
HOSPITAL B				
Occupation Therapists	26,547	79.48%		$20.36
Occupation Therapist Assistants	1,610	4.82%		$0.81
Occupation Therapist Aides	5,242	15.70%		$1.82
Total	**33,399**	**100.00%**		**$22.99**
Occupational Mix Adjustment				1.0253
NATIONAL				
Respiratory Therapy Services				
Respiratory Therapists	84,719,095.59	80.16%	1.59%	$19.26
Respiratory Therapy Technicians	20,965,596.00	19.84%	0.39%	$16.96
Total	**105,684,692**	**100.00%**	**1.98%**	**$18.80**
HOSPITAL A				
Respiratory Therapists	75,339	97.40%		$18.76
Respiratory Therapy Technicians	2,008	2.60%		$0.44
Total	**77,347**	**100.00%**		**$19.20**
Occupational Mix Adjustment				0.9794
HOSPITAL B				
Respiratory Therapists	73,592	65.62%		$12.64
Respiratory Therapy Technicians	38,549	34.38%		$5.83
Total	**112,141**	**100.00%**		**$18.47**
Occupational Mix Adjustment				1.0181
NATIONAL				
Pharmacy Services				
Pharmacists	55,307,036.23	48.08%	1.04%	$34.58
Pharmacy Technicians	55,248,144.37	48.03%	1.03%	$12.30
Pharmacy Assistants/Aides	4,480,980.40	3.90%	0.08%	$11.52
Total	**115,036,161**	**100.00%**	**2.15%**	**$22.98**
HOSPITAL A				

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Pharmacists	65,863	48.65%		$16.82
Pharmacy Technicians	69,525	51.35%		$6.32
Pharmacy Assistants/Aides	0	0.00%		$0.00
Total	**135,388**	**100.00%**		**$23.14**
Occupational Mix Adjustment				0.9931
HOSPITAL B				
Pharmacists	45,856	39.23%		$13.57
Pharmacy Technicians	64,986	55.60%		$6.84
Pharmacy Assistants/Aides	6,039	5.17%		$0.60
Total	**116,881**	**100.00%**		**$21.00**
Occupational Mix Adjustment				1.0944
NATIONAL				
Dietary Services				
Dieticians	19,056,751.23	42.10%	0.36%	$20.02
Dietetic Technicians	26,209,576.38	57.90%	0.49%	$11.64
Total	**45,266,328**	**100.00%**	0.85%	**$15.17**
HOSPITAL A				
Dieticians	13,943	100.00%		$20.02
Dietetic Technicians	0	0.00%		$0.00
Total	**13,943**	**100.00%**		**$20.02**
Occupational Mix Adjustment				0.7576
HOSPITAL B				
Dieticians	27,458	16.29%		$3.26
Dietetic Technicians	141,148	83.71%		$9.74
Total	**168,606**	**100.00%**		**$13.00**
Occupational Mix Adjustment				1.1668
NATIONAL				
Medical & Clinical Lab Services				
Medical & Clinical Lab Technologists	116,177,701.08	58.79%	2.17%	$20.74
Medical & Clinical Lab Technicians	81,437,014.90	41.21%	1.52%	$14.90

General Service Categories/SOCs	Number of Employee Hours	Percent of Service Category Hours	Percent of Total Employee Hours	BLS National Average Hourly Wage
Total	**197,614,716**	**100.00%**	**3.70%**	**$18.33**
HOSPITAL A				
Medical & Clinical Lab Technologists	166,522	90.82%		$18.84
Medical & Clinical Lab Technicians	16,841	9.18%		$1.37
Total	**183,363**	**100.00%**		**$20.20**
Occupational Mix Adjustment				0.9076
HOSPITAL B				
Medical & Clinical Lab Technologists	295,516	47.34%		$9.82
Medical & Clinical Lab Technicians	328,716	52.66%		$7.85
Total	**624,232**	**100.00%**		**$17.66**
Occupational Mix Adjustment				1.0381
Total Nursing, Therapy, Pharmacy, Dietary, and Medical & Clinical Occupations	**2,590,246,863.19**		**48.49%**	
All Other Occupations	**2,751,434,492.48**		**51.51%**	
Total Hospital Employees	**5,341,681,355.67**		**100.00%**	

In implementing an occupational mix adjusted wage index based on the above calculation, the final wage index values for 16 rural areas (36.0 percent) and 210 urban areas (4.4 percent) would decrease as a result of the adjustment. Six (6) rural areas (12.8 percent) and 111 urban areas (28.8 percent) would experience a decrease of 1 percent or greater in their wage index values. The largest negative impact for a rural area would be 2.1 percent and for an urban area, 4.0 percent. Meanwhile, 31 rural areas

(66.0 percent) and 176 urban areas (45.6 percent) would experience an increase in their wage index values. Although these results show that rural hospitals would gain the most from an occupational mix adjustment to the wage index, their gains may not be as great as might have been expected. Further, it might not have been anticipated that over one-third of rural hospitals would actually fare worse under the adjustment. Overall, a fully implemented occupational mix adjusted wage index would have a redistributive effect on Medicare payments to hospitals.

Comment: Several commenters raised concerns about the data CMS utilized to compute the occupational mix adjustment. One commenter noted that CMS computed the occupational mix adjustment using various sources of data from various time periods: (1) average hourly wage data from the BLS 2001 OES survey; and (2) hours data collected on the Medicare occupational mix survey from calendar year 2003 or 4 weeks in 2004. The commenter added that CMS applied the adjustment to wage costs collected on the Medicare cost report during FY 2001. The commenter believed that the data used in computing the occupational mix adjusted wage index should derive from the same time period because significant labor changes can occur in 2 to 3 years in the health care industry.

Some commenters also expressed concern about CMS' reliance on BLS data for average hourly rate information that led to CMS collecting hours data for occupations that are excluded from the wage index (certified registered nurse anesthestists (CRNAs), nurse practitioners (NPs) and clinical nurse specialists (CNSs)). The commenters recognized that CMS attempted to simplify the reporting and effort required by utilizing

the BLS information. However, they recommended that future surveys collect salaries and hours from hospitals and on the same basis as Worksheet S-3 of the cost report. The commenters believed that this would facilitate the intermediary's and CMS' review of the survey data.

Response: It is our intent to collect both salaries and hours data directly from hospitals for the computation of the occupational mix adjustment. We agree that, ideally, both the data used to compute the occupational mix adjustment and the wage data to which the adjustment is applied should derive from approximately the same time period and include the same occupational categories. However, we do not believe it was unreasonable in this instance, and in this short timeframe to use data from different time periods. We believe the consistency of our outcomes with the BLS OES data reflects this. In addition, if hospitals were concerned about collecting data from different time periods, we believe this is an issue that should have been commented upon when the actual occupational mix survey was published in 2003. We also believe that the BLS OES data are the best available for representing hospital hourly wage data. For future data collections, we will revise the occupational mix survey to allow hospitals to provide both salaries and hours data for each of the employment categories that are included on the survey. We will also assess whether future occupational mix surveys should be based on the calendar year or if the data should be collected on a fiscal year basis as part of the Medicare cost report. One logistical problem is that cost report data are collected yearly, but occupational mix survey data are collected only every 3 years.

Comment: Several comments addressed the methodology we used to calculate the occupational mix adjustment to the wage index. Most commented that the methodology appears theoretically sound, although the results appear counterintuitive. The commenters noted that one third of rural hospitals would experience a decline in their occupational mix adjusted wage index, while several large academic medical centers would experience an increase in their wage indexes. However, the commenters believed that the unexpected results are due more to errors in the data rather than our methodology for computing the occupational mix adjustment.

Four commenters cited problems with our computation of the occupational mix adjustment. The first commenter suggested that CMS should compute and apply the adjustment to the MSA average hourly wage rather than to each hospital's average hourly wage to reduce the effect that an individual hospital's data could have on an area wage index. The second commenter suggested that CMS should calculate an occupational mix adjustment for each of the 19 SOCs rather than the 7 general service category groupings. The third commenter noted that CMS applied the occupational mix adjustment for each general service category to a percentage of total salaries that was computed based on hours represented by each general service category. This commenter believed that, instead, the adjustment should have been applied to a percentage of total salaries that was based on wage costs represented by each of the general service categories. The fourth commenter cited that, in Step 5 of the occupational mix adjustment calculation in the proposed rule, CMS applied national weights to adjust all hospitals' total salaries for occupational mix, rather than applying hospital-specific weights. This commenter

suggested that, in applying the national weights to all hospitals' total wages, some area wage index values could be negatively impacted.

Response: We appreciate the input that we received from MedPAC, the Bureau of Labor Statistics, and the hospital community during our research and development of the occupational mix adjustment. We believe that our calculation of the occupational mix adjustment in this final rule is appropriate based on the purpose of the adjustment and the data we had available to calculate the adjustment.

We disagree with the comment that the occupational mix adjustment should be applied at the MSA level instead of the hospital level. By adjusting hospitals' data for occupational mix, we are treating the occupational mix adjustment consistent with the way we treat the wage index; that is, in calculating the wage index, we first compute adjusted salaries and hours for each hospital, then we sum the adjusted salaries and hours for all hospitals in an area to derive an area average hourly wage.

We also disagree with the suggestion that CMS should calculate an occupational mix adjustment for each of the 19 SOCs rather than the aggregated 7 general service category groupings. The adjustment is intended to control for hospitals' employment choices within certain service groupings, where, to an extent, the employees' skills are interchangeable. Therefore, we believe it is appropriate to apply the adjustment to the general service category grouping.

With regards to the suggestion that the adjustment should have been applied to a percentage of total salaries that was based on salary costs represented by each of the general service categories, the initial implementation of the occupational mix adjustment

did not provide for the collection of data on salaries. Therefore, we could not use the salaries for a general service category to derive the proportion of a hospital's total salaries to be adjusted for occupational mix. Based on our experience with wage and hours data, we believe that the proportions we derived from hours data would closely approximate the proportions that we would have derived if salaries data were available and used. Further, this use of hours data is consistent with a methodology we allow hospitals to use for allocating their wage-related costs on Worksheet S-3. Some hospitals base these allocations on proportions of total hours rather than salaries.

Finally, we acknowledge the error the commenter cited regarding Step 5. As shown above, we applied hospital-specific weights to adjust hospitals' total salaries in computing the occupational mix adjustment in this final rule.

Comment: Several hospitals stated that they had difficulty determining the impact of the occupational mix adjustment on their area wage index values. The commenters acknowledged that CMS provided public use files in March and May of the survey data and a public use file in June indicating hospitals' occupational mix adjustment factors. The commenters requested that CMS provide more detailed information about the findings of the occupational mix adjustment. One commenter suggested that CMS provide a table in the Addendum of the rule that shows what the area wage index values would have been without the occupational mix adjustment.

Response: In our continuing efforts to meet the information needs of the public, we will provide two additional public use files for the final occupational mix adjusted wage index: a file including each hospital's unadjusted and adjusted average hourly wage

and a file including each area's unadjusted and adjusted average hourly wage and wage index value. These additional files will be posted on the Internet, at http://cms.hhs.gov/providers/hipps/ippswage.asp. We will also post these files with future applications of the occupational mix adjustment.

D. Worksheet S-3 Wage Data for the FY 2005 Wage Index Update

The FY 2005 wage index values (effective for hospital discharges occurring on or after October 1, 2004 and before October 1, 2005) in section VI. of the Addendum to this final rule are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2001 (the FY 2004 wage index was based on FY 2000 wage data).

The FY 2005 wage index includes the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours (which includes direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services).
- Wage-related costs (The September 1, 1994 **Federal Register** included a list of core wage-related costs that are included in the wage index, and discussed criteria for including other wage-related costs (59 FR 45356)).

Consistent with the wage index methodology for FY 2004, the wage index for FY 2005 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2005 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397).

Data collected for the IPPS wage index are also currently used to calculate wage indexes applicable to other providers, such as SNFs, home health agencies, and hospices. In addition, they are used for prospective payments to rehabilitation, psychiatric, and long-term care hospitals, and for hospital outpatient services.

Comment: One commenter noted that the data CMS uses to compute the wage index is 4 years old and urged CMS to use more recent data. The commenter suggested that, due to the time lapse, the wage index does not sufficiently capture trends of health care professional shortages in certain labor markets and the corresponding salary increases associated with the rise in demand for certain health care professionals.

Response: We discussed this matter in a previous notice (65 FR 47070). Due to the time period allowed for: (1) hospitals to complete and submit their cost reports to their intermediaries, (2) fiscal intermediaries to perform a separate, detailed review of all

wage data and submit hospitals' reviewed wage data to CMS, and (3) CMS to compile a complete set of all hospitals' wage data from a common Federal fiscal year period, we do not have available more recent, complete, and reliable data to calculate the wage index. Therefore, hospitals' wage data are always 3 to 4 years old, depending on the end date of the hospital's cost reporting period, before we can use the data in calculating the wage index.

Comment: One commenter noted that, in the August 1, 2002 **Federal Register** rule (67 FR 50022), CMS stated that it would begin to collect contract labor wage costs and hours for management services and the following overhead services: administrative and general, housekeeping, and dietary. The commenter requested CMS to also add a line 25.01 to Worksheet S-3, Part II to collect wage costs and hours for contract laundry services and include the costs in the wage index calculation. Based on the commenter's analysis of the May public use file, 1,468 hospitals had no data on line 25 (direct costs for laundry services) and 1,599 hospitals had less than $100,000 in wage costs on this line. The commenter believed that the data indicates that many hospitals contract their laundry services, and including the costs for contract laundry services would provide equity in the wage index.

Response: In the August 1, 2002 rule, we stated that, while we agree that it may be appropriate to include indirect patient care contract labor costs in the wage index, in light of concerns about hospitals' ability to accurately document and report the costs, we believe that the best approach is to assess and include these costs incrementally. We will begin collecting data on contract management, administrative and general, housekeeping,

and dietary services with cost reporting periods beginning on or after October 1, 2003 (that is, the FY 2004 cost reports). Hospitals will submit their FY 2004 cost reports to their intermediaries during calendar year 2005 through early 2006. Intermediaries will complete their wage index desk reviews and submit hospitals' FY 2004 audited wage data to us by early 2007. We will use data from the FY 2004 cost reports to compute the FY 2008 wage index. Before including these additional costs in the wage index, we will analyze the impact of the costs on area wage index values and provide a detailed analysis for public comment. Our decision on whether to include these contract costs, and other contract costs in the future, such as, contract laundry services, will depend on the outcome of our analyses and public comment.

Comment: One commenter requested CMS to designate provider-based clinics (PBCs) as an IPPS-excluded area in order to remove the costs from the wage index. The commenter stated that PBCs are like physician private offices, which are excluded from the wage index. PBCs bill the technical component under certain outpatient ambulatory payment classifications (APCs) and the professional component under the physician fee schedule. The commenter noted that PBC costs are not paid under IPPS.

Response: We appreciate the commenter's suggestion. However, as this matter was not addressed in the FY 2005 proposed rule, or any previous rulemaking, we are not prepared to provide a decision about PBC costs in this final rule. We intend to explore a comprehensive assessment of the costs in a future rule.

E. Verification of Worksheet S-3 Wage Data

The wage data for the FY 2005 wage index were obtained from Worksheet S-3, Parts II and III of the FY 2001 Medicare cost reports. Instructions for completing the Worksheet S-3, Parts II and III are in the Provider Reimbursement Manual, Part I, sections 3605.2 and 3605.3. The data file used to construct the wage index includes FY 2001 data as of June 25, 2004. As in past years, we performed an intensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries to revise or verify data elements that resulted in specific edit failures. The unresolved data elements that were included in the calculation of the proposed FY 2005 wage index have been resolved and are reflected in the calculation of the final FY 2005 index. For the final FY 2005 wage index in this final rule, we removed the data for 237 hospitals from our database: 147 hospitals became critical access hospitals by the time we published from the FY 2005 wage index), and 76 hospitals were low Medicare utilization hospitals or failed edits that could not be corrected because the hospitals terminated the program or changed ownership. In addition, we removed the wage data for 14 hospitals with incomplete or inaccurate data resulting in zero or negative, or otherwise aberrant, average hourly wages. As a result, the final FY 2005 wage index is calculated based on FY 2001 wage data from 3,955 hospitals.

In constructing the FY 2005 wage index, we include the wage data for facilities that were IPPS hospitals in FY 2001, even for those facilities that have terminated their participation in the program as hospitals, as long as those data do not fail any of our edits

for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period. However, we exclude the wage data for CAHs (as discussed in 68 FR 45397). The wage index in this final rule excludes hospitals that are designated as CAHs by February 24, 2004, the date of the latest available Medicare CAH listing at the time we released the proposed wage index public use file on February 27, 2004.

F. Computation of the Unadjusted Wage Index

The method used to compute the FY 2005 wage index without an occupational mix adjustment follows:

Step 1--As noted above, we based the FY 2005 wage index on wage data reported on the FY 2001 Medicare cost reports. We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S-3, Parts II and III of the Medicare cost report for the hospital's cost reporting period beginning on or after October 1, 2000 and before October 1, 2001. In addition, we included data from some hospitals that had cost reporting periods beginning before October 2000 and reported a cost reporting period covering all of FY 2001. These data were included because no other data from these hospitals would be available for the cost reporting period described above, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2001 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2001 (for example, a hospital had two short cost reporting periods

beginning on or after October 1, 2000 and before October 1, 2001), we included wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2--Salaries--The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. In calculating a hospital's average salaries plus wage-related costs, we subtracted from Line 1 (total salaries) the GME and CRNA costs reported on lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3, 5 and 5.01, home office salaries reported on Line 7, and excluded salaries reported on Lines 8 and 8.01 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtracted from Line 1 the salaries for which no hours were reported. To determine total salaries plus wage-related costs, we added to the net hospital salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 9 and 10), home office salaries and wage-related costs reported by the hospital on Lines 11 and 12, and nonexcluded area wage-related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no corresponding hours are reported were not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 18) are excluded if no corresponding salaries are reported for those employees on Line 4.

Step 3--Hours--With the exception of wage-related costs, for which there are no associated hours, we computed total hours using the same methods as described for salaries in Step 2.

Step 4--For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocated overhead costs to areas of the hospital excluded from the wage index calculation. First, we determined the ratio of excluded area hours (sum of Lines 8 and 8.01 of Worksheet S-3, Part II) to revised total hours (Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, and Part III, Line 13 of Worksheet S-3). We then computed the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Line 13 of Worksheet S-3, Part III. Next, we computed the amounts of overhead wage-related costs to be allocated to excluded areas using three steps: (1) We determined the ratio of overhead hours (Part III, Line 13) to revised hours (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, and 7); (2) we computed overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 13, 14, and 18; and (3) we multiplied the computed overhead wage-related costs by the above excluded area hours ratio. Finally, we subtracted the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5--For each hospital, we adjusted the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make

the wage adjustment, we estimated the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2000 through April 15, 2002 for private industry hospital workers from the Bureau of Labor Statistics' Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2000	11/15/2000	1.07771
11/14/2000	12/15/2000	1.07273
12/14/2000	1/15/2001	1.06767
01/14/2001	02/15/2001	1.06245
02/14/2001	03/15/2001	1.05706
03/14/2001	04/15/2001	1.05168
04/14/2001	05/15/2001	1.04645
05/14/2001	06/15/2001	1.04139
06/14/2001	07/15/2001	1.03638
07/14/2001	08/15/2001	1.03134
08/14/2001	09/15/2001	1.02627
09/14/2001	10/15/2001	1.02133
10/14/2001	11/15/2001	1.01665
11/14/2001	12/15/2001	1.01224
12/14/2001	01/15/2002	1.00803
01/14/2002	02/15/2002	1.00395
02/14/2002	03/15/2002	1.00000
03/14/2002	04/15/2002	0.99610

For example, the midpoint of a cost reporting period beginning January 1, 2001 and ending December 31, 2001 is June 30, 2001. An adjustment factor of 1.03638 would be applied to the wages of a hospital with such a cost reporting period. In addition, for the data for any cost reporting period that began in FY 2001 and covered a period of less than 360 days or more than 370 days, we annualized the data to reflect a 1-year cost

report. Dividing the data by the number of days in the cost report and then multiplying the results by 365 accomplish annualization.

Step 6--Each hospital was assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B) or section 1886(d)(10) of the Act. Within each urban or rural labor market area, we added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7--We divided the total adjusted salaries plus wage-related costs obtained under both methods in Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8--We added the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divided the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage. Using the data as described above, the national average hourly wage is $26.3570.

Step 9--For each urban or rural labor market area, we calculated the hospital wage index value by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10--Following the process set forth above, we developed a separate Puerto Rico-specific wage index for purposes of adjusting the Puerto Rico standardized amounts. (The national Puerto Rico standardized amount is adjusted by a wage index calculated for all Puerto Rico labor market areas based on the national average hourly

wage as described above.) We added the total adjusted salaries plus wage-related costs (as calculated in Step 5) for all hospitals in Puerto Rico and divided the sum by the total hours for Puerto Rico (as calculated in Step 4) to arrive at an overall average hourly wage of $12.2568 for Puerto Rico. For each labor market area in Puerto Rico, we calculated the Puerto Rico-specific wage index value by dividing the area average hourly wage (as calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11--Section 4410 of Pub. L. 105-33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. Furthermore, this wage index floor is to be implemented in such a manner as to ensure that aggregate IPPS payments are not greater or less than those that would have been made in the year if this section did not apply. For FY 2005, this change affects 208 hospitals in 57 urban areas. The areas affected by this provision are identified by a footnote in Table 4A in the Addendum of this final rule.

G. Computation of the FY 2005 Blended Wage Index

As we proposed in the May 18, 2004 proposed rule, for the final FY 2005 wage index, we are using a blend of the occupational mix adjusted wage index and the unadjusted wage index, in order to minimize the redistributive impact of the occupational mix adjustment (as discussed in section III.C.2. of this preamble) for the first year of its implementation. Specifically, we are basing the FY 2005 wage index on a blend of 10 percent of an average hourly wage, adjusted for occupational mix, and 90 percent of an average hourly wage, unadjusted for occupational mix. Using this blend, the national

average hourly wage is $26.3624 and the Puerto Rico specific average hourly wage is $12.2569. We chose this blend for FY 2005 in recognition that this was the first time, for the administration of the occupational mix survey, hospitals had a short timeframe for collecting their occupational mix survey data and documentation, we could not collect optimum data (that is, wages and hours data from a 1-year period for all hospitals) within the mandatory timeframe for implementing the adjustment, and we had no baseline data to use in developing a desk review program that could ensure the accuracy of the occupational mix survey data.

In addition, we are moving cautiously with implementing the occupational mix adjustment in recognition of changing trends in the hiring of nurses, the largest group in our survey. Since the enactment of section 304(c) of Pub. L. 106-554, the law requiring the occupational mix adjustment to the wage index, some States have implemented laws that establish floors on the minimum level of registered nurse staffing that hospitals must maintain in order to continue to be licensed and certified by the State. In addition, some rural areas that are facing a shortage of physicians may be hiring more registered nurses as extenders or substitutes for physicians. Such trends may explain why the occupational mix impacts in section III.C.2. of this preamble are not as expected for rural areas in particular.

Further, we are using this blend because, although we want to minimize the immediate impact of the occupational mix adjustment on hospitals' wage index values, we do not want to nullify the value and intent of the occupational mix adjustment. We believe that the blended wage index we are proposing satisfies both of these goals. With

only 10 percent of the wage index adjusted for occupational mix, the wage index values for 14 rural areas (21.3 percent) and 205 urban areas (53.1 percent) would decrease as a result of the adjustment. However, the decreases would be minimum; the largest negative impact for a rural area would be only 0.21 percent and for an urban area, 0.40 percent. Conversely, 31 rural areas (66 percent) and 172 urban areas (44.6 percent) would benefit from this adjustment, with 1 urban area increasing 2,2 percent and all other areas gaining 0.7 percent or less. Overall, a wage index that has only 10 percent of the salaries adjusted for occupational mix would have a minimal redistributive effect on Medicare payments to hospitals. (See Appendix A to this final rule for further analyses of the impact of the occupational mix adjustment on the FY 2005 wage index.)

The wage index values in Tables 4A, 4B, 4C, 4F, 4G, and 4H and the average hourly wages in Tables 2, 3A, and 3B in the Addendum to this final rule include the occupational mix adjustment. We note that, although we are using a blended wage index for FY 2005, at this time we are not applying an incremental phase-in of the occupational mix adjustment beyond FY 2005. The application of the occupational mix adjustment beyond FY 2005 will be determined and discussed in subsequent IPPS updates.

Comment: Commenters generally agreed with CMS' decision to only partially implement the occupational mix adjustment with the FY 2005 wage index. A majority of commenters supported the proposed blended wage index in which the occupational mix adjusted portion is 10 percent. A few commenters suggested other applications of the adjustment as follows:

- Lower the percent adjusted for occupational mix to 5 percent or less. In addition, CMS should not raise the percent until the occupational mix survey process is improved.

- Apply an occupational mix adjustment to only 1 percent of the wage index.

- Apply a higher percentage of the occupational mix adjustment if the results for the hospital are positive and a lower percentage if the results are negative.

- Fully apply the adjustment to hospitals that are positively impacted and use a blend of 10 percent for hospitals that are negatively impacted.

- Phase in the adjustment, for example, over a period of 10 years (apply 10 percent per year). After the adjustment is fully implemented, cap the adjustment at 2 percent. That is, an occupational mix adjusted wage index value should be no greater or less than 2 percent of what the wage index value would have been in the absence of the occupational mix adjustment.

- Hold hospitals harmless on the use of occupational mix adjustment for 3 years.

One commenter stated that CMS should impose a temporary moratorium on the use of the occupational mix data until more accurate and reliable data can be gathered and studied.

Response: Due to the general support we received for our proposal to base the FY 2005 wage index on a blend of 10 percent of an average hourly wage adjusted for occupational mix and 90 percent of an average hourly wage unadjusted for occupational mix, we are proceeding as proposed. As we stated above, we will determine and discuss the application of future adjustments in subsequent IPPS updates.

H. Revisions to the Wage Index Based on Hospital Redesignation

1. General

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify by September 1 of the year preceding the year during which reclassification is sought. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassification to become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§412.230 through 412.280.

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with FY 2001, a MGCRB decision on a hospital reclassification for purposes of the wage index is effective for 3 fiscal years, unless the hospital elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of the Act provides that the MGCRB must use the 3 most recent years' average hourly wage data in evaluating a hospital's reclassification application for FY 2003 and any succeeding fiscal year.

Section 304(b) of Pub. L. 106-554 provides that the Secretary must establish a mechanism under which a statewide entity may apply to have all of the geographic areas in the State treated as a single geographic area for purposes of computing and applying a

single wage index, for reclassifications beginning in FY 2003. The implementing regulations for this provision are located at §412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute if: the rural county would otherwise be considered part of an urban area under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous MSAs. In light of the new CBSA definitions and the Census 2000 data, we undertook to identify those counties meeting these criteria. The eligible counties are identified below, as well as a discussion of counties that no longer meet the criteria under this provision.

2. Effects of Reclassification

Section 1886(d)(8)(C) of the Act provides that the application of the wage index to redesignated hospitals is dependent on the hypothetical impact that the wage data from these hospitals would have on the wage index value for the area to which they have been redesignated. These requirements for determining the wage index values for redesignated hospitals is applicable both to the hospitals located in rural counties deemed urban under section 1886(d)(8)(B) of the Act and hospitals that were reclassified as a result of the MGCRB decisions under section 1886(d)(10) of the Act. Therefore, as provided in

section 1886(d)(8)(C) of the Act,[1] the wage index values were determined by considering the following:

• If including the wage data for the redesignated hospitals would reduce the wage index value for the area to which the hospitals are redesignated by 1 percentage point or less, the area wage index value determined exclusive of the wage data for the redesignated hospitals applies to the redesignated hospitals.

• If including the wage data for the redesignated hospitals reduces the wage index value for the area to which the hospitals are redesignated by more than 1 percentage point, the area wage index determined inclusive of the wage data for the redesignated hospitals (the combined wage index value) applies to the redesignated hospitals.

• If including the wage data for the redesignated hospitals increases the wage index value for the urban area to which the hospitals are redesignated, both the area and the redesignated hospitals receive the combined wage index value. Otherwise, the hospitals located in the urban area receive a wage index excluding the wage data of hospitals redesignated into the area.

• The wage data for a reclassified urban hospital is included in both the wage index calculation of the area to which the hospital is reclassified (subject to the rules

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[1] Although section 1886(d)(8)(C)(iv)(I) of the Act also provides that the wage index for an urban area may not decrease as a result of redesignated hospitals if the urban area wage index is below the wage index for rural areas in the State in which the urban area is located, this was effectively made moot by section 4410 of Pub. L. 105-33, which provides that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State.

Also, section 1886(d)(8)(C)(iv)(II) of the Act provides that an urban area's wage index may not decrease as a result of redesignated hospitals if the urban area is located in a State that is composed of a single urban area.

described above) and the wage index calculation of the urban area where the hospital is physically located.

• Rural areas whose wage index values would be reduced by excluding the wage data for hospitals that have been redesignated to another area continue to have their wage index values calculated as if no redesignation had occurred (otherwise, redesignated rural hospitals are excluded from the calculation of the rural wage index).

• The wage index value for a redesignated rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located.

3. FY 2005 Issues

Recent policies and decisions that will affect hospitals' geographic classifications for FY 2005 are discussed below. First, we describe decisions by the MGCRB on applications received in accordance with the ongoing reclassification process described in the regulations at §§412.230 through 412.280. Second, we describe the implications for reclassification decisions by the MGCRB to be effective during FY 2005 of our adoption of new MSA definitions for the FY 2005 wage index. Third, we discuss the new counties identified under the standards at section 1886(d)(8)(B) of the Act, based on the new CBSAs and the Census 2000 data. Fourth, we discuss the interactions of these changes with reclassifications approved under the one-time appeal process for hospital wage index reclassifications at section 508 of Pub. L. 108-173. Fifth, we discuss our implementation of section 505 of Pub. L. 108-173. Under this provision, the Secretary must establish a new process, similar to the current wage index reclassification process,

to make adjustments to the hospital wage index, based on commuting patterns of hospital employees.

a. FY 2005 MGCRB Reclassifications

In the August 1, 2003 IPPS final rule, we indicated that hospitals submitting applications for reclassification by the MGCRB for FY 2005 should base those applications on the current (for Medicare payment purposes) MSAs (68 FR 45401). At the time this final rule was constructed, the MGCRB had completed its review of FY 2005 reclassification requests. There were 339 hospitals approved for wage index reclassifications by the MGCRB for FY 2005. Because MGCRB wage index reclassifications are effective for 3 years, hospitals reclassified during FY 2003 or FY 2004 are eligible to continue to be reclassified based on prior reclassifications to current MSAs during FY 2005. There were 55 hospitals reclassified for wage index in FY 2003 and 102 hospitals reclassified for wage index in FY 2004.

In the past, hospitals have been able to apply to be reclassified for purposes of either the wage index or the standardized amount. Existing regulations at §412.230(a)(5)(ii) state that, after 2002, a hospital may not be reclassified for purposes of the standardized amount if the area to which the hospital seeks reclassification does not have a higher standardized amount than the standardized amount the hospital currently receives. Standardized amount reclassifications are only effective for 1 year, so hospitals must reapply every year. At the time the FY 2005 reclassification applications were due, hospitals applied on the basis that the law still provided for a higher standardized amount for hospitals in large urban areas. However, section 401 of Pub. L. 108-173 established

that all hospitals will be paid on the basis of the large urban standardized amount beginning with FY 2004. Consequently, all hospitals will be paid on the basis of the same standardized amount, which effectively makes standardized amount reclassifications moot, at least for purposes of the standardized amount. As a result, the MGCRB denied all applications for standardized amount reclassifications for FY 2005. In light of the fact that all hospitals are now paid on the basis of the same standardized amount, in the proposed rule, we explained our proposed method for eliminating standardized amount reclassifications. Although there could still be some benefit in terms of payments for some hospitals under the DSH adjustment for operating IPPS, section 402 of Pub. L. 108-173 equalized DSH payments for rural and urban hospitals, with the exception that the rural DSH adjustment is capped at 12 percent (except that rural referral centers have no cap) (a detailed discussion appears in section IV.H. of this preamble).

No commenters objected to our proposal to eliminate standardized amount reclassifications.

b. Implementation of New MSAs

As discussed above, we are implementing the new CBSAs for FY 2005. Under these new CBSAs definitions, many existing MSAs are reconfigured. Therefore, because hospitals applied for reclassification during FY 2005 on the basis of the MSAs currently used to define labor market areas for FY 2004, the definition of the MSA to which they have been reclassified, or the area where they are located, may have changed under our implementation. Hospitals that were reclassified for FY 2005 were asked to verify that

the reclassified wage index for the labor market area into which they had been reclassified (in Table 4C in the Addendum to the May 18, 2004 proposed rule) exceeded the wage index of the labor market area where they are located (in Table 4A or 4B in the Addendum of the May 18, 2004 proposed rule) after our proposed implementation of the new MSAs. Hospitals could have withdrawn their FY 2005 reclassifications within 45 days of the publication of the proposed rule.

In some cases, the new CBSA definitions result in previously existing MSAs being divided into two or more separate MSAs. Given that the areas to which the hospitals reclassified no longer exist in FY 2005, we needed to propose rules we could use to determine such hospitals' reclassification areas. We proposed assigning the hospital to the nearest county in the current MSA, and the hospital's FY 2005 reclassification is to the new MSA (under the CBSA definitions) that includes that county to which it has been assigned.

For example, the Ann Arbor, MI MSA currently includes the counties of Lenawee, MI; Livingston, MI; and Washtenaw, MI. Under the new CBSA definitions, the Ann Arbor, MI MSA is comprised solely of the county of Washtenaw, MI. Lenawee, MI now comprises the Adrian, MI Micropolitan Area, and Livingston, MI is now in the Warren-Farmington Hills-Troy, MI Metropolitan Division of Detroit. Therefore, a hospital that was reclassified by the MGCRB into Ann Arbor for either FY 2003, FY 2004, or FY 2005, would be assigned to either the Ann Arbor, MI MSA or the Warren-Farmington Hills-Troy, MI Metropolitan Division, depending on whether the hospital was closer to Washtenaw or Livingston (A reclassified hospital located closest to

Lenawee County would be assigned to an MSA based on whether it is closer to Washtenaw or Livingston, which are still in MSAs. We would not consider Lenawee because it is now considered part of the statewide rural area).

Reclassified hospitals that have been assigned to a new MSA are identified in Table 9A in the Addendum of this final rule by the identification of the county used to designate them. We determined that the hospital is in closest proximity to the county listed based on mapping data available to us at the time of the preparation of this final rule. Hospitals that disagreed with our determination of the closest proximate county on which to assign them to a new MSA were given the opportunity to submit a comment indicating the basis for their disagreement.

Comment: Many hospitals approved for reclassification under the traditional reclassification process objected to our proposal to assign hospitals to the nearest county in the MSA to which it was reclassified. Several hospitals recommended allowing hospitals to amend their FY 2005 reclassification applications or implementing the policy adopted in 1994. Others recommended that CMS consider retracting the proposal, in its entirety and in doing so allow hospitals to be reclassified to the area approved by the MGCRB for the full 3 years. In the September 1, 1993 final rule (58 FR 46292). the adopted methodology for effectuating FY 1994 MGCRB decisions resulted in the assignment of hospitals to the revised labor market area that included "most or all of the counties that comprised the labor market area to which the hospital was reclassified by the MGCRB based on the current labor market area definitions." Others recommended

that CMS consider retracting the proposal in its entirety and in doing so allow hospitals to be reclassified to the area approved by the MGCRB for the full 3 years.

Finally, two sets of hospitals commented on special circumstances that would arise under the rule as proposed. One group of hospitals from Rhode Island commented that the nearest county proposal does not take into consideration instances where a hospital or group of hospitals reclassified to an area defined under the old MSA definitions is assigned to the nearest county which, under the new definitions, is in its own home MSA. In another situation, a group of hospitals in the Midwest described a situation where, under the new definitions, the MSA the hospitals reclassified to splits and the hospitals are assigned to the MSA that contains the nearest county from the old MSA. In some cases, a hospital may also satisfy the normal distance requirement for reclassification into one or more of the new MSAs that were once part of the old MSA. In these cases, the commenter believed that a hospital should be permitted to reclassify to any MSA that was once part of the old MSA for which it meets the normal proximity requirement.

Response: We acknowledge that the new MSA designations have considerable effect on hospital geographic reclassifications under both section 1886(d)(8)(B) and 1886(d)(10) of the Act. Because the MGCRB reclassifications approved for FY 2005, and prior years are based on the old MSA designations, it was necessary to reconcile (as we did with the FY 1994 reclassification decisions) the processes of implementing the new MSA designations with the MGCRB decisions for FY 2003, FY 2004, and FY 2005. As was the case with the implementation of new MSA definitions in FY 1994, we have

sought to implement the MGCRB decisions in the manner that is most consistent with implementing the new labor market areas. As we stated in the May 25, 1993 proposed rule (58 FR 30234), "…we believe that in reconciling the two processes, we must balance our obligation to implement the reclassifications prescribed by the MGCRB's decisions with our duty to implement the new labor market areas in as uniform a manner as possible. Thus, we believe that when a hospital is has been reclassified based on the old MSA definitions, payment to the hospital should be based on the new MSA definition most compatible with the reclassification decision." On the basis of our evaluations, we decided not to employ the FY 1994 reclassification assignment rule. This is because doing so would have led in many cases to anomalous results in the context of the current MSA changes. For example, we needed to take in account instances where MSAs split, creating smaller MSAs on the boundaries of what was the old MSA. If we were to apply the FY 1994 rule to the new MSA designations, many hospitals would have been reclassified into MSAs farther away than a new bordering MSA. We believe this would have been inconsistent with the proximity rules that govern reclassifications.

However, the commenters on the two situations described above persuade us that two refinements to the basic rule are appropriate.

- We will assign the hospital or group of hospitals previously reclassified in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act to an MSA that is splitting, to the MSA outside the hospital's own MSA that contains the nearest county from the old MSA. For example, under the new MSA designations, the Boston-Worcester-Lancaster-Lowell-Brockton, MA-NH NECMA was split into several new

MSAs. The reclassification of Rhode Island hospitals to the old Boston NECMA resulted, under our proposal, in an assignment to the Providence-New Bedford-River Falls, RI-MA MSA, their home MSA. This is because the nearest proximate county of the old Boston NECMA, Bristol County, is now part of the Providence-New Bedford-River Falls, RI-MA MSA. Under this revision, the Rhode Island hospitals approved for reclassification for FY 2005 will be assigned to the Boston-Cambridge-Quincy, MA-NH MSA, the nearest outside MSA that contains a county from the old Boston-Worcester-Lancaster-Lowell-Brockton, MA-NH NECMA.

- In cases where a hospital (or group of hospitals) was reclassified under section 1886(d)(8(B) or section 1886(d)(10) of the Act to an MSA that has been split, the hospital may be reclassified to any MSA containing counties from the old MSA reclassification provided that the hospital demonstrates that it meets the applicable proximity requirements in 42 CFR 412.230(b) and (c) (for individual hospitals), §412.232(a)(1) (for a rural group), and §412.234(a)(2) and (a)(3) (for an urban group) or in relation to the MSA.

We have changed the reclassification assignments for hospitals that brought this situation to our attention. Hospitals in this situation that wish to be reassigned to the nearest alternate county, for which they meet the applicable proximity criteria, may notify us in writing within 30 days of the date of publication of this final rule. The notification should contain:

- The hospital's name and street address.
- The hospital's provider number.

- The name, title, and telephone number of a contact person.
- The area (name and MSA number) identified in the FY 2005 reclassification application and the name and MSA number of the "assigned" area.
- Documentation certifying that they meet the requisite proximity requirement for assignment to the nearest alternate county.

We also note that the 1-year transition blend that we have adopted for FY 2005 will have the effect of giving hospitals that would experience a decrease in wage index due to the new MSA designations, 50 percent of the wage index determined using the old area definitions for MSAs to which the hospital reclassified, and 50 percent of the wage index determined using the new area definition for the MSA to which the hospital is assigned in this final rule. This provision will mitigate any negative effects of the new labor market areas on reclassifying hospitals and all other hospitals.

Comment: One commenter suggested that CMS provide that a hospital will not lose SCH status, or other special designations that are dependent upon being located in a rural area, by being redesignated into an MSA. The commenter further elaborated that the loss of SCH status can have profound implications for a hospital, including loss of special payment under the hospital inpatient and outpatient payment systems and loss of favorable treatment for purposes of geographic reclassification. The commenter recommended that CMS provide that hospitals with SCH status that are redesignated into an urban area will maintain SCH status. The commenter also recommended that, likewise, CMS provide that these hospitals will continue to be eligible for hold-harmless

payments under the outpatient PPS, even though these hospitals will no longer be physically located in an urban area.

Response: The regulations at §412.103(a)(3) provide for a hospital located in an urban area to be reclassified as a rural hospital if it would qualify as an SCH if it were located in a rural area, or if it meets any of the other conditions specified. Because any reclassification under this provision is effective as of the filing date of the application, existing SCHs that have been redesignated to urban areas and otherwise meet all of the requirements for SCH status could retain their SCH designation by filing an application for reclassification as rural with their CMS Regional Office before October 1, 2004.

In order to retain its SCH status when the area in which it is located is redesignated from rural to urban, a hospital must apply for reclassification as rural under the regulations at §412.103(a). Section 412.103(a) specifies that a prospective payment hospital that is located in an urban area may be reclassified as a rural hospital if it submits a complete application and meets any of the specified conditions, including §412.103(a)(3), which states, "The hospital would qualify as a rural referral center as set forth in §412.96, or as a sole community hospital as set forth in §412.92, if the hospital were located in a rural area." A hospital seeking reclassification under this section must submit a complete application in writing to its CMS Regional Office. Because any reclassification under this provision is effective as of the filing date of the application, existing SCHs that have been redesignated to urban areas effective October 1, 2004, and otherwise meet all of the requirements for SCH status, could retain their SCH

designation, without a break in status, by filing an application for reclassification as rural with their CMS Regional Office before October 1, 2004.

We note that a hospital located in an urban area and more than 35 miles from other like hospitals would qualify as an SCH under §412.92(a). In order to retain its SCH status by qualifying as an urban SCH under this provision, a hospital must submit an application to its fiscal intermediary, in accordance with the classification procedure at §412.92(b). According to that procedure, the fiscal intermediary would the review the request and send the request, with its recommendation, to the CMS Regional Office responsible for the hospital. The CMS Regional Office would review the request and the fiscal intermediary's recommendation and notify the fiscal intermediary of its approval or disapproval. SCH status is effective 30 days after the date of CMS' written notification to the fiscal intermediary. Therefore, written notification dated by September 1, 2004, would be effective by October 1, 2004.

We note that comments regarding the hospital outpatient PPS will need to be addressed as part of the outpatient prospective payment system rule that is under development.

Comment: One commenter requested CMS to clarify that rural RRCs will not lose that status when they become urban.

Response: Section 4202(b) of Pub. L. 105-33 states, in part, "Any hospital classified as a rural referral center by the Secretary * * * for fiscal year 1991 shall be classified as such a rural referral center for fiscal year 1998 and each subsequent year." In the August 29, 1997 final rule with comment period, we reinstated RRC status for all

hospitals that lost the status due to triennial review or MGCRB reclassification, but not to hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban (62 FR 45999).

However, subsequently, in the August 1, 2000 final rule, we indicated we were revisiting that decision (65 FR 47089). Specifically, we stated we would permit hospitals that previously qualified as an RRC and that lost their status due to OMB redesignation of the county in which they are located from rural to urban to be reinstated as an RRC. This policy extends to RRCs located in counties that become urban as a result of the new MSAs implemented in this final rule.

Comment: One commenter suggested that CMS utilize its broad discretion under the Act to designate urban hospitals as RRCs for purposes of geographic reclassification if such hospitals reflect the same characteristics of those facilities currently designated urban RRCs. The commenter stated that, otherwise, CMS will fail in its desire to treat all RRCs equally and will continue to significantly disadvantage other urban hospitals that play the same critical role in treating Medicare rural beneficiary populations. The commenter suggested designating any hospital meeting the criterion of §412.103(a)(3) as it relates to RRCs as an urban RRC for geographic reclassification purposes.

Response: While CMS has broad discretion regarding establishing criteria for geographic reclassification purposes under section 1886(d)(10) of the Act, we are limited in designating a hospital as an RRC. Section 1886 (d)(5)(C)(I) of the Act limits the Secretary to giving RRC status to a hospital that is classified as a rural hospital (with certain exceptions for previously designated RRCs, as noted above). In other words,

CMS is, in fact, limited from granting first-time RRC status to a hospital that is not classified as a rural hospital.

Comment: Another commenter stated that some hospitals, due to geography and market size, are located in an urban area but serve a high number of rural patients. The commenter further stated that CMS noted RRCs play a significant role in treating Medicare beneficiaries from rural areas, whether or not a particular hospital is physically located in a rural or urban area. The commenter asked that CMS review the RRC criteria and revise it so that urban hospitals can qualify for RRC status and be on the same level as their urban RRC counterparts.

Response: There is already a regulatory provision for these urban hospitals that are like RRCs to obtain that status by first being reclassified as rural. Section 412.103(a)(3) provides for hospitals that would otherwise qualify as an RRC if they were rural to be reclassified as rural.

c. Redesignations under Section 1886(d)(8)(B) of the Act

Beginning October 1, 1988, section 1886(d)(8)(B) of the Act required us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area under the standards published in the **Federal Register** on January 3, 1980 (45 FR 956) for designating MSAs (and for designating NECMAs), and if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the

standards, from) the central county or counties of all contiguous MSAs (or NECMAs). Hospitals that met the criteria using the January 3, 1980 version of these OMB standards were deemed urban for purposes of the standardized amounts and for purposes of assigning the wage data index.

Section 402 of Pub. L. 106-113 provides that, with respect to FYs 2001 and 2002, a hospital may elect to have the 1990 standards applied to it for purposes of section 1886(d)(8)(B) of the Act and that, beginning with FY 2003, hospitals will be required to use the standards published in the **Federal Register** by the Director of OMB based on the most recent decennial census. We implemented section 402 in the August 1, 2001 **Federal Register** (66 FR 39868). However, at that time, updated standards based on the Census 2000 data were not available.

For FY 2005, we are using OMB's 2000 CBSA standards and the Census 2000 data to identify counties qualifying under section 1886(d)(8)(B) of the Act for FY 2005. The number of qualifying counties, shown in the following chart, increases from 28 to 98. As we proposed, we are providing that, effective for discharges on or after October 1, 2004, hospitals located in the rural counties listed in the first column of the following table will be redesignated for purposes of assigning the wage index to the urban area listed in the second column.

Chart 6.--Counties Redesignated as Urban under Section 1886(d)(8)(B) of the Act (Based on CBSAs and Census 2000 Data)

Rural County	MSA
Cherokee, AL	Rome, GA
Macon, AL	Auburn, AL

Rural County	MSA
Talladega, AL	Anniston, AL
Hot Spring, AR	Hot Spring, AR
Litchfield, CT	Hartford, CT
Windham, CT	Hartford, CT
Bradford, FL	Gainsville, GA
Flagler, FL	Deltona-Daytona Beach-Ormond Beach, FL
Hendry, FL	Miami, FL
Levy, FL	Gainsville, FL
Walton, FL	Ft. Walton, Beach, FL
Banks, GA	Gainsville, FL
Chattooga, GA	Chattanooga, TN-GA
Jackson, GA	Atlanta, GA
Lumpkin, GA	Atlanta, GA
Morgan, GA	Atlanta, GA
Peach, GA	Macon, GA
Polk, GA	Atlanta, GA
Talbot, GA	Columbus, GA-AL
Bingham, ID	Idaho Falls, ID
Christian, IL	Springfield, IL
DeWitt, IL	Bloomington-Normal, IL
Iroquois, IL	Kankakee, IL
Logan, IL	Springfield, IL
Mason, IL	Peoria, IL
Ogle, IL	Rockford, IL
Clinton, IN	Lafayette, IN
Henry, IN	Indianapolis, IN
Spencer, IN	Evansville, IN-KY
Starke, IN	Chicago, IL-IN
Warren, IN	Lafayette, IN
Boone, IA	Ames, IA
Buchanan, IA	Waterloo, IA
Cedar, IA	Iowa City, IA
Allen, KY	Bowling Green, KY
Assumption Parish, LA	Baton Rouge, LA
St. James Parish, LA	Baton Rouge, LA
Allegan, MI	Holland, MI
Montcalm, MI	Grand Rapids, MI
Oceana, MI	Muskegon, MI
Shiawassee, MI	Lansing, MI
Tuscola, MI	Saginaw, MI
Fillmore, MN	Rochester, MN

Rural County	MSA
Dade, MO	Springfield, MO
Pearl River, MS	Biloxi-Gulfport, MS
Caswell, NC	Burlington, NC
Granville, NC	Durham, NC
Harnett, NC	Raleigh, NC
Lincoln, NC	Charlotte NC-SC
Polk, NC	Spartanburg, NC
Los Alamos, NM	Sante Fe, NM
Lyon, NV	Carson City, NV
Cayuga, NY	Syracuse, NY
Columbia, NY	Albany, NY
Genesee, NY	Rochester, NY
Greene, NY	Albany, NY
Schuyler, NY	Ithaca, NY
Sullivan, NY	Poughkeepsie-Newburgh, NY
Wyoming, NY	Buffalo, NY
Ashtabula, OH	Cleveland, OH
Champaign, OH	Springfield, OH
Columbiana, OH	Youngstown, OH-PA
Cotton, OK	Lawton, OK
Linn, OR	Corvalis, OR
Adams, PA	York, PA
Clinton, PA	Williamsport, PA
Greene, PA	Pittsburgh, PA
Monroe, PA	New York-Newark, NY-NJ-CT
Schuylkill, PA	Reading, PA
Susquehanna, PA	Binghamton, NY-PA
Clarendon, SC	Sumter, SC
Lee, SC	Sumter, SC
Oconee, SC	Greenville, SC
Union, SC	Spartanburg, SC
Meigs, TN	Cleveland, TN
Bosque, TX	Waco, TX
Falls, TX	Waco, TX
Fannin, TX	Dallas-Fort Worth-Arlington, TX
Grimes, TX	College Station-Bryan, TX
Harrison, TX	Longview, TX
Henderson, TX	Dallas-Fort Worth-Arlington, TX
Milam, TX	Austin, TX
Van Zandt, TX	Dallas-Fort Worth-Arlington, TX
Willacy, TX	Brownsville, TX

Rural County	MSA
Buckingham, VA	Charlottesville, VA
Floyd, VA	Blacksburg, VA
Middlesex, VA	Virginia Beach, VA
Page, VA	Harrisonburg, VA
Shenandoah, VA	Winchester, VA
Island, WA	Seattle, WA
Mason, WA	Olympia-Lacey, WA
Wahkiakum, WA	Longview, WA-OR
Jackson, WV	Charleston, WV
Roane, WV	Charleston, WV
Green, WI	Madison, WI
Green Lake, WI	Fond du Lac, WI
Jefferson, WI	Milwaukee, WI
Walworth, WI	Chicago, IL-IN

As in the past, hospitals redesignated under section 1886(d)(8)(B) of the Act are also eligible to be reclassified to a different area by the MGCRB. Affected hospitals were requested to compare the reclassified wage index for the labor market area in Table 4C in the Addendum of the proposed rule into which they have been reclassified by the MGCRB to the wage index for the area to which they are redesignated under section 1886(d)(8)(B) of the Act. Hospitals were given the opportunity to withdraw from an MGCRB reclassification within 45 days of the publication of the proposed rule.

When we apply the OMB 2000 CBSA standards, 16 rural counties no longer meet the qualifying criteria to be redesignated, either because they are now included in a metropolitan area (with the exception of Barry, MI and Cass, MI, most of the counties are now in the metropolitan area in which they were grouped in accordance with section 402) or they fail to meet the 25-percent cumulative out-migration threshold when we apply the new OMB standards. Counties that are now identified as metropolitan are:

Chilton, AL

Macoupin, IL

Piatt, IL

Brown, IN

Carroll, IN

Jefferson, KS

Barry, MI

Cass, MI

Ionia, MI

Greene, NC

Preble, OH

Counties that failed to meet the 25-percent threshold are: Marshall, AL; Putnam, FL; Wilson, NC; Van Wert, OH; and Lawrence, PA.

Comment: Several commenters expressed concern with our proposed adoption of the OMB area designations and the impact on county designations governed by section 1886(d)(8)(B). Specifically, these commenters objected to the proposed adoption because use of the 2000 Census data to develop the revised designations resulted in five counties no longer meeting the qualifying criteria for section 1886(d)(8)(B) county designation. The commenters argue that because they were not given adequate notice that these counties were in danger of losing their section 1886(d)(8)(B) county designation, the abrupt decrease will have a significant impact on operations. The commenters are requesting that CMS extend the three-year hold harmless transition to hospitals located in those counties losing their section 1886(d)(8)(B) county designation.

Response: In the proposed rule, to help alleviate dramatic negative impacts in payment for hospitals designated as urban under the old MSA standards, but slated to be classified as rural, we proposed to implement a 3-year hold harmless transition period that would allow these hospitals to maintain their assignment to the MSA where they are currently located for FY 2005, FY 2006, and FY 2007. Specifically, we will assign these hospitals, as we did in the proposed rule, the prereclassified wage index of the urban area to which they currently belong. (For purposes of wage index computation, the wage data of these hospitals will remain assigned to the statewide rural area in which they are located.) We are finalizing this policy in the final rule. We did not propose that the transition period apply to hospitals located in those counties losing their designation under section 1886(d)(8)(B). Consistent with our longstanding policy that counties redesignated under section 1886(d)(8)(B) of the Act, are considered urban for purposes of the standardized amount, we are extending the 3-year transition to the hospitals located in counties formerly designated as urban under 1886(d)(8)(B), because the hospitals are, in fact, losing their designated urban status. We are using the wage data from these hospitals as part of setting the rural wage index. The higher wage indexes these hospitals are receiving are being taken into consideration in determining whether they qualify for the out-commuting adjustment and the amount of any adjustment. During this 3-year transition period, these hospitals are eligible to apply for reclassification by the MGCRB. In FY 2008, these hospitals will receive their statewide rural wage index. Thus, the hospital would not be eligible, for example, for a large urban add-on under capital PPS.

Thus, it is the wage index, but not the urban or rural status of the hospitals, that is being affected by this transition.

Comment: Commenters indicated that CMS utilized an older 2000 Census Crosswalk that has since been updated in December of 2003. Commenters wanted to know whether or not CMS intends to use this updated crosswalk for the final regulation.

Response: Our initial investigation and analysis of the impact of the new metropolitan areas began in the early fall of 2003. In the process of this analysis, the update of the crosswalk was overlooked and was not incorporated into the proposed rule. We have updated the crosswalk for this final regulation and, therefore, the updates are incorporated in the calculations and the subsequent output in the tables.

Comment: Commenters noted that CMS improperly classified Merrimack, NH and Litchfield, CT. These counties are "deemed urban" and, therefore, must be included in an urban area.

Response: We recognize this oversight. Based on the strongest commuting ties, we have incorporated Merrimack, NH into the Manchester-Nashua, MA MSA (31700), and Litchfield, CT has been placed into the Hartford-West Hartford-East Hartford, CT MSA (25540).

Comment: Commenters expressed opposition to and support of the decision to not adopt micropolitan areas. They indicated that the financial and reimbursement impact of using these areas is unknown at this time, and it appears that further consideration of the effects of these changes by CMS is necessary. Some commenters

argued that those micropolitan areas that were previously included in a metropolitan are now unjustly dubbed ‘rural.’

Response: We have provided hospitals in urban counties now designated as micropolitan and therefore rural as ‘hold harmless,’ assigning them the urban wage index for the MSA from which they came. We will continue to review the role of micropolitan areas in the development of labor market areas for the purposes of the wage index.

d. Reclassifications Under Section 508 of Pub. L. 108-173

Under section 508 of Pub. L. 108-173, a qualifying hospital may appeal the wage index classification otherwise applicable to the hospital and apply for reclassification to another area of the State in which the hospital is located (or, at the discretion of the Secretary, to an area within a contiguous State). Hospitals were required to submit their applications by February 15, 2004. We implemented this process through notices published in the **Federal Register** on January 6, 2004 (69 FR 661) and February 13, 2004 (69 FR 7340). Such reclassifications are applicable to discharges occurring during the 3-year period beginning April 1, 2004 and ending March 31, 2007. Under section 508(b), reclassifications under this process do not affect the wage index computation for any area or for any other hospital and cannot be effected in a budget neutral manner.

The applications submitted under this process were reviewed and decided upon by the MGCRB. The MGCRB issued notifications of its decisions on April 16, 2004. Reclassifications under this one-time appeal process interact with: FY 2005 MGCRB reclassification decisions under the ongoing reclassification process described in the

regulations at §§412.230 through 412.280; the implementation of the new MSA definitions; and the new redesignations under section 1886(d)(8)(B) of the Act.

In the notices implementing this process, we indicated that, with limited exceptions, hospitals eligible for reclassification under section 508 of Pub. L. 108-173 are not otherwise reclassified, effective for discharges on or after October 1, 2004. Therefore, aside from the exceptions specified in the notices, hospitals reclassified under this one-time appeal process were not otherwise reclassified by the MGCRB for FY 2005. For the hospitals exempted from the "not otherwise classified" requirement and that received a section 508 reclassification under the one-time appeal process, the section 508 takes precedence over any other MGCRB reclassification. We show the reclassifications effective under the one-time appeal process in Table 9B, in the Addendum to this final rule.

Comment: One hospital commented that the proposed adoption of the new MSA designations will result in the hospital being located in a county that has been incorporated, under the new designations, into the MSA to which they were approved for reclassification. Because they will now be located in the area to which they were granted reclassification, the hospital argued that its FY 2005 reclassification is, in effect, moot.

Response: We acknowledge that there are situations where hospitals that have been reclassified by the MGCRB are located in counties that have been incorporated, under the new designations, into the area to which the hospitals were approved for reclassification. As a result, hospitals in this situation are already located in the area to which they requested to be reclassified. In this case, under the new designations, these

hospitals will be paid by virtue of this change based on the payment rates applicable to the requested area and their wage data will be reflected in the wage index for that area. Although we have acknowledged above that hospitals reclassified to MSAs that split need not be reclassified back into their home area, that rule would not apply in the situation raised by the commenter. In the commenter's case, the area to which it reclassified has now been expanded to absorb the hospital's home county. Thus, we need not identify an area that can serve as a substitute for the reclassification area. Rather, there is no need for the hospital to reclassify when it now is originally classified into its desired area.

Comment: Several hospitals approved for reclassification under section 508 objected to our proposal regarding the treatment of hospitals that were reclassified under section 508 to areas that have since divided because of implementation of the new labor market definitions. As we discuss in further detail in section III.H.3.b. above, in some cases, the new CBSA definitions result in previously existing MSAs being divided into two or more separate MSAs. Given that the areas to which the hospitals reclassified no longer exist in FY 2005, we proposed assigning the hospital to the nearest county in the current MSA, and the hospital's FY 2005 reclassification is to the new MSA (under the CBSA definitions) that includes that county to which it has been assigned. The hospitals argue that consistent with section 508, when a previous labor market area has split into several different areas, they should be permitted to select the area to which to reclassify.

Response: We appreciate the commenters' suggestions and their interest in this matter. Based on those comments, and on a careful review of the provisions of section

508, we have decided to change our proposed policy in the limited case of hospitals that reclassified in accordance with section 508 to areas that, because of the new labor market definitions, have now been divided into several areas. Because section 508(a)(1) of Pub. L. 108-173 allows a hospital to appeal its wage area classification to the Board and "select another area within the state (or, at the discretion of the Secretary, to a contiguous State) to which to be reclassified," we believe, in these limited circumstances, a hospital should be permitted to select the area into which it should be reclassified. Specifically, a hospital reclassified under the section 508 process to an MSA that, under the new labor market definitions, divided into several areas, will be given the opportunity to select which of those areas it wishes to reclassify to. We believe this is in keeping with the statutory intent of section 508. To effect the selection, we will automatically assign these hospitals to the divisor MSA with the highest wage index. Hospitals reclassified under the one-time appeals process that have been assigned to a new MSA are identified in Table 9B, column 7, in the Addendum of this final rule. If these hospitals disagree with our selection, they must submit to us, in writing, a request to select a different divisor area. Requests must be received by us within 30 days of publication of this final rule. Requests should be sent to the following address:

Centers for Medicare and Medicaid Services,

Center for Medicare Management,

Hospital and Ambulatory Policy Group,

Division of Acute Care,

Mailstop C4-08-06,

7500 Security Boulevard,

Baltimore, Maryland 21244-1850.

Attn: Section 508 Appeals

In the proposed rule, we also stated that hospitals reclassified under the section 508 one-time appeal process that are also in counties identified under the redesignation process in accordance with section 1886(d)(8(B) of the Act were asked to compare the wage index applicable to the area to which they were reclassified under section 508 with the wage index applicable to the area to which they were redesignated under section 1886(d)(8(B) of the Act, if those area are different. Again, affected hospitals were allowed to withdraw their one-time appeal process reclassifications within 45 days of the publication of the proposed rule.

Comment: A hospital association expressed concern that, due to our proposal to implement the new CBSAs, hospitals granted a reclassification under section 508 of Pub. L. 108-173 or the traditional MCGRB reclassification process may realize little or no benefit from the reclassification. The association stated that the requirement that a hospital base its decision to withdraw an existing reclassification is "unnecessary" and "unfair" because it requires the hospital to "give up" the reclassification when there exists the possibility that changes effected in the final rule could result in the reclassification being beneficial. The association believed that, for hospitals reclassified under section 508 or the traditional MGCRB process, we should automatically apply the higher wage index for each hospital, with no action required by the hospital. Many other

commenters recommended that CMS allow reclassifying hospitals 30 days after publication of the final rule to withdraw their reclassification requests.

Response: In the August 1, 2001 final rule, we included a detailed discussion of the withdrawal, termination, and cancellation procedures for reclassified hospitals (66 FR 39887). In that rule, we stated that a hospital may cancel a previous withdrawal or termination of a 3-year wage index reclassification by submitting written notice of intent to the MGCRB no later than the deadline for submitting reclassification applications effective at the start of the following fiscal year. This provision allows the hospital to reinstate the original reclassification for the wage index. As we stated in the August 1, 2001 final rule, we provided this option so that " a hospital that later discovers that the withdrawal of its approved wage index reclassification was disadvantageous would have the ability to reinstate its MGCRB approval for the wage index for the remaining years in the 3-year term." Even in light if the existing provision, we are persuaded by the comments received in response to the proposed rule, in this limited circumstance, to allow hospitals a 30-day period where they can make final, informed determinations regarding whether to maintain or withdraw their existing reclassification on the basis of the information published in the final rule. This 30-day period is also applicable to those hospitals that adhered to the established process and notified the MGCRB of their decision to withdraw or terminate their section 1886(d)(10) or section 508 reclassification. Hospitals will have 30 days after the publication date of this rule to submit, in writing, to the MGCRB a request to withdraw their reclassification request or to rescind their previous withdrawal or termination request.

e. Wage Index Adjustment Based on Commuting Patterns of Hospital Employees (Section 505 of Pub. L. 108-173)

Section 505 of Pub. L. 108-173 established new section 1886(d)(13) of the Act. The new section 1886(d)(13) requires that the Secretary establish a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees. The process provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county with a higher wage index. Such adjustments to the wage index are effective for 3 years beginning with discharges occurring on or after October 1, 2004. Adjustments under this provision are not subject to the inpatient PPS budget neutrality requirements at section 1886(d)(3)(E) or section 1886(d)(8)(D) of the Act.

The Secretary is required to establish criteria to identify "qualifying counties," and hospitals located in such qualifying counties are to receive an adjustment to their wage index. Section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county's wage index and the weighted average of the wage indexes of the surrounding higher wage index area(s) to which hospital employees commute that must be met in order for the county to qualify. Section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is also to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent. Section 1886(d)(13)(iii) of the Act requires that the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all

hospitals in the labor market area. Section 1886(d)(13)(E) of the Act indicates this process may be based on the process used by the MGCRB. This section also gives the Secretary the authority to require hospitals to submit data necessary to implement this provision, or to use other data sources as available.

Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the differences between the wage indexes of the MSA(s) with higher wage indexes and the wage index of the resident county, weighted by the overall percentage of hospital workers residing in the qualifying county who are employed in any MSA with a higher wage index. We have employed the prereclassified wage indexes in making these calculations. We also are not taking into account any of the transition payments that are being used to account for the change in labor market definitions announced by CMS. We believe it is reasonable to interpret the term "wage index" in section 1886(d)(13)(D) to mean the prereclassified, preadjusted wage index. In response to comment, we discuss below our reasons for using the prereclassified wage indexes in both identifying higher wage index areas and in calculating the out-migration adjustment. We believe that it is also reasonable to interpret "wage index" under section 1886(d)(13) as applying solely to the wage index that exists using the most recent CMS definitions for labor market areas. Section 505 is a new provision, first being implemented for FY 2005, and we do not believe it is necessary to incorporate transitional wage index payments, when there is no transition necessary. Hospitals were fully able to assess the

implications of the new labor market areas on implementation of section 505 through review of the proposed rule. Thus, the higher wage index areas will be identified, and the out-migration adjustment will be calculated without taking into account the effect on wage index caused by either of our transitional rules. We include a detailed discussion of these transitional rules in section III.B.3. of this preamble. The wage index increase is effective for 3 years, unless a hospital requests to waive the application of the payment adjustment. Hospitals that receive this payment adjustment are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

(1) Data

To implement this provision, we analyzed commuting data compiled by the U.S. Census Bureau. The data derive from a special tabulation of Census 2000 journey-to-work data, compiled from responses to the long-form (sample) census survey questions on where people worked. When the Census conducts its decennial survey, each household receives either a short form or a long form. On average, about 1 in every 6 households receive the long form. The results from the long form are used to formulate descriptive population estimates. Thus, the data set is based on the Census 2000 sample and represents estimates of the actual figures that would be obtained from a complete count.

The data provide information about commuting patterns of workers at the county level for residents of the 50 States and the District of Columbia. Each record within the dataset represents a combination of a particular resident county, a workplace county, and

a particular industry category. Thus, the record shows the county-of-residence by county-of-work commuter flows. The resident county represents the county where the worker resides, while the workplace county represents the county where the worker works. The industry category associated with workers is based on the 108 Industrial Structure codes developed by the Bureau of Economic Analysis. These Industrial Structure codes break down economic activities by defining industries (such as "fabricated metal product manufacturing," "legal services," and "gasoline stations"). We limited the data set to those employees working in the category designated "hospitals" (BEA code 622000).

Using these data, we are able to identify the total number of hospital workers who live in each county and the number of workers within that county who commute to hospitals in other counties. For example, the data can be used to determine that, from a sample of 100 hospital employees who live in County A, 50 commute to work at hospitals within County A, 20 commute to work at hospitals within County B, and 30 commute to work at hospitals within County C.

There are some intrinsic limitations to the data. The file shows the weighted worker estimate for flows using a threshold or minimum size of 50 unweighted worker (from all industry codes) records. This means that only county-to-county flows that are comprised of at least 50 unweighted worker records are shown in this file. The Census Bureau omitted all other county-to-county flows from the file for confidentiality reasons. While this could eliminate the workflows of some hospital residents, we believe the eliminations would not have a major impact on the policy.

When Census calculated this special tabulation, the estimates of workers numbering from 1 through 7 have been rounded to 4. Values of 8 or greater have been rounded to the nearest multiple of 5, unless the estimate already ended in 5 or 0, in which case it was not changed. In addition, in this special tabulation, workers are defined as people 16 years and older who were employed and at work during the Census long form reference week. This is the week prior to when the questionnaire was filled out, which was the last week of March 2000 for most people.

In addition, because these data derive from the decennial census, the data file will not change until the census is taken again in 2010. This does not mean that the list of qualifying counties will not change from year to year. The out-migration percentage for each county is a function both of the commuting data and changes in the wage index values. Because the wage indexes associated with each work and resident county change each year, a county's out-migration percentages can still vary each year because a higher wage index area in one year, might not be a higher wage index area in the next year. For example, if 100 hospital employees living in County A (wage index 1.00 in FY 2004) commute to County B (wage index 1.10 in FY 2004), then County B would be a higher wage index area for 2004. If in FY 2005, County A's wage index increases to 1.02 and County B's wage index decreases to 1.01, those 100 workers commuting from County A to County B will not be commuting to a higher wage index area for 2005. Consequentially, County A's out-migration percentage would decrease from 100 percent in 2004 to 0 percent in 2005. These normal changes in wage index values could also

result in a county not deemed a qualifying county for FY 2005, becoming a qualifying county in FY 2006 or later.

We believe these data provide a useable data source to implement this provision. However, in the May 18, 2004 proposed rule, we solicited comments on the availability and value of alternative data sources. Although the statute authorizes the Secretary to require all hospitals to submit data on the commuting patterns of their employees, such a requirement would be a major undertaking for the hospital industry and CMS. It was not possible to pursue this approach in time to implement the provision by FY 2005. However, in addition to soliciting comments on the merits of relying on the Census data, we welcomed comments on the feasibility of surveying hospitals on the residence and commuting patterns of all their hospital employees for purposes of developing future year adjustments.

Comment: One commenter questioned whether it would be possible in future years to update commuting data using data from U.S. Census Bureau's American Community Survey (ACS) rather than using data from the 2000 census.

Response: The ACS is part of the U.S. Census Bureau's effort to streamline and improve the census, and is intended to replace the long form and provide some demographic information every year instead of once every 10 years. Starting in July 2004, 1 in every 480 households throughout America will receive and be asked to participate in the survey each month. Since this is a new initiative, we are unable to determine the whether the data that will be collected is appropriate for use in calculating the out-migration adjustment. However, as the U.S. Census Bureau moves forward with

this initiative, we will continue to monitor the initiative's progress and evaluate the feasibility of using data from the ACS to calculate the out-migration adjustment.

Comment: Several comments stated that the commuting data does not reflect the "new potential for increased commuting," in a specific instance where a county used to be part of an MSA, but no longer is due to the new MSA definitions. The commenters stated that the reduced reimbursement resulting from the new MSA definitions will create the potential for increased commuting in future years, even though the county qualified for an out-migration adjustment. The commenters recommended we "adjust the commuting index to a more appropriate value based on opportunity and not based solely on historical data."

Response: The commenters did not provide suggestions on how we would consistently measure the "opportunity" for increased commuting. Therefore, we are unable to address the commenters' concerns at this time. As we stated in the proposed rule, we will use the decennial census in order to determine commuting rates. We note that as part of its new definitions of statistical areas, OMB takes into account the level of commuting. Thus, the new areas should reflect any increased commuting that has already occurred from one county to another.

Comment: One commenter stated that it is unclear as to how we will measure commuting patterns and determine the applicability of the wage index adjustment. The commenter requested that we describe the proposed data resources and methodology that will be used for applying the wage index adjustment.

Response: We note that in the May18, 2004 proposed rule and in this final rule, we discussed the data set used for measuring out-migration patterns and the process for determining the out-migration adjustments. (See sections III.H.3.e.(1) and 3.e.(3) of this preamble, respectively.)

Comment: A commenter asked if the data used by CMS to compute the out-migration adjustment will be made available via a public use file.

Response: We plan to make the data used for determining the qualifying counties and the out-migration adjustment available after the publication of this final rule on the CMS website at www.cms.gov.

Comment: One commenter requested that CMS allow hospitals to submit their own commuting data to apply for the out-migration adjustment.

Response: Because the adjustment is based on the number of hospital workers in a county who commute to other higher wage index areas, we believe it would be extremely problematic for individual hospitals to track and submit the data necessary for the out-migration adjustment. The hospital could not simply survey their own employees to obtain this necessary data, but would have to survey all hospital workers who live in the county where the hospital is located and commute to hospitals in other higher wage index areas.

In addition, we did not receive any specific comments on the availability of an alternative data source or on the feasibility of surveying hospitals on the residence and commuting patterns of their employees for purposes of developing future year adjustments. We also received comments supportive of our general implementation

process and its administrative simplicity. The commenters noted the merits of using this data set and not placing an additional burden on hospitals through a survey of employees. Therefore, we will use our proposed data set for purposes of computing the qualifying counties and the out-migration adjustment. However, we will continue to explore the possibility that hospitals could submit their own data in future refinements of our policy.

(2) Qualifying Counties

As noted previously, section 1886(d)(13)(B)(iii) of the Act requires that, to qualify for this commuting wage index adjustment, the average hourly wage for all hospitals in the county must be equal to or exceed the average hourly wage for all hospitals in the labor market area in which the county is located. To determine which counties meet this requirement, we calculated the average of hospitals' 3-year average hourly wages for all hospitals in a given county. We compared this county average 3-year average hourly wage to the 3-year average hourly wage for the labor market area where the county is located. We chose to use the 3-year average hourly wage because we believe it provides a more accurate and stable estimate for the wages paid by a given hospital over a period of time. This statutory requirement limits the number of eligible counties, as counties with an average 3-year average hourly wage less than the 3-year average hourly wage of the MSA where the county is located were not considered to meet this requirement.

Some resident counties do not have average hourly wages because either there is no hospital located in the county, or the only hospital in the county is new and has not yet submitted wage data. We did not consider these counties to have met the average hourly

wage criteria and thus hospitals in these counties are not yet eligible to receive an increase in wage index. This is consistent with our regulations at §412.230(e)(2)(iii), which require a new hospital to accumulate at least 1 year of wage data, before it is eligible to apply for reclassification.

As noted previously, section 1886(d)(13)(B)(ii) of the Act specifies that the Secretary is to establish the minimum out-migration threshold in order to qualify, which may not be less than 10 percent. To determine the out-migration percentage for each county, we identified higher wage index areas, by comparing 2005 prereclassified wage index of a resident county with the 2005 prereclassified wage index of the MSA or rural statewide area where the work county is located. We use the prereclassified wage index so that hospitals in the county are not disadvantaged by reclassification of other hospitals into the county.

Comment: One commenter recommended that the wage index amounts utilized in the calculation for the higher wage county be based on the wage index utilized for Medicare payment including those increases in wage index due to a group reclassification appeal. The commenter stated that not utilizing this higher wage index amount would put the hospitals addressed by the commuting adjustment provision at a serious disadvantage.

Response: We considered using the post-reclassified wage index as the basis for computing the higher wage index counties. In situations like the group reclassification where all hospitals in a given county are receiving the same wage index, it could be possible to use the post-reclassified wage index for determining higher wage index counties and for calculating the out-migration adjustment. However, it is not as

straightforward for counties where not all hospitals are receiving the same wage index due to individual hospital reclassifications. For example, in one county there may be two hospitals that receive different wage indexes because one hospital has been reclassified. Given the differing wage indexes in this situation, it is unclear which wage index would be most appropriate to use as the basis for comparison for this county or if some form of a blended wage index should be calculated. This issue is further complicated by the use of a blended wage index this year to mitigate the effects of the new MSA definitions. Due to these complicating factors, and the fact that the prereclassified wage index most accurately reflects the wages being paid to hospital employees in a given geographic area, we believe that the most equitable method is to use the prereclassified wage index when calculating the qualifying counties and the out-migration adjustment. However, we will continue to examine the possibility of employing post-reclassification wage indexes as we refine our policy for future adjustments.

Comment: One commenter asked how the out-migration adjustment will be made in subsequent years, specifically if CMS increases the wage index of qualifying counties by the out-migration adjustment when calculating higher wage index counties in subsequent years. The commenter identified a potential ripple effect if the data we use in year two incorporates the new higher wage index value (resulting from the additional out-migration adjustment) when identifying the county-to-county flows where hospital employees were commuting to a higher wage index area.

Response: We appreciate the opportunity to clarify this important point. We recognize that if we used the new wage index (wage index plus commuting adjustment)

when computing the higher wage index counties, the effect of the out-migration adjustment could ripple out each year to more counties. Consequently, in future years, we plan to identify the higher wage index counties and compute the adjustment using the prereclassified wage index without the additional out-migration adjustment. We believe that this will more appropriately reflect the intent of the statute without creating unanticipated effects.

Once we limited the dataset to those county-to-county flows where hospital employees were commuting to a higher wage index area, we calculated the out-migration percentage for resident counties. To calculate the out-migration percentage, we calculated the total number of hospital employees in a resident county who were commuting to a higher wage area as a percentage of the total number of hospital employees residing in the resident county. For example, there are 100 hospital employees who live in County A (wage index 1.0). Of those 100 employees, 50 commute to County B (wage index 1.10), 20 commute to County C (wage index 1.05), and 30 work within County A. Because 70 out of 100 people commute to higher wage areas, County A's out-migration percentage is equal to 70 percent.

To implement section 1886(d)(13)(B)(ii) of the Act, in the May 18, 2004 proposed rule (69 FR 28267), we proposed that the out-migration threshold to qualify for this adjustment would be the statutory minimum of 10 percent. We believe that this threshold provides an opportunity for a reasonable number of hospitals that would not have recourse to the normal reclassification process to receive an appropriate adjustment to their wage index. We welcomed public comment on this proposed threshold.

Comment: Many commenters supported our decision to set the out-migration threshold at the statutory minimum of 10 percent.

Response: We note that we did not receive any comments recommending that we increase the threshold and we do not plan to change the threshold in this final rule. Therefore, we are finalizing the out-migration threshold at the statutory minimum of 10 percent.

As noted previously, section 1886(d)(13)(B)(i) of the Act directs the Secretary to establish a threshold percentage difference between the county's wage index and the weighted average wage indexes of the higher wage index areas to which hospital employees commute. However, unlike the threshold for the level of out-migration, the statute does not designate a minimum level for this threshold. Because of the nature of the adjustment provided under this provision, in the May 18, 2004 proposed rule (69 FR 28268), we proposed to establish that the minimum difference in the wage indexes between the resident county and the work county can be any percentage greater than zero. We proposed this threshold because the wage index increment for hospitals in qualifying counties under the statutory formula is a function of the differences between that county's wage index and the wage indexes of the areas into which resident hospital workers of that county are commuting. In those cases where that difference is very small, the adjustment to the wage index will also be very small. (See the discussion of the statutory formula in section III.H.3.e.(3) of this preamble.) Therefore, we believe that a threshold of anything greater than zero is justifiable and consistent with the purposes of this provision.

Comment: Many commenters supported our decision not to set a minimum difference between the wage index that applies to the county and the higher wage index areas.

Response: We do not plan to change the minimum difference requirement in this final rule; and therefore, establish the minimum difference in the wage indexes between the resident county and the work county to be any percentage greater than zero.

Our analysis for the proposed rule indicated that 224 counties qualify under the proposed criteria. There were 411 hospitals located in these qualifying counties. For the final rule, we have identified 230 counties that qualify under the proposed criteria. There were 415 hospitals located in these qualifying counties. Hospitals located in qualifying counties are identified in Table 4J in the Addendum to this final rule. Of the 415 hospitals, 181 are reclassified under section 1886(d)(8) of the Act, redesignated under section 1886(d)(10) of the Act or received a section 508 reclassification and are signified in Table 4J in the Addendum to this final rule with asterisks. Given the statutory limitation on hospitals receiving the out-migration adjustment and reclassification under section 1886(d)(8) of the Act, redesignation under section 1886(d)(10) of the Act, or reclassification under section 508, we assume that hospitals represented by asterisks that have already been reclassified or redesignated, wish to retain their reclassification or redesignation and not receive the out-migration adjustment. Only one of the redesignated hospitals informed us that they would like to waive the application of their redesignation for the purposes of receiving the out-migration adjustment. As described in section III.H.3.e.(4) of this preamble, hospitals have an additional 30 days from the date of

publication of this final rule to notify CMS if they would like to waive their reclassification or redesignation in order to receive the out-migration adjustment.

(3) The Adjustment

Hospitals located in the qualifying counties identified in Table 4J in the Addendum to this final rule that have not already reclassified through section 1886(d)(10) of the Act, redesignated through section 1886(d)(8) of the Act, received a section 508 reclassification, or requested to waive the application of the out-migration adjustment will receive the wage index adjustment listed in the table. This adjustment increase is equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage area, multiplied by the sum of: the products, for each higher wage index area, of the difference between the wage index for such higher wage index area and the wage index of the qualifying county, and the percentage of hospital employees residing in the qualifying county who are employed in any higher wage index area who are employed in such higher wage index area. This increase in wage index is depicted using the following equation:

$$\text{Adjustment} = A * \Sigma[(B-C) * (D/E)]$$

A is the percentage of hospital employees residing in a qualifying county who are employed in any higher wage index area. B represents the wage index of the higher wage index area. C represents the wage index of the qualifying resident county. D represents the number of hospital employees residing in the qualifying county involved who are employed in such higher wage index area. E represents the total number of hospital

employees residing in qualifying county who are employed in any higher wage index area.

For example, County A is identified as a qualifying county. As illustrated before, if 100 hospital employees live in County A (wage index = 1.00), 50 commute to County B (wage index = 1.10), 20 commute to County C (wage index = 1.05); and 30 commute within County A, the out-migration percentage is equal to 70 percent.

The adjustment for hospitals in County A would be:

= .70 * (((1.10-1.00)*(50/70)) + ((1.05-1.00)*(20/70)))

= .70 * ((.10 * .714) +(.05 * .285))

= .70 * (0.0714 + 0.01428)

= .70 * (0.0856)

= 0.05998

So, hospitals in County A could receive a new wage index of 1.05998, instead of 1.000 for the following 3 years.

The adjustments calculated for qualifying hospitals are listed in Table 4J in the Addendum to this final rule**.** These adjustments are effective for each county for a period of 3 fiscal years beginning with discharges occurring on or after October 1, 2004. The commuting adjustments for each county will remain static for the 3-year period, after which the county's status as a qualifying county and the adjustment will be recalculated.

Comment: Several commenters questioned the temporary nature of the out-migration adjustment. They suggested that CMS modify the rule to extend the

out-migration adjustment beyond the 3-year period in order to reflect ongoing wage competition.

Response: Section 1886(d)(13)(F) of the Act specifies that the wage index increase shall be applied for a period of 3 fiscal years. Therefore, we do not have the discretion to extend the time period. However, we will evaluate and designate qualifying counties each year. Therefore, it is possible that after a qualifying county's 3-year period ends, the county again will become a qualifying county and receive a new out-migration adjustment for another 3-year time period.

Comment: Several commenters noted that the commuting adjustment is based the commuting flows of hospital employees alone, while clinicians can work in many nonhospital environments. Thus, the commenter stated that the data used for the commuting adjustment does not address the economic reality facing certain areas because it does not incorporate data from clinicians working in nonhospital environments.

Response: Section 1886(d)(13) of the Act specifies that the adjustment be based on the out-migration patterns of hospital employees. Thus, we do not have flexibility to incorporate data based on the commuting patterns of clinicians working in nonhospital environments in the out-migration adjustment.

Comment: One commenter requested that the out-migration adjustment be given to all counties within an MSA, to avoid competitive disadvantages within an MSA.

Response: Section 1886(d)(13) of the Act specifies that the adjustment is applied to qualifying counties, not to MSAs. In keeping with this provision, we are adopting the

provision that was in the proposed rule that we will apply the out-migration adjustment at a county level and not to all counties within an MSA.

Comment: Several commenters stated that the out-migration adjustment only captures the success of other hospitals recruiting labor from areas, but fails to recognize the cost of recruiting and retaining hospital employees. One commenter noted that the formula does not take into account the in-migration of hospital employees who live in other MSAs and recommends that CMS address this issue to include a more comprehensive measure of the interchange between adjacent MSAs.

Response: Section 1886(d)(13) of the Act specifies that the adjustment be made based on the out-migration of hospital employees. Therefore, we do not have the discretion to make additional adjustments based on the in-migration of hospital employees.

Comment: One commenter stated that the out-migration adjustment demonstrates that "CMS is aware that many hospital's wage index would be significantly affected by the OMB's revised definitions of geographic statistical areas." The commenter also stated that the provision does not go far enough to stabilize the severe impact of changes in the MSAs.

Response: Section 505 of Pub. L. 108-173 established a provision to recognize the out-migration of hospital employees. This statutory provision is separate and distinct from OMB's release of updated MSA definitions. We believe the commenter is incorrect in linking the two provisions, because the out-migration adjustment was not explicitly established to mitigate the effects of the new MSA definitions. We also note that the

blended wage index described in section III.G. of the preamble of this final rule is specifically intended to help mitigate the impacts of the adoption of the new MSA definitions.

(4) Automatic Adjustments

Section 1886(d)(13)(A) of the Act allows the Secretary to establish the process for receiving this increase in wage index through application or otherwise. Listed in Table 4J in the Addendum to this final rule are the counties and corresponding hospitals that qualify for an increase in wage index through our implementation of the section. This list includes the universe of hospitals that could receive the adjustment, including those who are redesignated under section 1886(d)(8) of the Act or reclassified under section 1886(d)(10) of the Act. Hospitals located in qualifying counties that have not already been reclassified or redesignated to another geographic area for purposes of the wage index amount (including reclassifications under section 508 of Pub. L. 108-173) will automatically receive the increase in wage index. This commuting wage index adjustment will be effective for the county for a period of 3 fiscal years, FY 2005 through FY 2007. As discussed previously, yearly changes in the wage indexes associated with areas could result in changes in the out-migration percentage for a given county. Irrespective of these changes, a county will not lose its status as a qualifying county due to wage index changes during the 3-year period, and counties will receive the same wage index increase for those 3 years. However, a county that qualifies in FY 2005 may no longer qualify in FY 2008, or it may qualify but receive a different adjustment level.

In the May 18, 2004 proposed rule, we invited public comment on the automatic application of such a wage index adjustment, and whether an application process should be developed under which individual hospitals would have to apply in order to receive the adjustment. We noted that, given the short timeframe before implementation of this provision on October 1, 2004, we believe that there is no practical alternative to providing for an automatic adjustment for FY 2005. However, one possibility was to employ an automatic adjustment process this year, and to replace the automatic process with an application process for future years. We invited comments on whether to establish the automatic process permanently, or to devise an application process for future years. We also invited public comment on whether any application process should be the responsibility of the MGCRB or some other entity.

Comment: One commenter expressed support for the automatic nature of the out-migration adjustment.

Response: We appreciate the commenter's support. In addition, we did not receive specific comments on whether we should devise an application process for the out-migration adjustment in future years. However, we believe that numerous comments in support of our general implementation process and its administrative simplicity suggest that hospitals also appreciate the merits of an automatic application of the out-migration adjustment. Thus, we are adopting our proposal of applying the adjustment on an automatic basis to all hospitals in qualifying counties except those that have already been reclassified under section 1886(d)(10) of the Act, or under section 508 of

Pub. L. 108-173 redesignated under section 1886(d)(8)of the Act, or requested waiver of the application of the out-migration adjustment.

Hospitals receiving this wage index increase under section 1886(d)(13)(F) of the Act are not eligible for reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act, including reclassifications under section 508 of Pub. L. 108-173. As previously noted, the wage index increase is effective for 3 years, unless a hospital elects to waive the application of the wage index adjustment. Hospitals that wished to waive the application of this wage index adjustment were asked to notify CMS within 45 days of the publication of the proposed rule. However, consistent with §412.273, hospitals that have been reclassified by the MGCRB were permitted to withdraw their applications within 45 days of the publication of the proposed rule in the **Federal Register**. Hospitals that have been reclassified by the MGCRB (including reclassifications under section 508 of Pub. L. 108-173) were permitted to terminate an existing 3-year reclassification within 45 days of the publication of the proposed rule in order to receive the wage index adjustment under this provision. Hospitals that are eligible for this adjustment and that have not been reclassified through section 1886(d)(10) of the Act or under section 508 of Pub. L. 108-173, redesignated through section 1886(d)(8) of the Act, or requested waiver of the application of the out-migration adjustment will automatically receive the wage index adjustment listed in Table 4J in the Addendum to this final rule. In our proposed rule, we stated that the request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification had to be received by the MGCRB within 45 days of publication of the proposed rule. We asked hospitals to carefully

review the wage index adjustment that they would receive under this provision (as listed in Table 2 in the Addendum to the proposed rule) in comparison with the wage index that they would receive under MGCRB reclassification (Table 9 in the Addendum to the proposed rule).

Comment: Many commenters questioned the timing of hospitals reclassification decisions for FY 2005 because of the changes to the wage index reclassification in this year's proposed rule (including the new MSA definitions, section 1886(d)(8)(B) redesignations, and the out-migration adjustment). The commenters noted that since the 45-day timeframe for hospitals to waive their reclassification request ends before publication of the final rule, hospitals are unable to appropriately evaluate the impacts of their reclassification decisions before to the deadline for withdrawing an approved reclassification. Commenters suggested that CMS allow hospitals 30 days after publication of the final rule to withdraw a reclassification request in order to receive the out-migration adjustment instead. Commenters also requested that CMS clarify that hospitals eligible for the out-migration adjustment, but were already reclassified for FY 2005, were not required to submit a formal waiver request to retain their existing reclassification.

In addition, several commenters questioned how the out-migration adjustment affects counties that are redesignated under section 1886(d)(8)(B) of the Act (Lugar counties). Specifically, one commenter requested clarification on how hospitals that are eligible for redesignation under section 1886(d)(8)(B) of the Act and the out-migration adjustment are to notify CMS as to which provision they wish to take advantage of

because hospitals are automatically redesignated under section 1886(d)(8)(B) of the Act, and do not have a reclassification request to withdraw. The commenter also requested that hospitals be given the opportunity to determine whether they want to accept the section 1886(d)(8(B) of the Act redesignation or the out-migration adjustment when the final rule is published.

Response: Section 1886(d)(13)(G) of the Act specifies that the out-migration adjustment is not eligible for a hospital that has received redesignation under section 1886(d)(8) of the Act or reclassification under section 1886(d)(10) of the Act during that period (unless they waive their reclassification/redesignation). In the vast majority of cases, we believe that it is most advantageous for hospitals that have been granted redesignation under section 1886(d)(8) of the Act, reclassification under section 1886(d)(10) of the Act or section 508 of Pub. L. 108-173 to retain the redesignation or reclassification instead of the out-migration adjustment. However, there may be a circumstance in which it is in the hospital's best interest to terminate its redesignation or reclassification because the out-migration adjustment results in a higher wage index. Given the number of changes in the proposed rule and the apparent confusion regarding the automatic application of the out-migration adjustment, we are allowing hospitals a 30-day period from the date of this final rule during which they can decide if they would rather take advantage of their redesignation or reclassification or the out-migration adjustment. Therefore, hospitals will have 30 days from the date of publication of this final rule to submit to CMS a request to withdraw their reclassification requests under section 1886(d)(10) of the Act, section 508 of Pub. L. 108-173, or their redesignated

status under section 1886(d)(8) of the Act and receive the out-migration adjustment instead. Hospitals must submit their request to the following address: Centers for Medicare & Medicaid Services, Center for Medicare Management, Attention: Wage Index Adjustment Waivers, Division of Acute Care, C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244-1850.

As previously noted, we will assume that hospitals that have been redesignated under section 1886(d)(8) of the Act, reclassified under section 1886(d)(10) of the Act or under section 508 of Pub. L. 108-173 would prefer to keep their redesignation/reclassification unless they explicitly notify CMS that they would like to receive the out-migration adjustment instead. Additionally, we are clarifying that hospitals that wish to retain their redesignation/reclassification (instead of getting the out-migration adjustment) for FY 2005 did not and do not have to submit a formal request to CMS, and will automatically retain their reclassification/redesignation status for FY 2005.

The hospitals listed in Table 4J include all the hospitals that could possibly take advantage of the out-migration adjustment. Hospitals marked with an asterisk represent those hospitals that could have received the out-migration adjustment, but are assumed to be taking advantage of their reclassification or redesignation status (and consequently not the out-migration adjustment) for FY 2005. These hospitals do not have to do anything if they would like to remain reclassified/redesignated and not receive the out-migration adjustment.

Comment: Several commenters requested that we clarify if hospitals will have the same option to withdraw their reclassification or redesignation if they would rather receive the out-migration adjustment in subsequent years.

Response: In subsequent fiscal years, we will use the same process we proposed for FY 2005 to allow hospitals to withdraw their reclassification or redesignation requests and receive the out-migration adjustment as long as their county remains a qualifying county. That is, hospitals will be able to terminate their reclassification or redesignation and take advantage of the out-migration adjustment if they notify CMS within 45 days of the notice of proposed rulemaking. We note that in upcoming years, we do not expect to allow any withdrawals after that date, as we have done in this final rule (allowing 30 days after publication of the final rule to withdraw a reclassification or redesignation). We note that by the time the proposed rule is published in 2005, hospitals will be familiar with the new labor market areas and the policies for adopting such areas will have been finalized.

Comment: Several commenters requested clarification on the ability of hospitals to apply for reclassification in future year if they receive the out-migration adjustment in FY 2005. Specifically, the commenter asked whether a hospital that qualifies for the out-migration adjustment effective for October 1, 2004 through September 30, 2005 will be able to request geographic reclassification effective for October 1, 2005 under the normal reclassification process. Similarly, another commenter asked if a hospital would be able to receive the out-migration adjustment at the time their MGCRB reclassification expires.

Response: It is our intent that hospitals should be able to evaluate the merits of reclassification and the out-migration adjustment on an annual basis. Given the statutory prohibition on hospitals being redesignated or reclassified (under section 1886(d)(8) or section 1886(d)(10) of the Act) and receiving the commuting adjustment, hospitals cannot receive both the out-migration adjustment and reclassification in the same year. We agree with the commenter that a hospital should not have to forgo the out-migration adjustment in FY 2005 in order to be able to apply for reclassification in FY 2006. Hospitals that qualify for the out-migration adjustment in a given year can take advantage of that adjustment in that year, and can still apply to be reclassified in the subsequent year. Hospitals that apply for reclassification for FY 2005 will be viewed as implicitly waiving the out-migration adjustment for that fiscal year, assuming they receive the reclassification requested. Conversely, if a hospital's reclassification request is not approved in a given year and the hospital remains eligible for the out-migration adjustment, the hospital will automatically receive the out-migration adjustment.

4. FY 2005 Reclassifications

The wage index values for FY 2005 (except those for hospitals receiving wage index adjustments under section 505 of Pub. L. 108-173) are shown in Tables 4A, 4B, 4C, and 4F in the Addendum to this final rule. Hospitals that are redesignated will be required to use the wage index values shown in Table 4C. Areas in Table 4C may have more than one wage index value because the wage index value for a redesignated urban or rural hospital cannot be reduced below the wage index value for the rural areas of the State in which the hospital is located. Therefore, those areas with more than one wage

index shown have hospitals from more than one State reclassified into them, and the rural wage index for a State in which at least one hospital is physically located is higher than the wage index for the area to which the hospital is reclassified.

Tables 3A and 3B in the Addendum to this final rule list the 3-year average hourly wage for each labor market area before the redesignation of hospitals, based on FYs 1999, 2000, and 2001 cost reporting periods. Table 3A lists these data for urban areas and Table 3B lists these data for rural areas. In addition, Table 2 in the Addendum to this final rule includes the adjusted average hourly wage for each hospital from the FY 1999 and FY 2000 cost reporting periods, as well as the FY 2001 period used to calculate the FY 2005 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period.

We are including in the Addendum of this final rule Table 9A, which shows hospitals that have been reclassified under either section 1886(d)(8) or section 1886(d)(10)(D) of the Act. This table includes 400 hospitals reclassified for FY 2005 by the MGCRB (for wage index purposes), as well as hospitals that were reclassified for the wage index in either FY 2003 (53 hospitals) or FY 2004 (102 hospitals) and are, therefore, in either the second or third year of their 3-year reclassification. This table also includes hospitals located in urban areas that have been redesignated rural in accordance with section 1886(d)(8)(E) of the Act (17). In addition, it includes rural hospitals

redesignated to urban areas under section 1886(d)(8)(B) of the Act for purposes of the wage index (98).

Under §412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. The request for withdrawal of an application for reclassification or termination of an existing 3-year reclassification that would be effective in FY 2004 must be received by the MGCRB within 45 days of the publication of the proposed rule. If a hospital elects to withdraw its wage index application after the MGCRB has issued its decision but prior to the above date, it may later cancel its withdrawal in a subsequent year and request the MGCRB to reinstate its wage index reclassification for the remaining fiscal year(s) of the 3-year period (§412.273 (b) (2) (i)). The request to cancel a prior withdrawal must be made in writing to the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year (§412.273 (d)). For further information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer the reader to §412.273, as well as the August 1, 2002 IPPS final rule (67 FR 50065) and the August 1, 2001 IPPS final rule (66 FR 39887).

Changes to the wage index that result from withdrawals of requests for reclassification, wage index corrections, appeals, and the Administrator's review process have been incorporated into the wage index values published in this final rule. These changes may affect not only the wage index value for specific geographic areas, but also the wage index value redesignated hospitals receive; that is, whether they receive the

wage index that includes the data for both the hospitals already in the area and the redesignated hospitals. Further, the wage index value for the area from which the hospitals are redesignated may be affected.

Applications for FY 2006 reclassifications are due to the MGCRB by September 1, 2004. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under §412.273(d). Applications and other information about MCGRB reclassifications may be obtained, beginning in mid-July 2004, via the CMS Internet website at: **http://cms.hhs.gov/providers/prrb/mgcinfo.asp**, or by calling the MCGRB at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

I. Requests for Wage Index Data Corrections

1. Worksheet S-3 Wage Data

In the August 1, 2003 final rule (68 FR 27194), we revised the process and timetable for application for development of the wage index, beginning with the FY 2005 wage index. The preliminary and unaudited Worksheet S-3 wage data file was made available on October 8, 2003 through the Internet on CMS's website at: **http://cms.hhs.gov/providers/hipps/ippswage.asp**. In a memorandum dated October 10, 2003, we instructed all Medicare fiscal intermediaries to inform the IPPS hospitals they service of the availability of the wage data file and the process and timeframe for requesting revisions (including the specific deadlines listed below). We

also instructed the fiscal intermediaries to advise hospitals that these data are also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in that wage data file, the hospital was to submit corrections along with complete, detailed supporting documentation to its intermediary by November 24, 2003. Hospitals were notified of this deadline and of all other possible deadlines and requirements, including the requirement to review and verify their data as posted on the preliminary wage data file on the Internet, through the October 10, 2003 memorandum referenced above.

The fiscal intermediaries notified the hospitals in early February of any changes to the wage data as a result of the desk reviews and the resolution of the hospitals' early November change requests. The fiscal intermediaries also submitted the revised data to CMS in early February. CMS published the proposed wage index public use file that included hospitals' revised wage data on February 27, 2004. In a memorandum also dated March 1, 2004, we instructed fiscal intermediaries to notify all hospitals regarding the availability of the proposed wage index public use file and the criteria and process for requesting corrections and revisions to the wage data. Hospitals had until March 12, 2004 to submit requests to the fiscal intermediaries for reconsideration of adjustments made by the fiscal intermediaries as a result of the desk review, and to correct errors due to CMS's or the intermediary's mishandling of the wage data. Hospitals were also required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries transmitted any additional revisions resulting from the hospitals' reconsideration requests

by April 16, 2004. The deadline for hospitals to request CMS intervention in cases where the hospital disagreed with the fiscal intermediary's policy interpretations was April 23, 2004.

Hospitals were also instructed to examine Table 2 in the Addendum to the proposed rule. Table 2 of the proposed rule contained each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2001 data used to construct the FY 2005 wage index. We noted that the hospital average hourly wages shown in Table 2 of the proposed rule only reflected changes made to a hospital's data and transmitted to CMS by March 15, 2004.

The final wage data public use file was released in May 2004 to hospital associations and the public on the Internet at **http:/www.cms.hhs.gov/providers/hipps/ippswage.asp**. The May 2004 public use file was made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary in the entry of the final wage data that result from the correction process described above (revisions submitted to CMS by the fiscal intermediaries by April 16, 2004). If, after reviewing the May 2004 final file, a hospital believed that its wage data were incorrect due to a fiscal intermediary or CMS error in the entry or tabulation of the final wage data, it was provided the opportunity to send a letter to both its fiscal intermediary and CMS that outlined why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). These requests had to be received by CMS and

the fiscal intermediaries no later than June 11, 2004. The intermediary reviewed requests upon receipt and contacted CMS immediately to discuss its findings.

After the release of the May 2004 wage index file, changes to the hospital wage data were only made in those very limited situations involving an error by the intermediary or CMS that the hospital could not have known about before its review of the final wage data file. Specifically, neither the intermediary nor CMS accepted the following types of requests:

- Requests for wage data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries on or before April 16, 2004.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the March 1, 2004 wage data file (or the March 8 occupational mix data; see section III.H.2. of this preamble).
- Requests to revisit factual determinations or policy interpretations made by the intermediary or CMS during the wage index data correction process.

2. Occupational Mix Data

The process and criteria for requesting corrections to the occupational mix survey data are described in section III.C.1 of this preamble. As stated in that section, from April 16, 2004 forward, the process for correcting the final occupational mix survey data is the same, and on the same schedule, as described above for correcting the final Worksheet S-3 wage data.

3. All FY 2005 Wage Index Data

Verified corrections to the wage index received timely (that is, by June 11, 2004) have been incorporated into the final wage index in this final rule, and are effective October 1, 2004.

We created the processes described above to resolve all substantive wage index data index correction disputes before we finalize the wage and occupational mix data for the FY 2005 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage data corrections or to dispute the intermediary's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision (See W. A. Foote Memorial Hospital v. Shalala, No. 99-CV-75202-DT (E.D. Mich. 2001), also Palisades General Hospital v. Thompson, No. 99-1230 (D.D.C. 2003)).

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage data to the fiscal intermediaries' attention. Moreover, because hospitals had access to the final wage index data by early May 2004, they had the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or CMS before the development and publication of the final FY 2005 wage index in this final rule, and the implementation of the FY 2005 wage index on October 1, 2004. If hospitals availed themselves of this opportunity, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified after publication of the final rule, we

retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with §412.63(x)(2) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show: (1) that the intermediary or CMS made an error in tabulating its data; and (2) that the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of FY 2005 (that is, by the June 11, 2004 deadline). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index. As described earlier, since a hospital had to show that it could not have known about the error, or that it did not have the opportunity to correct the error, before the publication of the FY 2005 wage index. As indicated earlier, since a hospital had the opportunity to verify its data, and the fiscal intermediary notified the hospital of any changes, we do not expect that midyear corrections will be necessary. However, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is approved.

Comment: One national hospital association commended CMS for the revised wage index development process and timeframe that CMS implemented with the FY 2005 wage index. The commenter believed that releasing the wage data file before intermediaries begin their desk reviews of the wage data makes the process more efficient than in prior years and recommended that CMS follow a similar process for 2006. The

commenter suggested that notifying hospitals of the schedule as soon as possible and extending the hospital review timeframe would enhance the process.

Another commented that nearly 13 percent of hospitals made changes to their wage data after the release of the February public use file. The commenter believed that this percentage of changes is too high and creates budgeting challenges for hospitals, as well as, contributes to difficulties in determining reclassification decisions.

Response: We will continue to explore ways to improve the process for developing the wage index. With the new process in place, the rate of revisions between the proposed (February) and final (May) public use files has decreased dramatically, from approximately 30 percent in prior years to less than 15 percent for the FY 2005 wage index. However, we agree with the commenter that the volume of changes after the proposed rule is still too high. We encourage hospitals to work with their intermediaries as early as possible to ensure that their wage data are correct early in the process. For the FY 2006 wage index, we will apply the same process that we used for the FY 2005 wage index.

Comment: One commenter requested that CMS provide more specific guidance to fiscal intermediaries for handling the June appeals, that is, hospitals' requests to correct errors in the May public use files, just as CMS provides for the earlier stages of the correction process.

Response: We plan to provide more specific instructions regarding the intermediaries' handling of the June appeals in forthcoming instructions for the wage index development process, beginning with the FY 2006 wage index.

Comment: One commenter suggested that CMS should put a process in place that allows other hospitals negatively impacted by another hospitals' incorrect data to make a request to obtain a correction. The commenter is concerned that sometimes the hospital with the incorrect data has no incentive to request a correction, for example, the hospital has closed or changed enrollment status to a CAH other non-IPPS hospital.

Response: The opportunity that the commenter requested is already available. If a hospital believes that another hospital's wage data may be erroneous in the public use files, the hospital may notify CMS that there is a potential problem with the other hospital's data. CMS and the other hospital's intermediary will review the data and attempt to contact the other hospital to determine the appropriate action. Any correction to a hospital's wage data can only be based on data that derives directly from the hospital.

J. Revision of the Labor-Related Share of the Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related: "The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates…." The portion of hospital costs attributable to wages and wage-related costs is referred to as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index. In the

past, we have defined the labor-related share for prospective payment acute care hospitals as the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system has been calculated as the sum of the weights for wages and salaries, fringe benefits, nonmedical professional fees, contract labor, postage, and labor-intensive services.

In its June 2001 Report to Congress, MedPAC recommended that the Secretary "should reevaluate current assumptions about the proportion of providers' costs that reflect resources purchased in local and national markets." (Report to the Congress: Medicare in Rural America, Recommendation 4D, page 80.) MedPAC recommended that the labor-related share include the weights for wages and salaries, fringe benefits, contract labor, and other labor-related costs for locally purchased inputs only. MedPAC noted that this would likely result in a lower labor share, which would decrease the amount of the national base payment amount adjusted by the wage index. As a result, hospitals located in low-wage markets (those with a wages index less than 1.0) would receive higher payments, while those located in high-wage labor markets would receive lower payments.

In our proposed and final regulations updating the IPPS for FY 2003 (67 FR 31404, May 9, 2002 and 67 FR 49982, August 1, 2002), we discussed the methodology that we have used to determine the labor-related share. We noted that, at that time, the results of employing that methodology suggested that an increase in the labor-related share (from 71.066 percent to 72.495 percent) was warranted. However, we

decided not to propose such an increase in the labor-related share until we conducted further research to determine whether a different methodology for determining the labor-related share should be adopted. The labor-related share has thus remained 71.066 percent.

Section 403 of Pub. L. 108-173 amended sections 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this "would result in lower payments than would otherwise be made." However, this provision of Pub. L. 108-173 did not the change the legal requirement that the Secretary estimate "from time to time" the proportion of hospitals' costs that are "attributable to wages and wage-related costs." In fact, section 404 of Pub. L. 108-173 requires the Secretary to develop a frequency for revising the weights used in the hospital market basket, including the labor share, to reflect the most current data more frequently than once every 5 years. This reflects Congressional intent that hospitals will receive payment based on a 62-percent labor share, or the labor share estimated from time to time by the Secretary, whichever results in higher payments.

Section 404 further requires us to include in the final IPPS rule for FY 2006 an explanation of the reasons for, and options considered, in determining the frequency for revising the weights used in the hospital market basket, including the labor share. In the meantime, we are also continuing our research into the assumptions employed in calculating the labor-related share. Our research involves analyzing the compensation share separately for urban and rural hospitals, using regression analysis to determine the proportion of costs influenced by the area wage index, and exploring alternative

methodologies to determine whether all or only a portion of professional fees and nonlabor intensive services should be considered labor-related. We will present our analysis and conclusions regarding the frequency and methodology for updating the labor share in the proposed and final rules for FY 2006.

In section IV.F. of this preamble, we discuss our incorporation of the requirements of section 403 of Pub. L. 108-173 in a new §412.64(h) of the regulations.

As discussed above, the Secretary had determined, prior to the enactment of Pub. L. 108-173, that the labor-related share would be 71.066 percent. As a result, application of a 62-percent labor share would result in lower payments for any hospital with a wage index greater than 1.0. Therefore, we are modifying our payment system software for FY 2005 to apply wage indexes greater than 1.0 to 71.066 percent of the standardized amount, and to apply wage indexes less than or equal to 1.0 to 62 percent of the standardized amount.

We did not receive any specific comments on the proposed implementation of section 403 of Pub. L. 108-173. Therefore, we are adopting as final the proposed policy change without modification.

IV. Other Decisions and Changes to the IPPS for Operating Costs and GME Costs

A. Postacute Care Transfer Payment Policy (§412.4)

1. Background

Existing regulations at §412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital.

Section 412.4(b) defines transfers from one acute care hospital to another, and §412.4(c) defines transfers to certain postacute care providers. Our policy provides that, in transfer situations, full payment is made to the final discharging hospital and each transferring hospital is paid a per diem rate for each day of the stay, not to exceed the full DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy provides for payment that is double the per diem amount for the first day (§412.4(f)(1)). Transfer cases are also eligible for outlier payments. The outlier threshold for transfer cases is equal to the fixed-loss outlier threshold for nontransfer cases, divided by the geometric mean length of stay for the DRG, multiplied by the length of stay for the case, plus one day.

Medicare adopted its IPPS transfer policy because, if the program were to pay the full DRG payment regardless of whether a patient is transferred or discharged, there would be a strong incentive for hospitals to transfer patients to another IPPS hospital early in the patients' stay in order to minimize costs while still receiving the full DRG payment. The transfer policy adjusts the payments to approximate the reduced costs of transfer cases.

Previously, when a patient chose to depart from a hospital against the medical opinion of treating physicians, the case was treated as a left against medical advice

(LAMA) discharge and coded as discharge status "07-Left Against Medical Advice (LAMA)" on the inpatient billing claim form. Because, by definition, LAMA discharges were assumed not to involve the active participation of the hospital administration, our policy had been to treat LAMA cases as discharges. This policy applied even if the patient was admitted to another hospital on the date of the LAMA discharge. Consequently, until FY 2004, we made a full DRG payment for any discharge coded as a LAMA case.

Last year, in response to an Office of Inspector General (OIG) report issued in March 2002 (A-06-99-00045), we became concerned that some hospitals were incorrectly coding transfers as LAMA cases. Therefore, in the August 1, 2003 final IPPS rule (68 FR 45405), we expanded our definition of a transfer under §412.4(b) to include all patients who are admitted to another IPPS hospital on the same day that the patient is discharged from an IPPS hospital, unless the first (transferring) hospital can demonstrate that the patient's treatment was completed at the time of discharge from that hospital. In other words, unless the same-day readmission is to treat a condition that is unrelated to the condition treated during the original admission (for example, the beneficiary is in a car accident later that day), any situation where the beneficiary is admitted to another IPPS hospital on the same date that he or she is discharged from an IPPS hospital would be considered a transfer, even if the patient left against medical advice from the first hospital.

This policy prohibits payment of two claims for the same patient on the same day. Therefore, if a hospital believes a claim has been wrongly denied, the original

discharging hospital must resubmit the claim with documentation that the discharge was appropriate and unrelated to the subsequent same-day admission.

Comment: One commenter requested that we clarify our policy regarding LAMAs. The commenter noted that in the FY 2004 proposed rule, we "considered and appropriately rejected…a knowledge standard" when we amended the transfer policy to include LAMAs. Under the standard that was rejected, a hospital would have been required to code LAMAs as transfers based on knowledge of a same-day admission to another hospital. However, the commenter notes that in the May 18, 2004 proposed rule, we stated that hospitals "are now allowed to report a patient as left against medical advice only if they have no knowledge that the patient has been admitted to another hospital on the same day." The commenter notes that this could be interpreted as reflecting a change in policy, returning to the knowledge standard that we rejected in the August 1, 2003 final rule.

Response: We did not intend to change our policy in the preamble of the May 18, 2004 proposed rule. A discharging hospital is not required to identify cases in which a patient is admitted to another hospital on the same day. Our claims processing software has been revised to identify cases in which a patient is admitted to a hospital after being discharged from another hospital on the same day.

Comment: Some commenters noted that the edits to the CWF will cause claims to be rejected and that providers will have to recode the claims and resubmit them. Others expressed concerns that hospitals appropriately discharge their patients to home "only to have other providers outside of the hospital admit patients to other entities and

healthcare settings," imposing on hospitals an unfair burden that is caused by patient choice and is not of their own doing. As a result, claims are frequently denied for these providers as a result of the lack of a method to ensure consistent inpatient processing of claims. The commenter cites "unplanned situations (for example, LAMA, readmissions post-discharge to home, patients seeking additional care at other facilities)" that result in "unnecessary payment delays and rework of claims" by the facilities that originally treated the patients. The commenter further argues, "these unnecessary process issues result in additional overhead costs that will never be recovered by the already reduced transfer per diem payments that the original treating facility ultimately receives."

Response: As we discussed above, we adopted this policy in the August 1, 2003 final rule (68 FR 45404 through 45406) in response to an OIG report indicating that transfers were frequently miscoded as LAMAs. Since we have implemented the systems edits to identify these cases, the number of cases identified by these edits has provided further evidence that this policy is appropriate.

2. Changes to DRGs Subject to the Postacute Care Transfer Policy (§§412.4(c) and (d))

Under section 1886(d)(5)(J) of the Act, a "qualified discharge" from one of 10 DRGs selected by the Secretary to a postacute care provider is treated as a transfer case beginning with discharges on or after October 1, 1998. This section required the Secretary to define and pay as transfers all cases assigned to one of 10 DRGs selected by the Secretary, if the individuals are discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection 1886(d) hospital. (Section 1886(d)(1)(B) of the Act identifies the hospitals and hospital units that are excluded from the term "subsection (d) hospital" as psychiatric hospitals and units, rehabilitation hospitals and units, children's hospitals, long-term care hospitals, and cancer hospitals.)

- A SNF (as defined at section 1819(a) of the Act).

- Home health services provided by a home health agency, if the services relate to the condition or diagnosis for which the individual received inpatient hospital services, and if the home health services are provided within an appropriate period (as determined by the Secretary).

In the July 31, 1998 IPPS final rule (63 FR 40975 through 40976), we specified the appropriate time period during which we would consider a discharge to postacute home health services to constitute a transfer as within 3 days after the date of discharge. In addition, in the July 31, 1998 final rule, we did not include in the definition of postacute care transfer cases patients transferred to a swing-bed for skilled nursing care (63 FR 40977).

Section 1886(d)(5)(J) of the Act directed the Secretary to select 10 DRGs based upon a high volume of discharges to postacute care and a disproportionate use of postacute care services. As discussed in the July 31, 1998 final rule, these 10 DRGs were selected in 1998 based on the MedPAR data from FY 1996. Using that information, we identified and selected the first 20 DRGs that had the largest proportion of discharges to postacute care (and at least 14,000 such transfer cases). In order to select 10 DRGs from the 20 DRGs on our list, we considered the volume and percentage of discharges to

postacute care that occurred before the mean length of stay and whether the discharges occurring early in the stay were more likely to receive postacute care. We identified 10 DRGs to be subject to the postacute care transfer rule starting in FY 1999.

Section 1886(d)(5)(J)(iv) of the Act authorizes the Secretary to expand the postacute care transfer policy beyond 10 DRGs for FY 2001 or subsequent fiscal years. In the FY 2004 IPPS final rule (68 FR 45412), we expanded the postacute care transfer policy to include additional DRGs. We established the following criteria that a DRG must meet, for both of the 2 most recent years for which data are available, in order to be added to the postacute care transfer policy:

- At least 14,000 postacute care transfer cases;
- At least 10 percent of its postacute care transfers occurring before the geometric mean length of stay;
- A geometric mean length of stay of at least 3 days; and
- If a DRG is not already included in the policy, a decline in its geometric mean length of stay during the most recent 5 year period of at least 7 percent.

We identified 21 new DRGs that met these criteria. We also determined that one DRG from the original group of 10 DRGs (DRG 263) no longer met the volume criterion of 14,000 transfer cases. Therefore, we removed DRGs 263 and 264 (DRG 264 is paired with DRG 263) from the policy and expanded the postacute care transfer policy to include payments for transfer cases in the new 21 DRGs, effective October 1, 2003. As a result, a total of 29 DRGs were subject to the postacute care transfer policy in FY 2004.

In the FY 2004 IPPS final rule, we indicated that we would review and update this list periodically to assess whether additional DRGs should be added or existing DRGs should be removed (68 FR 45413). We have analyzed the available data from the FY 2003 MedPAR file. For the 2 most recent years of available data (FY 2002 and FY 2003), we have found that no additional DRGs qualify under the four criteria set forth in the IPPS final rule for FY 2004. We have also analyzed the DRGs included under the policy for FY 2004 to determine if they still meet the criteria to remain under the policy. In addition, we have analyzed the special circumstances arising from a change to one of the DRGs included under the policy in FY 2004.

As discussed in the May 18, 2004 IPPS proposed rule (69 FR 28212) and in section II.B.9. of this final rule, we proposed to eliminate DRG 483. Under our proposal, the cases that would have been placed into DRG 483 would be split into two proposed new DRGs, 541 (Tracheostomy With Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses With Major O.R. Procedure) and 542 (Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure). This would be done by subdividing the cases in the existing DRG 483 based on the presence of a major O.R. procedure, in addition to the tracheostomy code that is currently required to be assigned to this DRG. Therefore, if the patient's case involves a major O.R. procedure (a procedure whose code is included on the list that is assigned to DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), except for tracheostomy codes 31.21 and 31.29), the case would be assigned to the proposed new DRG 541. We indicated that if

the patient does not have an additional major O.R. procedure (that is, there is only a tracheostomy code assigned to the case), the case would be assigned to proposed new DRG 542. In section II.B.9. of this preamble, we are finalizing our proposal to eliminate DRG 483 and create new DRGs 541 and 542.

As discussed in the May 18, 2004 proposed rule, neither of the new DRGs 541 and 542 would have enough cases to meet the first criterion for inclusion in the postacute care transfer policy. DRG 483 had 44,788 total cases with 15,520 transfer cases in FY 2002, and 44,618 total cases with 20,034 transfer cases in FY 2003. These cases will now split between new DRG 541 (20,812 total cases) and new DRG 542 (23,387 total cases). As a result, neither of these new DRGs would meet the existing threshold of 14,000 transfer cases (6,779 projected transfer cases for new DRG 541, and 8,570 projected transfer cases for new DRG 542). Nevertheless, we indicated that we believe the cases that will now be incorporated into these two new DRGs remain appropriate candidates for application of the postacute care transfer policy. The new DRGs 541 and 542 will contain the same cases that were included in existing DRG 483, which qualified for inclusion in the postacute care transfer policy. Furthermore, many of the cases in the new DRGs 541 and 542 will continue to require postacute care.

For the proposed rule, when we analyzed the cases that we projected would fall into the two new DRGs in the FY 2005 GROUPER Version 22.0, we found that a high proportion of cases in both the new DRGs were projected to be transfer cases: 33 percent of all cases in DRG 541, and 37 percent in DRG 542. In addition, based on the data from cases in DRG 483 in the FY 2003 MedPAR file, a high proportion of the transfer cases in

these proposed new DRGs were projected to fall into the short-stay transfer category: 41 percent of transfer cases in new DRG 541 and 42 percent of transfer cases in new DRG 542 were projected to occur before the geometric mean length of stay for these new DRGs. By contrast, among all DRGs, approximately 15 percent of transfer cases are short-stay transfer cases. The percentage of transfer cases that were short-stay cases that would be in both new DRGs 541 and 542 would be more than 2 standard deviations above the mean percentage of short-stay cases across all DRGs. (Two standard deviations above the mean across all DRGs is 37 percent for FY 2005.) Therefore, we proposed that the subdivision of DRG 483 should not change the original application of the postacute care transfer policy to the cases once included in that DRG. We did not believe that it was appropriate for these cases to fall outside the scope of this policy solely because of a revision to the DRG structure that was driven by policy reasons unrelated to the postacute care transfer provision. We proposed that the high proportion of transfer cases among all cases that would be assigned to these new DRGs, along with the unusually high proportion of short-stay cases among those transfer cases, provided solid reasons for considering whether alternate criteria might better address the special circumstances that can arise from changes in DRGs unrelated to the postacute care transfer policy.

Therefore, in the May 18, 2004 proposed rule, we proposed alternate criteria to be applied in cases where DRGs do not satisfy the existing criteria, for discharges occurring on or after October 1, 2004 (69 FR 28273-28374). The proposed new criteria were designed to address situations such as those posed by the split of DRG 483, where there

remain substantial grounds for inclusion of cases within the postacute care transfer policy, although one or more of the original criteria may no longer apply. Therefore, we proposed to examine DRGs for inclusion within the policy against two sets of criteria, first, the original four criteria, and then, the proposed alternate set of criteria. Under our proposal, DRGs that did not satisfy the first set of criteria would still be included if they satisfied the second set. Specifically, a DRG would still be subject to the postacute care transfer policy under the alternative set of criteria if, for the 2 most recent years for which data are available, there were at least 5,000 total transfers to postacute care among the cases included in the DRG, and if, among the cases included in the DRG, the percentage of transfer cases that were short-stay transfer cases was at least 2 standard deviations above the geometric mean length of stay across all DRGs (which is 37 percent for FY 2005). We indicated that we would also continue to require a geometric mean length of stay of at least 3 days among the cases included in the DRG. Finally, we proposed to require that, if a DRG was not already included in the policy, it either experienced a decline in its geometric mean length of stay during the most recent 5-year period of at least 7 percent or contained only cases that would have been included in a DRG to which the policy applied in the prior year.

Under the proposed alternate criteria, DRGs 430, 541, and 542 would have qualified for inclusion in the postacute care transfer policy. DRG 430 met the proposed threshold of 5,000 transfer cases in both of the 2 most recent years, with 11,973 transfer cases and 46 percent short-stay transfer cases in FY 2002, and 12,202 transfer cases and 38 percent short-stay transfers in FY 2003. In addition, DRG 430 experienced a

7-percent decline in length of stay from FY 2000 to FY 2004. DRG 430 also had a 5.8 day average length of stay during those years. As discussed in the proposed rule, the cases to be included in new DRGs 541 and 542 contain a sufficient number of transfers to meet the first alternate criterion, and among the cases to be included in these DRGs, the percentages of transfer cases occurring before the geometric mean length of stay new DRGs exceed 2 standard deviations above the geometric mean length of stay for all DRGs. The average lengths of stay for the cases to be included in new DRGs 541 and 542 are 37.7 days and 28.9 days, respectively.

We proposed to revise the regulations governing the postacute transfer policy to include the alternative criteria described above (§412.4(d)). We also proposed that DRG 430 and new DRGs 541 and 542 would be included in the postacute care transfer policy.

In the May 18, 2004 proposed rule, we also called attention to the data concerning DRG 263, which was subject to the postacute care transfer policy until FY 2004. We removed DRG 263 from the postacute care transfer policy for FY 2004 because it did not have the minimum number of cases (14,000) transferred to postacute care (13,588 transfer cases in FY 2002, with more than 50 percent of transfer cases being short-stay transfers). The FY 2003 MedPAR data show that there were 15,602 transfer cases in the DRG in FY 2003, of which 46 percent were short-stay transfers. Because we removed the DRG from the postacute care transfer policy in FY 2004, it must meet all criteria to be included under the policy in subsequent fiscal years. Because the geometric mean length of stay for DRG 263 shows only a 6-percent decrease since 1999, DRG 263 does

not qualify to be added to the policy for FY 2005 under the existing criteria that were included in last year's rule. DRG 263 would have qualified under the volume threshold and percent of short-stay transfer cases under the proposed new alternate criteria contained in the proposed rule. However, it still did not meet the proposed required decline in length of stay to qualify to be added to the policy in FY 2005.

Comment: Several commenters objected to the proposed alternate criteria for DRGs to be included in the postacute care transfer policy. Some commenters believed that the proposed criteria were inappropriate because they appeared contrived to ensure that cases in the former DRG 483, which had a very high DRG weight and resulted in significant Medicare payments, would not be paid at the higher rate associated with those cases. One commenter stated that if CMS' creation of the two new DRGs for tracheostomies with and without surgical procedures does not create less variation in length of stay and cost per case, there is no need to split DRG 483 and no need to expand the transfer policy criteria. The commenters argued that if the split of DRG 483 into more specific DRGs will better account for variations in the original DRG, then the historical logic behind the transfer policy in these cases is no longer valid. Some commenters also believed that the alternate criteria did not meet the objective of the provision, which is to ensure that the postacute care transfer policy only subjects high volume DRGs to this payment method.

Response: We disagree with some of the points raised by these commenters. In the proposed rule (69 FR 28273) we clearly indicated that the alternate criteria to be included in the postacute care transfer policy still required relatively high volumes of

postacute care transfer cases, as well as very high proportions of short stay transfer cases. We specifically chose a very high threshold for the percent of these postacute care transfer cases that are short-stay cases in order to avoid including inappropriate DRGs within the postacute care transfer policy. In many areas of Medicare program policy we employ a threshold of one standard deviation or less in order to qualify for inclusion to or exclusion from certain provisions. In this instance, we deliberately chose a much higher threshold in order to ensure that only those DRGs with the highest rate of short-stay postacute care transfers would be included in the policy.

However, in the light of these and other comments, we are not adopting the proposed alternate criteria in this final rule. We note that the postacute care transfer policy was not considered at the time the decision was made to split DRG 483. We do not intend to change our rationale for reorganizing DRGs into more coherent groups or to compromise the clinical cohesiveness of the DRG system in order ensure cases are included in or excluded from the postacute care transfer policy or other CMS policies. We have discussed the reasons for splitting DRG 483 in section II.B.9. of the proposed rule and in this final rule. However, we do note that, while these cases will continue to be included in the postacute care transfer policy and subject to per diem payments, we anticipate that fewer cases will actually receive these reduced payments as the new DRGs better reflect the resources required to treat these patients. As a result, hospitals will have less incentive to discharge these patients to postacute care.

Comment: Some commenters suggested that in place of the proposed alternate criteria, we should adopt a policy of keeping cases within the scope of the postacute care

transfer policy permanently once they initially qualify for inclusion in the policy. These commenters noted that removing DRGs from the postacute care transfer policy makes the payment system less stable and results in inconsistent incentives over time. They also argued that "a drop in the number of transfers to postacute settings is to be expected after the transfer policy is applied to a DRG, but the frequency of transfers may well rise again if the DRG is removed from the policy." Other commenters expressed concern about our changing of the policy criteria in 2 consecutive years. These commenters argued that such frequent changes in policy give the appearance that the policy has been contrived to achieve certain desired results and make the regulatory process unpredictable and unfair. They further imply that these "band-aid fixes" to the 20-year old Medicare system do not bode well for the confidence of outside organizations in regards to the program.

Response: We did consider grandfathering cases already included in the policy because this approach is, on the surface, the simplest method of ensuring these cases continue to be paid appropriately. However, we determined that in order to adopt this approach, we would also need to determine an appropriate timeframe for the grandfathering period. We did not believe that we could adequately predict or project what timeframe would be appropriate, not only in the case of the splitting of DRG 483 into DRGs 541 and 542, but also for future situations where this kind of split may occur. Therefore, we tried to develop appropriate, alternative criteria based on actual case data that could be monitored and applied from year to year.

However, due to the large number of comments received and the strong arguments they have raised in favor of a more straightforward approach, we have decided

not to adopt the alternate criteria proposed in the May 18, 2004 proposed rule. Instead, in this final rule we are adopting the policy of simply grandfathering, for a period of 2 years, any cases that were previously included within a DRG that has split, when the split DRG qualified for inclusion in the postacute care transfer policy for both of the previous 2 years. Under this policy, the cases that were previously assigned to DRG 483, and that will now fall into DRGs 541 and 542, will continue to be subject to the postacute care transfer policy for the next 2 years. We will monitor the frequency with which these cases are transferred to postacute settings and the percentage of these cases that are short-stay transfer cases. Because we are not adopting the proposed alternate criteria for DRG inclusion the postacute care transfer policy at this time, DRG 430 (Psychoses) does not meet the criteria for inclusion and will not be subject to the postacute care transfer policy for FY 2005.

We appreciate the recommendation to address situations such as the splitting of DRGs by simply including all cases within the postacute care transfer policy permanently once they have initially qualified. While we are not adopting this policy at this time, we will actively consider it for adoption at a later date. Meanwhile, we believe that grandfathering the cases formerly included in DRG 483 for 2 years is an appropriate interim measure that ensures a consistent payment approach to these cases while affording us sufficient time to undertake a thorough review of this issue. In the meantime, we welcome comments on how to treat the cases formerly included in a split DRG after the grandfathering period. We note that, if we were to adopt the policy recommended by the commenter, cases in DRGs 263 and 264 would again become

subject to the policy. As noted above, these DRGs are already very close to meeting the criteria required to be re-included in the policy. However, we will monitor cases until next year or until such time that another change to this policy is warranted.

The table below displays the 30 DRGs that we are including in the postacute care transfer policy, effective for discharges occurring on or after October 1, 2004. This table includes the effects of dropping DRG 483, which we are deleting from the DRG list, and adding the two new DRGs 541 and 542 that will now incorporate the cases formerly assigned to DRG 483. As discussed above, these cases are being grandfathered into the policy for 2 years. The other DRGs meet the criteria specified above during both of the 2 most recent years for which data were available prior to the publication of this final rule (FYs 2002 and 2003), as well as their paired-DRG if one of the DRGs meeting the criteria includes a CC/no-CC split.

DRG	DRG Title
12	Degenerative Nervous System Disorders
14	Intracranial Hemorrhage and Stroke with Infarction
24	Seizure and Headache Age >17 With CC
25	Seizure and Headache Age >17 Without CC
88	Chronic Obstructive Pulmonary Disease
89	Simple Pneumonia and Pleurisy Age > 17 With CC
90	Simple Pneumonia and Pleurisy Age >17 Without CC
113	Amputation for Circulatory System Disorders Except Upper Limb and Toe
121	Circulatory Disorders With AMI and Major Complication, Discharged Alive
122	Circulatory Disorders With AMI Without Major Complications Discharged Alive
127	Heart Failure & Shock
130	Peripheral Vascular Disorders With CC
131	Peripheral Vascular Disorders Without CC
209	Major Joint and Limb Reattachment Procedures of Lower Extremity
210	Hip and Femur Procedures Except Major Joint Age >17 With CC

DRG	DRG Title
211	Hip and Femur Procedures Except Major Joint Age >17 Without CC
236	Fractures of Hip and Pelvis
239	Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy
277	Cellulitis Age >17 With CC
278	Cellulitis Age >17 Without CC
294	Diabetes Age>35
296	Nutritional and Miscellaneous Metabolic Disorders Age >17 With CC
297	Nutritional and Miscellaneous Metabolic Disorders Age >17 Without CC
320	Kidney and Urinary Tract Infections Age >17 With CC
321	Kidney and Urinary Tract Infections Age >17 Without CC
395	Red Blood Cell Disorders Age >17
429	Organic Disturbances and Mental Retardation
468	Extensive O.R. Procedure Unrelated to Principal Diagnosis
541 (formerly 483)	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses With Major O.R. Procedure
542 (formerly 483)	Tracheostomy with Mechanical Ventilation 96+ Hours or Principal Diagnosis Except Face, Mouth and Neck Diagnoses Without Major O.R. Procedure

Section 1886(d)(5)(J)(i) of the Act recognizes that, in some cases, a substantial portion of the costs of care is incurred in the early days of the inpatient stay. Similar to the policy for transfers between two acute care hospitals, the transferring hospital in a postacute care transfer receives twice the per diem rate for the first day of treatment and the per diem rate for each following day of the stay before the transfer, up to the full DRG payment. However, three of the DRGs subject to the postacute care transfer policy exhibit a disproportionate share of costs very early in the hospital stay in postacute care transfer situations. For these DRGs, hospitals receive 50 percent of the full DRG payment plus the single per diem (rather than double the per diem) for the first day of the

stay and 50 percent of the per diem for the remaining days of the stay, up to the full DRG payment.

In previous years, we determined that DRGs 209 and 211 met this cost threshold and qualified to receive this special payment methodology. Because DRG 210 is paired with DRG 211, we include payment for cases in that DRG for the same reason we include paired DRGs in the postacute care transfer policy (to eliminate any incentive to code incorrectly in order to receive higher payment for those cases). The FY 2003 MedPAR data show that DRGs 209 and 211 continue to have charges on the first day of the stay that are higher than 50 percent of the average charges in the DRGs. Therefore, we proposed to continue the special payment methodology for DRGs 209, 210, and 211 for FY 2005 (69 FR 28274).

We received no comments on this proposal. Therefore, we will continue the special payment methodology for these DRGs in FY 2005.

Comment: One commenter requested that we require physicians and postacute care facilities to notify the original treating hospital that a patient has been treated within 3 days at another facility. The commenter indicated that this step would reduce the burden on hospitals in relation to the postacute transfer policy.

Response: While we appreciate the commenter's concern to reduce the burdens on hospitals, we are reluctant to impose this burden on other entities, especially since these other entities are not affected by the payment decisions that are involved.

B. Payments for Inpatient Care in Providers That Change Classification Status During a Patient Stay (§§412.2(b)(3) and 412.521(e)

Situations may occur in hospital inpatient care settings where a Medicare provider changes its Medicare payment classification status during a patient's stay, for example, an acute care hospital is reclassified as a LTCH. (We refer to the patients in these situations as "crossover patients.") Different Medicare payment systems apply to care furnished to Medicare beneficiaries during inpatient stays, depending on the classification status of the provider. For example, payments to an acute care hospital for inpatient services are made under the IPPS on a per discharge basis, using a DRG classification system. Payments to LTCHs that are classified under section 1886(d)(1)(B)(iv)(I) of the Act are made under the LTCH PPS on a per discharge basis using a LTC-DRG classification system. The main difference between a LTCH that is classified under section 1886(d)(1)(B)(iv)(I) of the Act and an acute care hospital is the average length of stay at the hospital. Specifically, section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as "a hospital which as an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

Questions have arisen as to how Medicare should pay for an inpatient stay in a hospital when the hospital changes its classification status during the course of the beneficiary's single hospital stay. Specifically, how should Medicare pay for a patient's stay when the first part of that stay is in the acute care hospital (before the hospital was reclassified as a LTCH and the second part of that stay is in the same hospital after it is reclassified as a LTCH. Although the situation may occur in other settings, this payment issue is most prevalent for services furnished to crossover patients in a newly established LTCH. The fact is that all new LTCHs that seek LTCH classification under section

1886(d)1)(B)(iv)(I) of the Act begin as other provider types, generally as acute care hospitals, and then these providers under the regulations at §412.23(e)(3) are required to meet the average length of stay criterion by showing that for the period of at least 5 months of a preceding 6-month period, the hospital's average Medicare inpatient length of stay is greater than 25 days. Once the entity meets the criteria under §412.23(e)(3), they are reclassified as LTCHs and are then paid under the LTCH PPS. It is for those patients who were admitted to the acute care hospital before the acute care hospital was reclassified as a LTCH and are discharged after the hospital is classified as a LTCH that we proposed to codify a revised crossover policy in the May 18, 2004 IPPS proposed rule.

To address payment for inpatient care for such crossover patients, we had issued instructions for hospital billing purposes (paper-based manual, Hospital Manual, HCFA Pub. 10, section 404, which has been replaced by the Medicare Claims Processing Manual, Pub. 100-4, Chapter 3, section 100.4.1) that were in effect prior to the implementation of the PPS for LTCHs (that is, prior to October 1, 2002). The manual instructed hospitals as follows: "The hospital must submit a discharge bill with the old provider number and an admission notice with the new provider number. The date of discharge and the date of admission are the same date, which is the first day of the new fiscal period. All subsequent billings are submitted under the new provider number."

It is important to note that at the time this manual provision was written, IPPS-excluded hospitals were reimbursed under the reasonable cost-based (TEFRA) payment system, not other prospective payment systems. Thus, under the manual

instructions, if a patient was in an acute care hospital and the hospital reclassified to a LTCH during the patient's stay, Medicare would then make payment for what was, in reality, only one episode of care as if it were two episodes. Specifically, the days of the stay while the facility was certified as an acute care hospital generated a full DRG payment under the IPPS; and the services provided from the time the facility was reclassified as a LTCH were paid under the TEFRA payment system. The patients were treated as if they were "admitted" to the "new" facility until the patient was actually discharged. We had proposed to revisit the issue of Medicare payment for crossover patients now that there has been a fundamental change in the Medicare payment system for LTCHs. That is, LTCHs are now being paid under a LTCH PPS which was effective for LTCHs for cost reporting periods beginning on or after October 1, 2002.

Under the LTCH PPS for crossover patients, under the existing Manual instructions, Medicare makes a full DRG payment under the IPPS to the acute care hospital for the "first portion" of the patient stay, and when the acute care hospital is reclassified as a LTCH, Medicare makes a second PPS payment under the LTCH PPS for the "second portion" of the stay. We believe that this results in excessive Medicare payments and results in the inappropriate use of the Medicare Trust Fund. We believe the result described above is contrary to a basic premise of a PPS, which is that a single PPS payment is adequate and appropriate reimbursement for the entire bundle of services that a hospital provides during the course of a patient's stay. We believe the care provided prior to and after the reclassification of a LTCH is really one bundle of services associated with a single hospitalization. The “discharge” from the acute care hospital and

"admission" to the LTCH has only been a "paper discharge" that was triggered solely by a change in the classification status of the hospital treating the patient. In the instant case, the beneficiary by mere coincidence, was an inpatient of the acute care hospital when it reclassified—the acute care hospital did not materially change the medical care it provided to the beneficiary during his/her single hospitalization because its classification as an acute care hospital ended on one day and changed to LTCH classification on the next day. Under the existing manual instructions, the hospital is receiving not one payment, but two PPS payments, for a bundle of services that should have been adequately and properly reimbursed by a single PPS payment.

As explained in the May 18, 2004 proposed rule (69 FR 28275), presently, if the DRG assigned to the "discharge" from the acute care hospital for a crossover patient falls within one of the DRGs covered by the postacute care transfer policy at §412.4(c) of the regulations, the provider will receive a payment under the postacute care transfer policy as if the patient, who in fact has not moved, was transferred to a postacute care provider. Payment under the postacute care transfer policy is triggered when a discharge bill with the old provider number and an admission notice with the new provider number is submitted and processed by the Medicare standard bill processing systems as a transfer. Because the patient is, in reality, at the "same" facility (an acute care hospital that has been reclassified as a LTCH) and is in one episode of care, we do not believe the application of the existing transfer policy is the appropriate methodology for dealing with the crossover patient situation described above. Under the postacute care transfer policy, the affect on payment is limited to a specific scenario; the payment to the transferring

hospital is only affected if the patient is discharged prior to the day before the geometric mean length of stay for the DRG. When the patient is discharged by the day before the geometric mean length of stay, the "discharging" acute care hospital will receive the equivalent of the full IPPS DRG payment and the LTCH hospital will also receive a full LTCH PPS payment. Therefore, although the transfer policy addresses discharges from an acute care hospital that occur prior to the geometric mean length of stay for each DRG, it does not address crossover patients where the hospital is reclassified after the patient has a length of stay of at least the geometric mean length of stay.

As we have stated previously in this discussion, we believe that it is inappropriate to continue to allow the current payment policy for crossover patients. An acute care hospital before reclassification as a LTCH may admit and treat patients with multicomorbidities that result in longer hospital stays than are characteristic of the patient census at a LTCH. Invariably, at the time the acute care hospital becomes a LTCH, there will be patients who were admitted to the acute care hospital and who remain in the facility when it is reclassified as a LTCH and are ultimately discharged from the LTCH. An acute care hospital's change in classification status to a LTCH should have no impact on the course of treatment that is already underway for the patient in what would now be a LTCH. Thus, since we believe the proposed patient is receiving one consistent course of treatment throughout this stay, in the May 18, 2004 proposed rule, we proposed to revise the present policy and allow for only one Medicare payment for the patient's entire stay. In proposing this change in policy, we proposed to provide for one Medicare payment where previously there would have been two payments made for one stay;

instead payment would be based on the PPS of the facility that is actually discharging the patient.

Under the proposed approach, we would include those days of care and costs incurred by the hospital for the crossover patient before the facility met the LTCH classification criteria, in determining payments to the LTCH for that patient under the LTCH PPS. Under this policy, for example, if an acute care hospital admits a patient on December 28 and the hospital reclassifies to a LTCH on January 1 when its cost reporting period begins, and the patient is physically discharged from the LTCH on February 5, one payment would be made for this entire stay (December 28 – February 5), and payment would be based on the LTCH-DRGs under the LTCH PPS. We are counting the patient's entire hospitalization (that is, all days and costs of the patient stay in the facility that occurred prior to and after reclassification) in determining the applicable payment under the LTCH PPS. This provision would also count all the days of the patient stay, that is prior to and after reclassification, as LTCH days for purposes of determining whether the facility continues to meet the average length of stay requirement for LTCHs. We believe this is consistent with the discretionary authority granted to the Secretary at section 1886(d)(1)(B)(iv)(I) of the Act for determining lengths of stay for LTCHs. Specifically, section 1886(d)(1)(B)(iv)(I) of the Act provides that a LTCH is a hospital that has an average length of stay (as determined by the Secretary) of greater than 25 days. Thus, the Secretary determines how a LTCH's average length of stay is to be determined. (We are also using the broad discretionary authority provided in section 1871 of the Act to not

count the days of the patient's stay in the acute care hospital prior to reclassification as acute care days.)

In addition, we are using the broad authority in section 1871 of the Act to not pay for the days of the patient's stay in the acute care hospital as acute care days. Section 1871 authorizes the Secretary to promulgate regulations that are necessary to carry on the administration of the Medicare program. In addition, as stated in the proposed rule, we believe counting all days for the patient's stay and applying them in determining the PPS at the hospital that actually discharges the patients even though part of the stay was in a prior cost reporting period is consistent with the policy as recently revised at §412.23(e)(3) of the regulations, which provides that if a LTCH patient is admitted in one cost reporting period and discharged in a second cost reporting period, all of the days of the patient's stay even those from prior fiscal years are counted in the cost reporting period in which the patient is discharged. In this example of the crossover patient, including the days in December may result in a full LTC-DRG payment rather than a lower payment possible under the short-stay outlier policy (§412.529) based solely on the length of the stay of the patient at the LTCH once it was reclassified. (Under the short-stay policy, we would adjust (lower) the Federal prospective payment if the payment is for a length of stay that is up to and including five-sixths of the geometric average length of stay for the LTC-DRG assigned to the case.)

While this final rule specifically addresses the situation of a crossover patient that is in an acute hospital that reclassifies as a LTCH during the course of the patient's stay, we believe the policy may be equally applicable to other crossover situations. For

example, an acute care hospital may meet the requirements to be paid as a rehabilitation hospital (under IRF PPS) and there could be rehabilitation patients who were admitted to the acute care hospital who were not discharged from the hospital until after the facility was designated as an IRF. However, at this time, we are not making a change to the existing payment policy in situations other than the LTCH crossover patient. We have only addressed the LTCH crossover patient since, based on the statutory and regulatory qualifying criteria, every LTCH must first be certified as a hospital before it can meet the LTCH criteria. Therefore, it is inevitable that there will be crossover patients in the newly classified LTCH. However, the same is not true for other hospital certifications. For example, a rehabilitation hospital can be certified as an IRF, without first being certified and paid as an acute care hospital for inpatient services. However, we intend to revisit the existing crossover patient policy as it affects other crossover situations in the future and would welcome receiving the industry's views on how Medicare payment policy should address those situations.

Accordingly, we are finalizing our proposed revisions to §412.2(b) of the regulations to add a new paragraph (3) which would be applicable to acute care hospitals, and to add a new paragraph (e) to §412.521 which would be applicable to LTCHs. The additions will specify that Medicare would make only one payment for a crossover patient to the LTCH that is discharging the patient based on the entire stay, both prior to the change to LTCH status and after the change. In order to implement the final policy, we will create systems adjustments that will enable the single claim generated by the discharging provider to include patient days under the initial provider number. We note

that our final provisions to define and pay for crossover patient stays as one episode of care based on the PPS of the discharging provider are consistent with existing regulations. (Existing regulations have established that payment under the per discharge PPS constitutes "payment-in-full" for acute care hospitals and for LTCHs.

Comment: The commenters agreed that hospitals should not be receiving two payments for crossover patients, and stated that our proposed change in policy to pay for only one stay appears reasonable. Moreover, they suggested that we consider applying this policy to all conversions, including acute care to rehabilitation, rehabilitation to LTCH, and LTCH to rehabilitation so that payment rules could be consistent with those presented in this final rule.

Response: We appreciate the commenters' support of our policy change to allow only one payment in crossover situations. As we stated above, we believe this policy could be equally applicable in other crossover situations, and will be revisiting the crossover policy as it affects other similar situations in the future.

Therefore, we are proposing to finalize our proposal without modification.

C. Geographic Reclassifications - Definitions of Urban and Rural Areas (§412.63(b), §412.64(b), and 412.102)

1. Revised MSAs

As we discussed in section III.B. and III.G. of the May 18, 2004 proposed rule and of this final rule, we proposed how we would implement OMB's revised standards for defining MSAs and our plan to use the New England MSAs established by OMB. These proposals relate to our policies in established regulations under §412.63(b) governing geographic classification of hospitals for purposes of the wage index and the standardized amounts in determining the Federal rates for inpatient operating costs. In this section, we define the geographic areas for purposes of reclassification of hospitals. Therefore, consistent with our proposed changes to reflect the new definitions of CBSAs based on the Census 2000 data, effective for discharges occurring on or after October 1, 2004, in the May 18, 2004 proposed rule (69 FR 28277), we proposed to revise §412.63(b) and add a new §412.64(b) to reflect the existing geographic classification definitions.

We note that commenters did not expressed objections to this specific proposal. However, commenters expressed concern regarding various aspects of our proposal to adopt the new definition of CBSAs. We address these comments throughout this final rule.

2. Transition Period for DSH Payments to Redesignated Hospitals

Section 412.102 of the regulations provides for a 3-year transition to the standardized amount and DSH adjustment payments to a hospital redesignation from urban to rural.

Comment: One commenter asked CMS to clarify whether the transition period that allows urban hospitals reclassified as rural to maintain their assignment to the MSA where they are currently located for 3 years applies to both the wage index and the DSH payment adjustment.

Response: As described in §412.102, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between the urban DSH payments applicable to the hospital before its designation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the urban DSH payment applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural.

D. Equalization of Urban and Rural Standardized Amounts (§412.63(c) and §412.64)

Sections 1886(d)(2)(D) and (d)(3) of the Act previously required the Secretary to compute two average standardized amounts for discharges occurring in a fiscal year: one for hospitals located in large urban areas and one for hospitals located in other areas. In addition, under sections 1886(d)(9)(B)(iii) and (d)(9)(C)(i) of the Act, the average

standardized amount per discharge was determined for hospitals located in large urban and other areas in Puerto Rico. In accordance with section 1886(b)(3)(B)(i) of the Act, prior to April 1, 2003, the large urban average standardized amount was 1.6 percent higher than the other area average standardized amount. The two standardized amounts are currently equal, as discussed in the following paragraphs.

Section 402(b) of Pub. L. 108-7 required that, effective for discharges occurring on or after April 1, 2003, and before October 1, 2003, the Federal rate for all IPPS hospitals would be based on the large urban standardized amount. Subsequently, Pub. L. 108-89 extended section 402(b) of Pub. L. 108-7 to discharges occurring on or after October 1, 2003, and before April 1, 2004. Finally, section 401(a) of Pub. L. 108-173 required that, beginning with FY 2004 and thereafter, an equal standardized amount is to be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. This provision in effect makes permanent the equalization of the standardized amounts at the level of the previous standardized amount for large urban hospitals. Section 401(c) also equalizes the Puerto Rico-specific urban and other area rates.

Accordingly, in the May 18, 2004 proposed rule (69 FR 28277) and in this final rule, we are providing for a single national standardized amount and a single Puerto Rico standardized amount for FY 2005 and thereafter, as discussed in detail in the Addendum to this final rule. We are revising existing §412.63 that includes the provisions related to computation of the standardized amount to make it applicable to fiscal years through FY 2004 and establishing a new §412.64 that will include the provisions applicable to the

single national standardized amount applicable for FY 2005 and subsequent years. Similarly, we are revising existing §412.210 for Puerto Rico to make it applicable to fiscal years through FY 2004 and adding a new §412.211 for FY 2005 and subsequent years for the Puerto Rico standardized amount. We are also make conforming changes to various other sections of the regulations to reflect the single standardized amount for the States and for Puerto Rico.

The comments received in response to this specific proposal concurred with the proposal on the basis that it is consistent with the implementation of recent legislative changes.

E. Reporting of Hospital Quality Data for Annual Hospital Payment Update (§412.64(d))

1. Background

Section 501(b) of Pub. L. 108-173 amended section 1886(b)(3)(B) of the Act to add a new subclause (vii) to revise the mechanism used to update the standardized amount for payment for inpatient hospital operating costs. Specifically, the amendment provides that the update percentage increase (also known as the market basket update) for each of FYs 2005 through 2007 will be reduced by 0.4 percentage points for any "subsection (d) hospital" that does not submit data on a set of 10 quality indicators established by the Secretary as of November 1, 2003. (The statutory reference to a "subsection (d) hospital" restricts the application of this provision to hospitals paid under the IPPS. Therefore, the provision does not apply to hospitals and hospital units excluded from the IPPS, nor to payments to hospitals under other systems such as the outpatient hospital PPS.) The statute also provides that any reduction will apply only to the fiscal

year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year. This measure establishes an incentive for IPPS hospitals to submit data on the quality measures established by the Secretary.

In the May 18, 2004 proposed rule (69 FR 28277), we proposed to implement the provisions of section 501(b) as described at the CMS website: **www.cms.hhs.gov/quality/hospital**.

At a press conference on December 12, 2002, the Secretary of HHS announced a series of steps that HHS and its collaborators are taking for public reporting of hospital quality information. These collaborators include the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the National Quality Forum, the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor-Congress of Industrial Organizations and the Agency for Healthcare Research and Quality, as well as CMS, QIOs, and others.

CMS began the public reporting initiative in July 2003 with a professional website that provides data intended for health care professionals. The professional website will be followed by a consumer website. The information on the consumer website will include the data from the professional website but in an easy-to-use format for consumers. It is intended to be an important tool for individuals to use in making decisions about their health care coverage. This information will assist beneficiaries by

providing comparison information for consumers who need to select a hospital. It will also serve as a way of encouraging hospitals to adopt quality improvement strategies.

The 10 measures that were employed in this voluntary initiative as of November 1, 2003, are:

- Heart Attack (Acute Myocardial Infarction)

  Was aspirin given to the patient upon arrival to the hospital?

  Was aspirin prescribed when the patient was discharged?

  Was a beta-blocker given to the patient upon arrival to the hospital?

  Was a beta-blocker prescribed when the patient was discharged?

  Was an ACE inhibitor given for the patient with heart failure?

- Heart Failure

  Did the patient get an assessment of his or her heart function?

  Was an ACE inhibitor given to the patient?

- Pneumonia

  Was an antibiotic given to the patient in a timely way?

  Had a patient received a pneumococcal vaccination?

  Was the patient's oxygen level assessed?

These measures have been endorsed by the National Quality Forum (NQF) and are a subset of the same measures currently collected for the JCAHO by its accredited hospitals. Many hospitals are currently participating in the Department's National Voluntary Hospital Reporting Initiative (NVHRI) and are already submitting data to the QIO Clinical Warehouse. The Secretary adopted collection of data on these 10 quality

measures in order to: (1) provide useful and valid information about hospital quality to the public; (2) provide hospitals a sense of predictability about public reporting expectations; (3) begin to standardize data and data collection mechanisms; and (4) foster hospital quality improvement.

2. Requirements for Hospital Reporting of Quality Data

For the hospital reporting initiative for the Medicare annual payment update provided for under section 501(b) of Pub. L. 108-173, we will be collecting data on the 10 clinical measures for all patients. We refer to this program as the Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU) program to distinguish it from the continuing NVHRI.

The procedures for participating in the RHQDAPU can be found on the QualityNet Exchange at the website: **www.qnetexchange.org** in the "Reporting Hospital Quality Data for Annual Payment Update Reference Checklist." This checklist also contains all of the forms to be completed by hospitals participating in the program. In order to participate in the RHQDAPU, hospitals must follow the following steps:

- The hospital must identify a QualityNet Exchange administrator who follows the registration process and submits the information through the QIO. This must be done, regardless of whether the hospital uses a vendor for transmission of data.

- All participants must first register with the QualityNet Exchange, regardless of the method used for data submission. If a hospital is currently participating in the voluntary reporting initiative, re-registration on the QualityNet Exchange is unnecessary. However, registration includes completion of the RHQDAPU Notice of Participation

form. All hospitals must send the RHQDAPU form to their QIOs no later than August 1, 2004, for the FY 2005 update.

- The hospital must collect data for all 10 measures and submit the data to the QIO Clinical Warehouse either using the CMS Abstraction & Reporting Tool (CART), the JCAHO Oryx Core Measures Performance Measurement System (PMS), or another third-party vendor who has met the measurement specification requirements for data transmission to the QualityNet Exchange. The QIO Clinical Warehouse will submit the data to CMS on behalf of the hospitals. The submission will be done through QualityNet Exchange, which is a secure site that voluntarily meets or exceeds all current Health Insurance Portability and Accountability Act (HIPAA) requirements, while maintaining QIO confidentiality as required by law. The information in the Clinical Warehouse is considered QIO data, and therefore, is subject to the stringent confidentiality regulations in 42 CFR Part 480.

Hospitals must begin the submission of data under the provisions of section 1886(b)(3)(B)(vii)(II) of the Act, as added by section 501(b) of Pub. L. 108-173, by July 1, 2004. Because section 501(b) of Pub. L. 108-173 grants a 30-day grace period for submission of data with respect to FY 2005, in the May 18, 2004 proposed rule, we proposed to allow hospitals until August 1, 2004, for completed submissions to be successfully accepted into the QIO Clinical Warehouse. Hospitals would be required to submit data for the first calendar quarter of 2004 discharges in order to meet the requirements for the FY 2005 payment update. Hospitals participating in the NVHRI that submitted the required 10 measures for the fourth calendar quarter of 2003 by the

CMS-established deadline of May 15, 2004, and that met the registration requirements for the market basket update, would be given until August 15, 2004, to submit data for the first calendar quarter of 2004. There will be no chart-audit validation criteria in place for the FY 2005 payment update beyond the CART edits, currently in force, applied to data entering the QIO Clinical Warehouse. In addition, we proposed that we would estimate the minimum number of discharges anticipated to be submitted by a hospital using Medicare administrative data. We proposed to use this anticipated minimum number to establish our expectations of the number of cases for each hospital. Hospitals that do not treat a condition or have very few discharges would not be penalized and would receive the full annual payment update if they submit all the data they do possess. New hospitals should begin collecting and reporting data immediately and complete the registration requirements for the market basket update. The same standards that are applied to established hospitals would be applied to new hospitals when determining the expected number of discharges for the calendar quarters covered for each fiscal year.

In the May 18, 2004 proposed rule, we stated that the annual payment updates would be based on the successful submission of data to CMS via the QIO Clinical Warehouse by the established deadlines. Hospitals may withdraw from RHQDAPU at any time up to August 1, 2004. Hospitals withdrawing from the program would not receive the full market basket update. Instead, they would receive a 0.4 percentage points reduction in the update. By law, a hospital's actions each fiscal year will not affect its update in a subsequent fiscal year. Therefore, a hospital must meet the requirements for

RHQDAPU each fiscal year the program is in effect, and failure to receive the full update in one fiscal year will not affect its update in a succeeding fiscal year.

Comment: All of the commenters who addressed our proposed plans to implement section 501(b) of Pub. L. 108-173 supported hospitals providing quality performance data. Most of the commenters also mentioned that it was important for CMS and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to align their respective quality measures and procedures to make collection and submission of this data as easy as possible.

Response: We are working with the JCAHO to accomplish this alignment on the current quality measures. We are also setting up a process to align any and all future measures that may be required by either organization. In addition, we have taken the necessary steps to ensure that this alignment is reflected in our chart audit validation process. We are committed to making the submission of the quality measures as seamless as possible for submitting either the core measures defined by JCAHO or the quality measures contained in the CMS Abstraction and Reporting Tool (CART).

Comment: Many of the comments expressed concerns about the proposed chart audit validation procedures.

Response: We believe that all of the data to be collected by CMS in its Clinical Warehouse must be timely, complete, and accurate. To accomplish this, we proposed reabstraction of data submitted to the Warehouse using the Clinical Data Abstraction Contractors (CDAC). The CDAC will request paper charts from each hospital that has submitted data to the warehouse and reabstract the quality measures using the CMS

CART. Based upon the percent agreement rate at the element level (that is, the variables abstracted from the chart and used to construct each measure), hospitals achieving an 80-percent agreement with the CDAC abstraction will be considered as providing valid data. We will randomly sample charts for each hospital each quarter and aggregate across all charts to calculate the percent agreement. Several comments were concerned about our process for requesting copies of the charts. Under the proposed rules, hospitals are allowed 30 days to provide the charts. A followup request is sent, if necessary, 15 days following the initial request. Charts not received by the 31st day are considered missing and a zero-percent agreement is assigned to that missing chart.

Comment: One commenter asked that we notify the hospital through our QNet Exhange website to alert the hospitals that a request for charts has been sent.

Response: We agree that this alert would be helpful and have included this in future enhancements to our processes.

Comment: Several commenters asked that we allow hospitals to submit additional information should the initial results be unfavorable.

Response: At this time, we believe allowing hospitals to submit additional information would create an untenable workload for our contractors. We have approximately 4,000 hospitals submitting data in response to section 501(b) of Pub. L. 108-173. In addition, we are collecting data from other hospitals that are participating in the NVHRI. We estimate that we will be receiving data from as many as 4,500 hospitals. We also believe it is important to keep the turnaround time for processing the validation records as short as possible. It is important both for our reporting requirements and for

the hospitals to receive the validation results as soon as possible. To allow extensions for providing data on a piecemeal basis would extend the process beyond reasonable time limits. The CDAC process for requesting charts has been in place for over 6 years. We have been collecting both quality data and administrative data from all hospitals in the country during that time. We believe our process is functioning well, and we take steps to ensure that the chart requests are properly addressed and sent in a timely manner. We believe that hospitals understand the importance of these requests and will provide the charts in a timely manner.

Comment: Many of the commenters expressed concern about reconciling differences between the hospital abstracted and CDAC abstracted data. Several commenters asked that we allow hospitals to supplement the submitted medical charts during an appeal process.

Response: We have devised an appeal process that allows a hospital to review the validation results with their local QIO. If, after this review, the QIO agrees with the hospital's interpretation, the appeal is forwarded to the CDAC for review and correction, if necessary. We do not believe we can allow hospitals to supplement the submitted medical charts during this appeal process. The original request asks for the complete chart, and we expect to receive all the information and documentation necessary to support the abstraction of the quality measures. Additional documentation puts the CDAC abstractors at a disadvantage and extends the time to complete the validation process. We understand that human error is possible and this is why we have set the required percent agreement at less than 100 percent.

Comment: Other commenters recommended that the adjudication of any differences noted between the hospital abstraction and the CDAC abstraction should be subject to third party review and verification.

Response: We believe that adopting this recommendation would create a lengthy and complicated process. We also believe that abstraction of the clinical data to calculate the quality measures is a straight-forward process. The information requested by each question in the abstraction tool is either there, as stated, or it is not. These data are not qualitative in their derivation and not subject to human opinion. Also, our stated policy for ensuring that the data in the warehouse meet our requirements for consistency and accuracy is that the CDAC abstraction using the CART tool constitutes the correct data, or gold standard. We have devoted a great deal of resources to ensuring that the CDAC abstraction process is consistent and accurate through our training and internal quality assurance. We consistently achieve inter rater reliability rates approaching 100 percent in the CDAC.

Comment: All of the commenters who addressed the sampling process asked that we reduce the percent agreement from our current 80 percent to at least 60 percent initially and gradually raise the rate to 80 percent.

Response: We do not believe that this is necessary or desirable for two reasons. First, we believe that the 80 percent level is a minimum level of agreement that we can accept at any time. This means that four out of five comparisons are the same. A 60 percent agreement would mean that only three out of five comparisons are the same. We

do not believe this level of agreement is acceptable to meet our goal of ensuring submission of timely, complete, and accurate data.

Second, for the FY 2005 annual payment update, we do not have a chart audit validation requirement. We realize that hospitals need time to understand the chart audit validation process and learn how to provide accurate and reliable data. We also need time to implement and test our procedures to ensure that we meet our goals of timely and accurate submission of data and provide a fair opportunity to hospitals to become familiar with the process. In support of the NVHRI program, we have started the validation process on data submitted to the warehouse beginning with calendar year 2003. We are providing feedback to the participating NVHRI hospitals that have deposited data in the warehouse and have instructed the QIOs to assist hospitals in correcting any issues or problems that are identified. The first data submission requirement for section 501(b) is the first calendar quarter of 2004. We will conduct chart audit validation on these data and provide feedback to all of the hospitals. The results of this first quarter will not affect annual payment update determinations for FY 2005 or subsequent fiscal years. We believe that this test period will provide hospitals the necessary lead time to improve their data abstraction processes and provide them with the opportunity to achieve the necessary 80 percent level of agreement prior to institution of the validation requirement for the annual payment update for FY 2006. By allowing the hospitals a penalty free period to meet the 80 percent level we maintain consistent expectations regarding the submission of accurate data and reduce any confusion that a constantly changing goal might introduce.

Comment: One commenter suggested we modify our assessment of percent agreement to differentiate between transcription errors and errors of omission. This commenter contended that the goal of the validation process is to determine if the standard of care has been met.

Response: We disagree. The goal of the chart audit validation process is to ensure that the hospital is submitting accurate data. In order to calculate quality measures, which are used to determine the standard of care, we need to have complete and accurate data. Errors of omission and transcription errors both contribute to errors in calculation of quality measures. Therefore, we believe it is important to include both errors in calculating the percent agreement. We agree that it is important to differentiate between these errors in order to provide feedback to the hospitals. The process we have in place to provide this feedback gives each hospital the detail abstraction results from the CDAC so that staff may determine the types of errors and take appropriate action.

In support of our goal of obtaining complete, timely and accurate data, the chart audit validation process will be applied to all data submitted to the clinical data warehouse. Several commenters argued that the validation in support of section 501(b) should only apply to the 10 quality measures required to be submitted. While such a restriction would not be in support of our policy on the integrity of the data in the clinical warehouse, we understand that receiving the full annual payment update is only subject to submission of the 10 required measures. To varying degrees, all of the data contained in the clinical warehouse are used to inform different parties on the quality of care delivered to patients. Therefore, we plan to apply the validation results in a two-step process. For

purposes of the annual payment update, the validation will be restricted to the 10 measures. For purposes related to publishing data, we will apply the validation results to all of the measures submitted. This second validation will not affect the annual payment update.

Comment: Several commenters made suggestions on the quarterly sample size used to assess the percent agreement. One commenter recommended that we allow hospitals to submit additional records if the hospitals fail the initial validation. A second commenter suggested that we request a larger number of records and allow the hospital to select a subset to forward to the CDAC.

Response: In order to maintain the integrity of the chart audit validation process, the selection of records must be random and independent of the hospital's control to ensure that the records being reviewed are representative of the data submitted by the hospital. We do not believe we can compromise the validity of the audit procedure by giving up control of the cases selected.

Comment: Several commenters suggested that we consider optional standards for small volume hospitals. They contended that small differences in data validation can produce large percent differences that may adversely affect validation rates.

Response: Our plans call for calculating the percent agreement based upon the individual variables abstracted from each chart aggregated across all of the charts abstracted. That is, we will pool the variables to create a denominator and then calculate the percent agreement. This approach creates a percent agreement that is independent of the number of cases a hospital may treat. The problem for small volume hospitals is that

they may not generate enough cases to meet our minimum sample sizes. Our chart audit validation rules would have us then request all of the charts generated by these small volume hospitals and we would, in essence, be evaluating the "universe" of data for these hospitals. In such a case, we would be calculating the actual percent agreement for that hospital, rather than estimating this percent as in a hospital where we have sampled the cases. It is our intent to monitor the demands our processes will have on small volume hospitals and to consider modifications so as to not over burden these hospitals. However, we do believe that Medicare beneficiaries are entitled to the same high level of quality care in all hospitals providing services and that all hospitals should be subject to a similar level of assurance by CMS.

Comment: Several commenters requested that we engage in a series of training programs and briefings to educate the hospitals about the validation process and, in particular, provide information on the variables used in calculating the percent agreement.

Response: We agree that this is an important aspect of this process and we have instructed the QIOs to assist hospitals to understand the results of the chart audit validation as well as begin to educate the hospitals on the process itself. We have published on our QNet Exchange website all of the documentation that supports the chart audit validation process, including the list of variables included in our calculations. However, we will continue to explore better ways to educate hospitals, through our QIOs, on all of our processes.

Comment: Several commenters urged us to allow reasonable variation in abstracted data, especially for the variables containing continuous data such as the timing data. One commenter stated that our allowed variances seemed to be arbitrary.

Response: We note that we have published the variation allowed for each of these continuous data variables. Our decisions on how much variation to allow in calculating these timing measures are the result of input from our clinical experts. Each variable was carefully considered in this context. For example, the variation allowed for the pneumonia and surgical infection timing is based on the fact that the measures derived from those values are measured in hours. In contrast, the acute myocardial infarction indicators are measured in minutes so the timing variables need to be more accurate. We will conduct research on this issue as we collect data to test and refine our theoretical expectations against the empirical data.

Comment: One commenter urged us to streamline and automate our registration and attestation processes so that potential administrative problems do not prevent eligible hospitals from receiving their annual payment update.

Response: We agree that this is an important issue. It is our policy to guard against just such a situation. We will be upgrading our systems, with input from the hospital community, to minimize this potential problem.

Comment: One commenter raised concerns about the accessibility of the clinical warehouse data through our QNet Exchange server. The commenter suggested that other users, such as corporate quality assurance staff employed by a hospital system and not necessarily the specific hospital, as well as staff from JCAHO accredited ORYX vendors

should be able to see a hospital's data to assist that hospital in its data collection and reporting and quality assurance activities.

Response: Under current policy, only staff from a specific hospital are allowed to access that hospital's data through a system of user registration and password protections. This is a result of the laws and regulations that govern the data our QIOs maintain in the Clinical Warehouse. Specifically, regulations prohibit QIOs from releasing data that identifies individual hospitals without first notifying the hospitals and allowing a 30-day response period. In principle, we agree with the suggestion that other users, such as corporate quality assurance staff employed by a hospital system and not necessarily the specific hospital, as well as staff from JCAHO accredited ORYX vendors should be able to see a hospital's data (not patient-identified data) to assist that hospital in its data collection and reporting and quality assurance activities. We believe we can resolve the legal issues satisfactorily and we anticipate implementation of mechanisms to allow this type of access in the Fall of 2004.

Comment: Several commenters expressed a concern that the designation of the 10 quality indicators in section 501(b) fixes, by law, measures that in fact are subject to change depending upon medical science and the evolving field of quality measurement. While realizing that CMS cannot change the required data by regulation, the commenters nonetheless believed that some accommodation should be considered for allowing these measures to be modified or changed as the knowledge in the field of quality measurement changes.

Response: We agree that the field of quality measurement is a changing landscape and that, sometimes, accommodations need to be made. However, we would point out that section 501(b) contains a sunset clause for these 10 measures. Submission of the data on the 10 quality measures is only required for FYs 2005, 2006, and 2007 in order for a hospital to receive the full annual payment update. Otherwise, we are required to enforce the law as written.

Comment: Several commenters made note of our attempts to estimate the minimum number of cases that CMS expects from each hospital. They were particularly concerned that this number will not be an accurate representation of the number of cases a hospital may treat.

Response: The estimate of the minimum number of cases that we are providing is based upon the average number of Medicare discharges per quarter found in the administrative data for each hospital over the last 2 years. In contrast, section 501(b) requires that the submitted data include all payers and not just the Medicare beneficiaries. We recognize that this distinction is a shortcoming in our calculation of the minimum number of cases. However, we do not have any data from which to estimate how many non-Medicare patients a hospital treats. Our intent is to monitor the submissions from the hospitals and to update our estimates as we gain experience, taking into account sampling where appropriate.

Comment: One commenter believed it was important that its organization participate in the formulation of quality measures, given the importance attached to these measures.

Response: All of the measures CMS currently collects, as well as those measures collected by the JCAHO, are endorsed by the National Quality Forum (NQF). This organization uses a consensus process to develop quality measures for all health care settings. Its deliberations include all aspects of a quality measure, including current standards of practice, documentation requirements, and the scientific research supporting the measure. Membership is open to all interested parties. These organizations can contact the NQF and participate through this mechanism. The 10 measures are required by statute and have been endorsed by the NQF.

Comment: One commenter was concerned about new hospitals that are not able to meet the registration and reporting requirements simply because they were not in existence during the first quarter of calendar year 2004, but will be operating throughout FY 2005.

Response: We agree that new hospitals should not be disadvantaged by their inability to report data prior to opening. Therefore, we will hold these hospitals harmless with respect to the update. The instructions we have given the QIOs are to have these new hospitals register with QNet Exchange as soon as possible; complete the pledge to participate in the annual payment update; complete the form that tells CMS the hospital has zero discharges for the first quarter of calendar year 2004, and begin submitting the required data as it becomes available in the future.

Comment: Several commenters were concerned about our intent to publish the quality measure data that we receive through section 501(b). These commenters focused

on the validation of the published data and on the use of composite hospital level scores, as opposed to individual measures.

Response: We have stated that we intend to use validation results as part of the criteria for publishing the hospital data. This is still our intent. However, we recognize that situations may change and we may have to modify this decision. It is our practice, in this situation, to notify the community should this decision change. As to the use of a composite score at the hospital level, we have not made our final decisions about the format for publishing these data, but we are considering the use of composite scores.

3. Submission of Hospital Data for FYs 2006 and 2007

For FYs 2006 and 2007, we will require hospitals to submit data quarterly, starting August 15, 2004. Eligibility for the full annual payment update will be based on the most recent four quarters of data. These data would be submitted on the same schedule for data transmission currently in force for CART data. That is, data must be submitted to the QIO Clinical warehouse no later than 15 calendar days after the fourth month following the end of the calendar quarter. This schedule is available at **http://www.qnetexchange.org**. We will establish validation requirements for submitted data for FYs 2006 and 2007. Submissions would, at a minimum, need to be accurate, timely, and complete. That is--

- The hospital-submitted data must meet minimum levels of reliability through chart audit re-abstractions over all topics. At the data element level, there must be an 80 percent agreement between the original abstraction and the re-abstraction using the CART tool.

- The submitted data must be on schedule, pass all warehouse edits, and be successfully accepted into the warehouse.

- Completeness of submitted data will be assessed to ensure the number of submitted cases corresponds to the number of bills submitted by the hospital to CMS.

We are planning to publish the most recent 12 months of discharge data (4 quarters) for all data accepted into the warehouse and passing all validation requirements. For FY 2005, we will publish as much data as we have available. Hospitals will have the opportunity to review the information prior to posting on the CMS website. However, there will be no opportunity to withhold the publication of the information. The preview will only be to correct obvious errors. Comments regarding the requirements for the submission of quality data for FY 2006 and FY 2007 are presented above in conjunction with the comments regarding the general requirements for hospital reporting of quality data.

4. Regulation Change

In the May 18, 2004 proposed rule (69 FR 28279), we proposed to establish a new §412.64(d)(2) to provide that, for FYs 2005, 2006, and 2007, the applicable percentage change is reduced by 0.4 percentage points in the case of any subsection (d) hospital that does not submit data to CMS on the 10 quality indicators established by the Secretary as of November 1, 2003. Any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year.

Comment: MedPAC reiterated its support of the concept of tying payment to quality performance. MedPAC did question the need to financially reward or penalize hospitals just for submitting data. It also noted that the statute requires hospitals to report on the quality measures that were a part of the NVHRI as of November 2003. MedPAC recommended that the Secretary should have the authority to update the measures on a regular basis, adding or retiring measures as clinical guidelines change or when providers reach high levels of performance in certain areas.

Response: While payment for performance may be an ultimate goal, the current law is specific in tying the annual payment update data to reporting only. We point out that hospitals, as a condition of participation and payment, are required to submit charts of Medicare patients for review upon the request of the program. The failure to do so may result in a denial of payment for that discharge. We appreciate MedPAC's recommendation that the Secretary should have the authority to update the measures that are reported. As MedPAC's comment implies, adoption of this recommendation would require a statutory change.

Comment: One commenter asked whether the Medicare intermediaries would receive specific instructions about how to implement this differential update for hospitals that do and do not submit quality data.

Response: As we indicated in the proposed rule, we will be modifying our payment software to apply the correct updates to hospitals, depending on whether they submit the requisite data on the 10 quality indicators. The software will automatically

provide payment based on the fully updated rate to hospitals that have submitted data on the requisite quality measures.

In this final rule, we are adopting, as final, the new §412.64(d)(2) as proposed. This new section of the regulations provides that, for FYs 2005, 2006, and 2007, the applicable percentage change is reduced by 0.4 percentage points in the case of any subsection (d) hospital that does not submit data to CMS on the 10 quality indicators established by the Secretary as of November 1, 2003. Any reduction will apply only to the fiscal year involved, and will not be taken into account in computing the applicable percentage increase for a subsequent fiscal year.

We show the different standardized amounts that apply to hospitals that submit the requisite quality data, and to hospitals that do not, in the Addendum to this final rule.

F. Revision of the Labor-Related Share for the Hospital Wage Index (§412.64(h))

As discussed in section III. of the preamble of this final rule, section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related. The portion of hospital costs attributable to wages and wage-related costs is referred to as the labor–related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index. In the past, we have defined the labor-related share for prospective payment acute care hospitals as the national average

proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share for the acute care hospital inpatient prospective payment system has been calculated as the sum of the weights for wages and salaries, fringe benefits, nonmedical professional fees, contract labor, postage, and labor-intensive services. For FY 2004, the labor share of the hospital wage index was established at 71.066 percent.

Section 403 of Pub. L. 108-173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must use 62 percent as the labor-related share unless application of this percentage "would result in lower payments than would otherwise be made." However, this provision of Pub. L. 108-173 did not change the legal requirement that the Secretary estimate "from time to time" the proportion of hospitals' costs that are "attributable to wages and wage-related costs." In fact, section 404 of Pub. L. 108-173 requires the Secretary to develop a frequency for revising the weights used in the hospital market basket, including the labor share, to reflect the most current data more frequently than once every 5 years. Section 404 further requires us to include in the final IPPS rule for FY 2006 an explanation of the reasons for, and options considered, in determining such frequency.

Under section III. of this final rule (and in the May 18, 2004 proposed rule), we discuss our implementation of section 1886(d)(3)(E) of the Act, as amended by section 403, as it applies to the development of the FY 2005 wage index. In this section IV.F. of the preamble, we are incorporating the provisions of section 403 of Pub. L. 108-173 under a new §412.64(h). Specifically, we are specifying that CMS will adjust the

proportion of the Federal rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined by the regulations) of the hospital compared to the national average level of hospital wages and wage-related costs. The wage index will continue to be updated annually. In addition, we are specifying that CMS will determine the proportion of the Federal rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual regulation updating the system of payment for inpatient hospital operating costs. However, CMS will employ 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in the preceding sentence.

We did not receive any public comments on our proposed implementation of section 403 of Pub. L. 108-173. Therefore, we are adopting as final, the proposed addition of the section 403 provisions in §412.64(h) of the regulations.

G. Wage Index Adjustment for Commuting Patterns of Hospital Employees (§412.64(i))

As discussed in section III.H.3.e. of this final rule (and in the May 18, 2004 proposed rule), section 505 of Pub. L. 108-173 established new section 1886(d)(13) of the Act. We refer readers to section III.H.3.e for a discussion of this adjustment.

We are incorporating the provisions of section 505 of Pub. L. 108-173 in the regulations by adding a new §412.64(i).

To identify "qualifying counties," we use commuting data compiled by the U.S. Census Bureau based on a special tabulation of Census 2000 journey-to-work data. This information is gathered from responses to the Census long-form (sample) questions on where people worked. The resulting county-of-residence by county-of-work commuter flow file uses 108 Industrial Structure codes, developed by the Bureau of Economic Analysis. We limited the data set to those employees working in the category designated "hospitals." (BEA code 622000).

In order to be considered a qualifying county, the hospitals in such county must meet the criteria listed §412.64(i). First, the difference between the county's wage index and the weighted wage index of the surrounding higher wage index areas to which hospital workers commute must be greater than zero. Thus, any increase in the wage index resulting from this provision that is greater than zero percent would be recognized for meeting this criterion. Second, the county must meet the minimum out-migration threshold of 10 percent (the minimum out-migration percentage permitted by statute). Third, the average hourly wage of the hospitals located in the county must equal or exceed the wage index of the labor market area in which the county is located.

As stated in section III.H.3.e. of this preamble, for this third criterion, we will use the average of hospitals' 3-year average hourly wage for all hospitals in a given county. We compared this county average hourly wage to the 3-year average hourly wage for the labor market area where the county is located. We are using the 3-year average hourly

wage because we believe it gives a better estimate for the wages paid by a given hospital over a period of time.

In addition, as stated in section III.H.3.e of this preamble that we will apply the out-migration adjustment in an automatic manner. All hospitals located in qualifying counties will automatically receive the increase in wage index, unless the hospital has already been reclassified to another geographic area, including reclassifications under section 508 of Pub.L. 108-173. If a hospital has been redesignated under section 1886(d)(8)(B) of the Act, reclassified under section 1886(d)(10) of the Act, or reclassified under section 508 of Pub.L.108-173, we assume that the hospital wishes to remain reclassified/redesignated and does not want to receive the out-migration adjustment. This wage index increase will be effective for a period of 3 fiscal years, FY 2005 through FY 2007.

Hospitals receiving this wage index increase under section 1886(d)(13)(F) of the Act are not eligible for reclassification under section 1886(d)(8)(B) or section 1886(d)(10) of the Act, or under section 508 of Pub. L. 108-173. Therefore, in the proposed rule, consistent with §412.273, we stated that hospitals that were reclassified by the MGCRB were permitted to terminate their reclassifications or redesignations within 45 days of the publication of the proposed rule in the **Federal Register** (that is, by July 2, 2004).

In this final rule, we have allowed for a one time rule for FY 2005 that would allow hospitals a 30-day period after publication of this final rule when they can decide if they would rather take advantage of their redesignation/reclassification or the

out-migration adjustment. Hospitals will have 30 days after the publication of this rule in the **Federal Register** to either-- (1) submit to us a request to terminate their reclassifications under section 1886(d)(10) of the Act (or under section 508 of Pub. L. 108-173) or redesignated status under section 1886(d)(8)(B) of the Act and receive the out-migration adjustment instead; or (2) reactive a hospital's reclassification/redesignation if a hospital withdrew its reclassification/redesignation within 45 days of publication of the May 18, 2004 proposed rule. (Only one hospital requested waiver of its redesignation.) If we do not receive a request for termination or reactivation within this 30-day period, we will assume that hospitals that have been redesignated under section 1886(d)(8)(B) of the Act or reclassified under section 1886(d)(10) of the Act or under section 508 of Pub. L. 108-173 would prefer to keep their redesignation/reclassification. In addition, if within 30 days of publication of this final rule, we do not receive a request from the one hospital that withdrew its redesignation to reactivate such redesignation, we will assume that the hospital wishes to receive the out-migration adjustment. Finally, we wish to clarify that (except for the one hospital that has already withdrawn its redesignation) hospitals that wish to retain their redesignation/reclassification (instead of receiving the out-migration adjustment) for FY 2005 did not and do not have to submit a formal request to CMS, and will automatically retain their reclassification/redesignation status for FY 2005.

H. Additional Payments for New Medical Services and Technology: Policy Changes (§§412.87 and 412.88)

As discussed in section II.D. of the preamble of this final rule (and in the preamble of the May 18, 2004 proposed rule), sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS, effective for discharges beginning on or after October 1, 2001. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary after notice and opportunity for public comment.

Sections 1886(d)(5)(K)(ii) through (d)(5)(K)(vi) of the Act further provide--

- For an additional payment for new medical services and technology in an amount beyond the DRG prospective payment system payment rate that adequately reflects the estimated average costs of the service or technology.

- That the requirement for an additional payment for a new service or technology may be satisfied by means of a new technology group (described in section 1886(d)(5)(L) of the Act), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge.

● For the collection of data relating to the cost of a new medical service or technology for not less than 2 years and no more than 3 years after an appropriate inpatient hospital services code is issued. The statute further provides that discharges involving new services or technology that occur after the collection of these data will be classified within a new or existing DRG group with a weighting factor derived from cost data collected for discharges occurring during such period.

Section 412.87(b)(1) of our existing regulations provides that a new technology will be an appropriate candidate for an additional payment when it represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries (see the September 7, 200l final rule (66 FR 46902)). Section 412.87(b)(3) provides that, to receive special payment treatment, new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system.

In the August 1, 2003 final IPPS rule, we revised the threshold amount for determining if payment for a new technology or medical service is inadequate, effective for FY 2005 and subsequent fiscal years (68 FR 45392). We lowered the previously established threshold of 1 standard deviation to 75 percent of 1 standard deviation (based on the logarithmic values of the charges) beyond the geometric mean standardized charges for all cases in the DRG to which the new technology is assigned (or the case-weighted average of all relevant DRGs, if the new technology occurs in many different DRGs), transformed back to charges.

Section 503(b) of Pub. L. 108-173 amended section 1886(d)(5)(K)(ii)(I) of the Act to specify that in determining whether payments for a new technology or medical service are inadequate, the Secretary is to determine and apply a threshold amount that is the "lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of 1 standard deviation for the DRG involved." As a result of enactment of section 503(b), as we proposed in the May 18, 2004 proposed rule, we are revising our regulations at §412.87(b)(3) to incorporate the revised threshold amount.

The report language accompanying section 533 of Pub. L. 106-554 indicated Congressional intent that the Secretary implement the new mechanism on a budget neutral basis (H.R. Conf. Rep. No. 106-1033, 106th Cong., 2nd Sess., at 897 (2000)). Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments to annual DRG classifications and relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. Therefore, in the past, we accounted for projected payments under the new medical service and technology provision during the upcoming fiscal year at the same time we estimated the payment effect of changes to the DRG classifications and recalibration. The impact of additional payments under this provision was then included in the budget neutrality factor, which was applied to the standardized amounts and the hospital-specific amounts.

To balance appropriately the Congressional intent to increase Medicare payments for eligible new technologies with concern that the total size of those payments not result in significantly reduced payments for other cases, we set a target limit for estimated

add-on payments for new technology under the provisions of sections 1886(d)(5)(K) and (L) of the Act at 1.0 percent of estimated total operating prospective payments. In accordance with §412.88(c) of the regulations, if the target limit was exceeded, we would reduce the level of payments for approved technologies across the board, to ensure estimated payments did not exceed the limit.

Section 503(d)(1) of Pub. L. 108-173 amended section 1886(d)(5)(K)(ii)(III) of the Act to remove the budget neutrality provision for add-on payments for a new medical service or technology. Section 503(d)(2) specifies that "There shall be no reduction or other adjustment to payments under section 1886 of the Social Security Act because an additional payment is provided" for new technology. Accordingly, as a result of the enactment of section 503(d) of Pub. L. 108-173, we will no longer include the impact of additional payments for new medical services and technologies in the budget neutrality factor. In addition, as we proposed in the May 18, 2004 proposed rule, we are deleting §412.88(c) of the regulations. All the comments that we received on add-on payments for new technologies are addressed in section II.E. of the preamble to this final rule.

I. Rural Referral Centers (§412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at §412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center. For discharges occurring before October 1, 1994, rural referral centers received the benefit of payment based on the other urban standardized amount rather than the rural standardized amount. Although the other urban and rural standardized amounts are the same for discharges occurring on or after October 1, 1994,

rural referral centers continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Pub. L. 108-173 raised the DSH adjustment for other rural hospitals with less than 500 beds and rural referral centers. Other rural hospitals with less than 500 beds are subject to a 12-percent cap on DSH payments. Rural referral centers are not subject to the 12.0 percent cap on DSH payments that is applicable to other rural hospitals (with the exception of rural hospitals with 500 or more beds). Rural referral centers are not subject to the proximity criteria when applying for geographic reclassification, and they do not have to meet the requirement that a hospital's average hourly wage must exceed 106 percent of the average hourly wage of the labor market area where the hospital is located.

Section 4202(b) of Pub. L. 105-33 states, in part, "[a]ny hospital classified as a rural referral center by the Secretary***for fiscal year 1991 shall be classified as such a rural referral center for fiscal year 1998 and each subsequent year." In the August 29, 1997 final rule with comment period (62 FR 45999), we also reinstated rural referral center status for all hospitals that lost the status due to triennial review or MGCRB reclassification, but not to hospitals that lost rural referral center status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. However, subsequently, in the August 1, 2000 final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as a rural referral center and lost their status due to OMB redesignation of the county in which they are located from rural

to urban to be reinstated as a rural referral center. Otherwise, a hospital seeking rural referral center status must satisfy the applicable criteria.

One of the criteria under which a hospital may qualify as a rural referral center is to have 275 or more beds available for use (§412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as a rural referral center if the hospital meets two mandatory prerequisites (a minimum case-mix index and a minimum number of discharges) and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume) (§412.96(c)(1) through (c)(5)). (See also the September 30, 1988 **Federal Register** (53 FR 38513)). With respect to the two mandatory prerequisites, a hospital may be classified as a rural referral center if--

- The hospital's case-mix index is at least equal to the lower of the median case-mix index for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median case-mix index for all urban hospitals nationally; and

- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.)

1. Case-Mix Index

Section 412.96(c)(1) provides that CMS will establish updated national and regional case-mix index values in each year’s annual notice of prospective payment rates for purposes of determining rural referral center status. The methodology we use to

determine the proposed national and regional case-mix index values is set forth in regulations at §412.96(c)(1)(ii). The proposed national median case-mix index value for FY 2005 includes all urban hospitals nationwide, and the proposed regional values for FY 2005 are the median values of urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals receiving indirect medical education payments as provided in §412.105). These proposed values are based on discharges occurring during FY 2003 (October 1, 2002 through September 30, 2003) and include bills posted to CMS' records through March 2004.

In the May 18, 2004 proposed rule (69 FR 28281), we proposed that, in addition to meeting other criteria, if they are to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2004, rural hospitals with fewer than 275 beds must have a case-mix index value for FY 2003 that is at least--

- 1.3550; or
- The median case-mix index value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in §412.105) calculated by CMS for the census region in which the hospital is located. (See the table set forth in the May 18, 2004 proposed rule at 69 FR 28282.)

Based on the latest data available (FY 2003 bills received through March 2004), in addition to meeting other criteria, hospitals with fewer than 275 beds, if they are to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2004, must have a case-mix index value for FY 2004 that is at least--

- 1.2496; or

● The median case-mix index value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in §412.105) calculated by CMS for the census region in which the hospital is located.

The final median case-mix index values by region are set forth in the following table:

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.2157
2. Middle Atlantic (PA, NJ, NY)	1.2118
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.2365
4. East North Central (IL, IN, MI, OH, WI)	1.1957
5. East South Central (AL, KY, MS, TN)	1.0901
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.0855
7. West South Central (AR, LA, OK, TX)	1.1371
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.1696
9. Pacific (AK, CA, HI, OR, WA)	1.2698

Hospitals seeking to qualify as rural referral centers or those wishing to know how their case-mix index value compares to the criteria should obtain hospital-specific case-mix index values (not transfer-adjusted) from their fiscal intermediaries. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, these case-mix index values are computed based on all Medicare patient discharges subject to DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS will set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining rural referral center status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the May 18, 2004 proposed rule, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2001 (that is, October 1, 2000 through September 30, 2001), which is the latest available cost report data we had at that time. In last year's final rule we inadvertently indicated that we relied upon data regarding discharges occurring during FY 2002. However, we have now determined that our values for FY 2004 were based upon data regarding discharges occurring during FY 2000.

Therefore, in the May 18, 2004 proposed rule (69 FR 28282), we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial rural referral center status for cost reporting periods beginning on or after October 1, 2004, must have as the number of discharges for its cost reporting period that began during FY 2001 a figure that is at least--

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located. (See the table set forth in the May 18, 2004 proposed rule at 69 FR 28282.)

Based on the latest discharge data available at this time, that is, for cost reporting periods that began during FY 2002, the final median number of discharges for urban hospitals by census region area are as follows:

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,557
2. Middle Atlantic (PA, NJ, NY)	9,466
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	9,602
4. East North Central (IL, IN, MI, OH, WI)	8,323
5. East South Central (AL, KY, MS, TN)	6,986
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	6,576
7. West South Central (AR, LA, OK, TX)	6,307
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,367
9. Pacific (AK, CA, HI, OR, WA)	6,954

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges is the minimum criterion for all hospitals.

We reiterate that if an osteopathic hospital is to qualify for rural referral center status for cost reporting periods beginning on or after October 1, 2004, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2002.

We note that in section IV.N.3 of this preamble, we discuss public comments that we received on the effects on RRCs of the new geographical area designations for wage index purposes.

J. Additional Payments to Hospitals with High Percentage of End-Stage Renal Disease (ESRD) Discharges (§412.104)

Under existing regulations at §412.104(a), CMS provides for additional Medicare payments to a hospital for inpatient dialysis provided to Medicare beneficiaries with end-stage renal disease (ESRD) if the hospital's ESRD Medicare beneficiary discharges are 10 percent or more of its total Medicare discharges. This provision states that discharges classified into DRG 302 (Kidney Transplant), DRG 316 (Renal Failure), or DRG 317 (Admit for Renal Dialysis) are excluded for purposes of determining a hospital's eligibility for this special payment. We have been informed that, under this provision, hospitals may be counting all discharges of ESRD Medicare beneficiaries towards determining the 10 percent factor rather than counting only those discharges where the ESRD beneficiary received inpatient dialysis.

When we established this regulation in the August 31, 1984 final rule (49 FR 34747), we stated that this special payment was intended to ameliorate those circumstances in which the concentration of ESRD beneficiaries receiving inpatient dialysis may be such that the hospital would not be able to absorb the entire expense with revenue from other less costly cases. We further stated that we believed those few hospitals most extremely impacted by the ESRD beneficiary population should be afforded some protection against the chance of encountering inpatient dialysis expenses that could not be offset by revenue from cases in which the DRG payment was greater than the hospital's cost. Because this special payment is intended to limit the adverse impact on hospitals delivering inpatient dialysis services to ESRD beneficiaries, we

firmly believe that only those discharges of beneficiaries who receive dialysis services during an inpatient stay should be counted in determining a hospital's eligibility for the additional payment. After a careful review of §412.104(a), we acknowledge that hospitals may require additional guidance in appropriately determining their eligibility for this special payment. Therefore, in the May 18, 2004 proposed rule (69 FR 28282), we proposed to revise §412.104(a) to make it clear that, in determining a hospital's eligibility for the additional Medicare payment, only discharges involving ESRD Medicare beneficiaries who have received a dialysis treatment during an inpatient hospital stay are to be counted. We indicated that this proposed change would be applied prospectively, effective for cost reporting periods beginning on or after October 1, 2004.

Comment: One commenter requested clarification as to whether the proposed change to §412.104, which provides for an additional payment to hospitals with a high percentage of ESRD discharges, applies to LTCHs.

Response: The additional payment to hospitals with a high percentage of ESRD discharges provided at §412.104 is applicable only to short-term, acute care hospitals paid under the IPPS. It does not apply to LTCHs paid under the LTCH PPS.

Comment: Some commenters opposed the proposed revisions to the regulation because they believe this regulation was intended to compensate hospitals for higher costs of treating all ESRD patients, not just those receiving inpatient dialysis treatment.

Response: Section 412.104 specifically provides for an additional payment to a hospital for inpatient dialysis provided to ESRD beneficiaries. This payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD

beneficiaries for the hospital. Therefore, we believe it is entirely consistent with the regulations to provide this additional payment only when dialysis is actually provided during the inpatient stay.

Comment: Several commenters expressed concern that a revision of the regulation would place an undue financial burden on hospitals that treat a significant number of ESRD beneficiaries, and that hospitals may discontinue these services in the future.

Response: Our data indicate that approximately 41 hospitals are currently receiving approximately $15 million dollars through this add-on payment. While we cannot precisely quantify the impact of this revision, we believe that the impact will be modes because ESRD patients admitted to the hospital will typically require dialysis during their hospital stay.

Comment: Some commenters believed that, because hospitals and fiscal intermediaries are currently counting all ESRD beneficiaries, the proposed change would lead to confusion. The commenter also indicated that, in the cost report, there is no way to indicate only discharges of ESRD beneficiary who are receiving dialysis.

Response: We do not believe that this policy will create confusion. The cost report instructions will be amended to reflect the policy in the final rule. As we stated earlier, we believe this revision to the regultaion will have little effect on additional hospitals with respect to the add-on payment.

Comment: Several commenters expressed concern that the proposed revision would distort the existing formula to compute the add-on payment and would under

compensate those hospitals that now treat a large number of African-American patients who seem to be those affected largely by ESRD.

Response: The formula is now based on several factors; the most significant is the cost of inpatient dialysis. We are not revising the formula. Therefore, we do not agree that the revision would distort the formula. Further, we do not believe this revision would adversely affect any specific group of beneficiaries.

Comment: Several commenters expressed concern that CMS did not comply with the Regulatory Flexibility Act (RFA), in proposing this revision.

Response: As we indicated in the proposed rule (69 FR 28807), our impact analysis identified those hospitals currently receiving compensation through the add-on payment, as well as the amount paid to each hospital. Currently, there are approximately 41 hospitals receiving approximately $15 million. As we stated in the proposed rule, we are unable to quantify the impact more precisely.

Comment: One commenter objected to the exclusion of DRGs 316 and 317 from the add-on payment. The commenter believed the exclusion places an unfair burden on hospitals.

Response: We do not believe that the exclusion of these DRGs is inappropriate, because their weights already include a payment amount for inpatient dialysis.

Comment: One commenter recommended that the add-on payment for inpatients receiving dialysis be updated. Specifically, the commenter recommended that the average weekly cost of dialysis be increased from the current $335.

Response: Under §412.104(b)(3), the average cost of dialysis includes only those costs that are determined to be directly related to the dialysis services. These costs include salary, employee health and welfare, drugs, supplies, and laboratory services. We will review these costs and consider the commenter's recommendation to update the average weekly cost of dialysis as part of our next annual IPPS rulemaking

Comment: One comment referenced correspondence that CMS had written with instructions to include all ESRD beneficiaries when considering the add-on payment.

Response: The correspondence cited reflected our policy at the time the correspondence was issued. However, we have further evaluated that policy and, as we stated in the proposed rule, believe that a revision is necessary to ensure that the add-on payment is made in accordance with the intent of the law.

K. Indirect Medical Education (IME) Adjustment (§412.105)

1. IME Adjustment Factor Formula Multipliers (Section 502(a) of Pub. L. 108-173 and §412.105(d)(3)(vii) and §412.105(d)(3)(viii) through (d)(3)(xii) of the Regulations)

Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved graduate medical education (GME) program receive an additional payment to reflect the higher indirect costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at §412.105. The IME adjustment is based in part on the applicable IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds, which is represented as *r*, and a formula multiplier, which is represented as *c*, in the

following equation: c x [{1 + r} $^{.405}$ - 1]. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Pub. L. 108-173 modified the formula multiplier c to be used in the calculation of the IME adjustment. Prior to enactment of Pub. L. 108-173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. Section 502(a) modifies the formula multiplier beginning midway through FY 2004 and provides for a new schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

In the May 18, 2004 proposed rule (69 FR 28283), we proposed to revise §412.105(d)(3)(vii) and add §412.105(d)(3)(viii) through (d)(3)(xii) to incorporate these changes in the formula multipliers.

Comment: One commenter opposed decreases in the IME adjustment factor. The commenter asserted that hospitals are already being taxed beyond their ability to shoulder

the costs of graduate medical education and that further decreases in payment for such costs will threaten important educational programs.

Response: The proposed regulatory changes to the IME adjustment factor are mandated by section 502(a) of Pub. L. 108-173. We do not have the discretion to change the IME adjustment factor that is mandated by statute. However, the changes to the IME factor provided by section 502(a) of Pub. L. 108-173 generally constitute increases, not decreases as indicated by the commenter. As stated above, prior to enactment of Pub. L. 108-173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. Section 502(a) modified the formula multiplier beginning midway through FY 2004 and provided for a new schedule of formula multipliers for FYs 2005 and thereafter, as previously noted.

We are adopting, as final without modification, the proposed revision of §412.105(d)(3)(vii) and the proposed addition of §412.105(d)(3)(viii) through (d)(3)(xii) to incorporate changes in the formula multipliers.

2. IME Adjustment Formula Multiplier for Redistributed FTE Resident Slots (Section 422(b)(1)(C) of Pub. L. 108-173)

Under new section 1886(h)(7)(B) of the Act, added by section 422(a) of Pub. L. 108-173, a hospital may receive an increase in its FTE resident cap as a result of the agency's redistribution of unused resident positions. (This provision is discussed in detail in section IV.J.2. of the preamble of this final rule.) Section 422(b)(1)(C) of Pub. L. 108-173 amended section 1886(d)(5)(B) of the Act to add a new subclause (ix) to provide that, for discharges occurring on or after July 1, 2005, for a hospital whose FTE resident

cap is increased as a result of a redistribution of unused resident positions, the IME adjustment factor is to be calculated using a formula multiplier of 0.66 with respect to any additional residents counted by the hospital as a result of that increase in the hospital's FTE resident cap. Thus, in the May 18, 2004 proposed rule (69 FR 28283), we proposed that a hospital that counts additional residents as a result of an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act would receive IME payments based on the sum of two different IME adjustment factors: (1) an IME adjustment factor that is calculated using the schedule of formula multipliers described in section IV.G.1. of this preamble established by section 502(a) of Pub. L. 108-173, and which also uses the hospital's number of FTE residents, not including residents attributable to an FTE cap increase under section 1886(h)(7)(B) of the Act, in the numerator of the resident-to-bed ratio; and (2) an IME adjustment factor that is calculated using the formula multiplier of 0.66, and the additional number of FTE residents that is attributable to the increase in the hospital's FTE resident cap under section 1886(h)(7)(B) of the Act in the numerator of the resident-to-bed ratio. (The number of available beds used in the denominator would be the same for both IME adjustments.)

We note that section 422(b) of Pub. L. 108-173, which addresses the application of the IME adjustment to the residents counted as a result of an increase in a hospital's FTE resident cap under section 422(a), makes no reference to section 1886(d)(5)(B)(vi) of the Act. That is, the statute does not provide for an exclusion from application of the cap on the resident-to-bed ratio at section 1886(d)(5)(B)(vi)(I) of the Act or from application of the rolling average count at section 1886(d)(5)(B)(vi)(II) of the Act for

residents added as a result of FTE cap increases under section 1886(h)(7)(B). There is no specific pronouncement in section 422 exempting residents counted as a result of the FTE resident cap increases under section 422(a) from the cap on the resident-to-bed ratio and the rolling average, and we see no apparent reason to treat those residents differently for purposes of these two provisions. Therefore, in the May 18, 2004 proposed rule, we proposed to require that if a hospital increases its IME FTE count of residents as a result of section 1886(h)(7)(B) of the Act, those FTE residents are immediately subject to the cap on the resident-to-bed ratio and the rolling average calculation. We explained further that, given potentially significant shifts of FTE positions among hospitals as a result of the new section 1886(h)(7) of the Act, the inclusion of FTE residents added as a result of section 1886(h)(7)(B) of the Act in the cap on the resident-to-bed ratio and in the rolling average introduces a measure of stability and predictability, and mitigates radical shifts in IME payments from period to period. Thus, a hospital's increase in IME payment may be delayed for one year to the extent that the resident-to-bed ratio for the current cost reporting period is capped by the resident-to-bed ratio for the previous cost reporting period. Further, the additional FTE residents would be phased in over a 3-year period in the hospital's FTE count because they are immediately included in the rolling average calculation.

The following illustrates how we proposed to calculate the IME payment for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. For example, Hospital A has a fiscal year end (FYE) of September 30, and a 1996 IME FTE cap of 20 FTEs. During its FYEs September 30,

2003, September 30, 2004, and September 30, 2005, Hospital A trains 25 FTE residents. Effective July 1, 2005, under section 1886(h)(7)(B) of the Act, Hospital A receives an increase to its IME 1996 cap of 5 FTEs, for a total adjusted IME cap of 25 FTEs. Hospital A has maintained an available bed count of 200 beds in FYE September 30, 2004 and throughout FYE September 30, 2005. For the FYE September 30, 2005 cost report, the IME adjustment factor is calculated as follows:

Step 1. For discharges occurring on October 1, 2004, through September 30, 2005 for residents NOT counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 20+20+20/3 = 20.
- Current year resident-to-bed ratio: 20/200 = .10
- Cap on resident-to-bed ratio (from prior year): 20/200 = .10
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: .10 = .10.
- Compute IME adjustment factor: $1.42 \times [\{1 + .10\}^{.405} - 1] = 0.0559$.

Step 2. For discharges occurring on July 1, 2005 through September 30, 2005 for residents counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 25+20+20/3 = 21.7.
- Resident-to-bed ratio for 7/1/05—9/30/05: 21.7/200 = .11
- Cap on resident-to-bed ratio (from prior year): 20/200 = .10
- Compare, and use the lower of, prior year resident-to-bed ratio and resident-to-bed ratio for 7/1/05—9/30/05: .10 < .11. Capped by prior year ratio of .10.

- Compute IME adjustment factor: $0.66 \times [\{1 + 0\}^{.405} - 1] = 0.0$.

In this example, the addition of 5 FTE residents under section 1886(h)(7)(B) caused Hospital A's resident-to-bed ratio for discharges occurring on July 1, 2005, through September 30, 2005, to exceed the resident-to-bed ratio of .10 from the prior year. Since the multiplier of 0.66 is to be used for determining IME payment "insofar as an additional payment amount . . . is attributable to resident positions redistributed to a hospital . . ." under section 1886(d)(5)(B)(v) of the Act, as amended by section 422(b)(1)(C) of Pub. L. 108-173, Hospital A does not receive any IME payment attributable to the 5 FTE residents added as a result of section 1886(h)(7)(B) of the Act for discharges occurring on July 1, 2005, through September 30, 2005. As shown under the fifth bullet point in Step 2 of the example above, a resident-to-bed ratio of zero is used to compute the IME adjustment for FTE residents attributable to increases in the FTE resident cap under section 1886(h)(7)(B) of the Act for discharges occurring on or after July 1, 2005 and on or before September 30, 2005. The ratio of .10 would not be used to compute the IME adjustment for FTE residents attributable to an increase in the FTE resident cap under section 1886(h)(7)(B) because the ratio of .10 is attributable to the 20 FTE residents from the prior year, and is not related to residents added under section 1886(h)(7)(B) of the Act. (We noted that a hospital's resident-to-bed ratio in the current year might decrease despite residents added as a result of section 1886(h)(7)(B) of the Act, due to an increase in the number of available beds in the denominator of the current year resident-to-bed ratio. In such a case, because the current year ratio would be less than the prior year ratio, the hospital's resident-to-bed ratio would not be capped by

the prior year resident-to-bed ratio, and, therefore, the hospital could receive an IME payment in the current year (that is, there would not be a 1-year delay) relating to residents added under section 1886(h)(7)(B) of the Act).

However, an increase in the resident-to-bed ratio in the current period may establish a higher cap for the following period, and, all other things being equal, a hospital could then receive IME payment for FTE residents added as a result of section 1886(h)(7)(B) of the Act after a 1-year lag. In the example above, Hospital A would receive an IME payment for residents added as a result of section 1886(h)(7)(B) of the Act in its cost reporting period ending September 30, 2006, as follows:

Step 1. For residents NOT counted pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 20+20+20/3 = 20.
- Current year resident-to-bed ratio: 20/200 = .10
- Cap on resident-to-bed ratio (from prior year): 20/200 = .10
- Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: .10 = .10.
- Compute IME adjustment factor: $1.37 \times [\{1 + .10\}^{.405} - 1] = 0.0559$.

Step 2. For 5 FTE residents counted pursuant to with section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 25+25+20/3 = 23.3.
- Resident-to-bed ratio for FYE 9/30/06: 23.3/200 = .12
- Cap on resident-to-bed ratio (from prior year): 25/200 = .13

● Compare, and use the lower of, prior year resident-to-bed ratio and current year resident-to-bed ratio: .13 > .12. Current year ratio of .12 is the lower of the two.

● Take the difference between the rolling average count of FTE residents counted as a result of section 1886(h)(7)(B) of the Act, and the rolling average count of FTE residents not counted as a result of section 1886(h)(7)(B) of the Act, (rolling average count under step 2 minus rolling average count under step 1): 23.3 - 20 = 3.3.

● Compute current year resident-to-bed ratio attributable to residents added under section 1886(h)(7)(B): 3.3/200 = 0.02.

● Compute IME adjustment factor: $0.66 \times [\{1 + .02\}^{.405} - 1] = 0.0053$.

Step 3. Compute IME payment for FYE September 30, 2006: [Total DRG payments for discharges occurring on October 1, 2005 through September 30, 2006] x [0.0592] (that is, 0.0539 + 0.0053).

In the May 18, 2004 proposed rule, we proposed to revise §412.105 to incorporate these changes under proposed new paragraph (d)(4), proposed new paragraph (e)(2), proposed new paragraph (f)(1)(iv)(B), and proposed added new last sentence of paragraph (f)(1)(v).

Comment: One commenter stated that the calculation of the IME payment relating to additional residents counted as a result of an increase in the hospital's FTE cap received under section 1886(h)(7)(B) of the Act is extremely cumbersome and will require difficult and extensive changes to the Medicare cost report, particularly if the additional residents are to be subject to the rolling average and the resident-to-bed ratio. The commenter suggested that instead of revising Worksheet E, Par A to include this

calculation, CMS should consider including this calculation on a separate worksheet, with the results added to Worksheet E, Part A.

Response: First, we note that we are required by section 1886(d)(5)(B)(ix) to apply a different IME formula multiplier to calculate the IME payment relating to these residents. Therefore, some level of additional complexity is not avoidable. Additionally, we have stated in previous responses concerning the IME calculation relating to residents counted under section 1886(h)(7)(B) of the Act, under our final policy, we are not requiring that these residents be subject to the rolling average and resident-to-bed ratio calculations. Thus, we believe our final policy substantially reduces the complexity of the proposed calculations that concerned the commenter. Even so, we do realize that the presence of an additional calculation on Worksheet E, Part A for IME (and also on Worksheet E-3, Part IV for direct GME) further complicates an already difficult calculation. We will attempt to revise the worksheets in the simplest and least disruptive manner.

Comment: Several commenters noted that there is a mathematical error on page 28284 of the May 18, 2004 **Federal Register**. The second column on page 28284, in "Step 1", shows an IME computation of: 1.37 x [{1-.10}$^{.405}$-1] = 0.0559. The result of this computation should be .053917, not the .0559 as indicated.

Response: We agree with the commenters that the computed result for "Step 1" of the example is 0.053917, not 0.0559.

Comment: One commenter noted that there appears to be an error on page 28284 of the May 18, 2004 **Federal Register**. On page 28284, third column, in "Step 3", shows

an IME adjustment factor computation of: 0.0539 + 0.0053 = .0592. The commenter believes the adjustment factor should be calculated as 0.0559 + 0.0053 = .0612 since 0.0559 is the factor calculated in "Step 1" for residents not counted as a result of cap redistribution.

Response: As noted previously, "Step 1" of the IME adjustment factor calculation (shown in the second column of page 28284) contains an error. The result of "Step 1" should read 0.0539, not the 0.0559 as indicated. With this change, "Step 3" shows the correct IME adjustment factor calculation (0.0539 + 0.0053 = .0592).

3. Counting Beds and Patient Days for Purposes of Calculating the IME Adjustment (§412.105(b)) and DSH Adjustment ((§412.106(a)(1)(i))

As stated in section IV.K.1 of the preamble, §412.105 of our existing regulations specifies that the calculation of the IME adjustment is based on the IME adjustment factor, which is calculated using hospitals' ratios of residents to beds. The determination of the number of beds is based on available bed days. This determination of the number of available beds is also applicable for other purposes, including the level of the disproportionate share hospital (DSH) adjustment payments under §412.106(a)(l)(i).

In the FY 2004 IPPS proposed rule (68 FR 27201 through 27208, May 19, 2003), we proposed changes to our policy on determining the number of beds and patient days as it pertains to both the IME and DSH adjustments. In the FY 2004 IPPS final rule (68 FR 45415 through 45422), we indicated that, due to the nature and number of public comments we received on the proposed policies regarding unoccupied beds, observation beds for patients ultimately admitted as inpatients, dual-eligible patient days, and

Medicare+Choice (M+C) days, we would address the comments in a separate document. In the May 18, 2004 proposed rule, we stated that we planned to respond to comments in this final rule. Under section IV.L.3. of this preamble, we are responding to public comments received on the proposals in the May 19, 2003 and the May 18, 2004 proposed rules as they relate to both the IME and DSH payment adjustments and finalizing our policies in these four areas.

4. Technical Changes

- In §412.105(a)(1), introductory text, we include a cross-reference to "paragraph (f) and (h)" of §412.105. Paragraph (h) no longer exists in this section. Therefore, in the May 18, 2004 proposed rule (69 FR 28284), we proposed to remove the cross-reference to paragraph (h).

- In §412.105(f)(1)(i)(A), we reference national organizations listed in §415.200(a). The cross-reference to §415.200(a) is incorrect. In the May 18, 2004 proposed rule (69 FR 28284), we proposed to correct the cross-reference to read "§415.152."

We did not receive any comments on these two proposals for technical changes and, therefore, are adopting them as final.

- In section IV.O. of the preamble of this final rule (and in the May 18, 2004 proposed rule), we discuss our redesignation of existing §413.86 governing payments for direct costs of GME to nine separate sections. Many of the paragraphs in the existing §413.86 are cited in §412.105 governing the IME adjustment. We proposed to make

changes to the cross-reference in §412.105 to conform them to these redesignated separate sections.

We did not receive any comments on this proposal; and therefore, are adopting this proposal as final.

L. Payment to Disproportionate Share Hospitals (DSHs) (Section 402 of Pub. L. 108-173 and §412.106 of Existing Regulations)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional payments to subsection (d) hospitals that serve a disproportionate share of low-income patients. The Act specifies two methods for a hospital to qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to indigent patients. These hospitals are commonly known as "Pickle hospitals." The second method, which is also the most commonly used method for a hospital to qualify, is based on a complex statutory formula under which payment adjustments are based on the level of the hospital's DSH patient percentage, which is the sum of two fractions: the "Medicare fraction and the Medicaid fraction." The Medicare fraction is computed by dividing the number of patient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the total number of patient days furnished to patients entitled to benefits under

Medicare Part A. The Medicaid fraction is computed by dividing the number of patient days furnished to patients who, for those days, were eligible for Medicaid but were not entitled to benefits under Medicare Part A by the number of total hospital patient days in the same period.

$$\text{DSH Patient Percentage} = \frac{\text{Medicare, SSI Days}}{\text{Total Medicare Days}} + \frac{\text{Medicaid, Non-Medicare Days}}{\text{Total Patient Days}}$$

2. Enhanced DSH Adjustment for Rural Hospitals and Urban Hospitals with Fewer Than 100 Beds

Hospitals whose DSH patient percentage exceeds 15 percent are eligible for a DSH payment adjustment (prior to April 1, 2001, the qualifying DSH patient percentage varied, in part, by the number of beds (66 FR 39882)). The DSH payment adjustment may vary based on the DSH patient percentage and the type of hospital. The statute provides for different payment adjustments for urban hospitals with 100 or more beds and rural hospitals with 500 or more beds, hospitals that qualify as RRCs or SCHs, and other hospitals.

Effective April 1, 2004, section 402 of Pub. L. 108-173 amended section 1886(d)(5)(F) of the Act to revise the formulae used to calculate DSH payment adjustments for certain hospitals that qualify for the adjustments under the second method. Specifically, under the new section 1886(d)(5)(F)(xiv), added by section 402, for hospitals that are not large urban or large rural hospitals, DSH payments are calculated using the same DSH adjustment formula used for large urban hospitals. However, the DSH payment adjustment for most of these categories of hospitals, except

for hospitals classified as RRCs, including RRCs that are also SCHs, is capped at 12 percent. In addition, the formula for large urban hospitals with 100 beds or more, and large rural hospitals with 500 beds or more, has not been revised by section 402. Finally, Pickle hospitals are not affected by this change; they will continue to receive a DSH adjustment under the alternative formula.

Effective for discharges occurring on or after April 1, 2004, the following DSH payment adjustment formulae apply for the following specified categories of hospitals:

- For urban hospitals with fewer than 100 beds and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent: (Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.

≥15% <20.2% 2.5%+[.65 x (DSH pct. - 15%)]

- For urban hospitals with fewer than 100 beds and whose disproportionate patient percentage is greater than 20.2:

(Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For urban hospitals with fewer than 100 beds, the maximum DSH payment adjustment is 12 percent.

- For rural hospitals that are SCHs and are not RRCs and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent).

≥15% <20.2% (2.5% + [.65 x (DSH pt.% - 15%])

- For rural hospitals that are SCHs and are not RRCs and whose disproportionate patient percentage is greater than 20.2 percent:

(Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For rural hospitals that are SCHs and are not RRCs, the maximum DSH payment adjustment is 12 percent.

- For RRCs whose disproportionate patient percentage is greater than or equal to 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.

≥15% <20.2% 2.5% + [.65 x (DSH pct. - 15%)]

- For RRCs whose disproportionate patient percentage is greater than 20.2 percent:

(Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For rural referral centers there is no maximum DSH payment adjustment.

- For rural hospitals that are both RRCs and SCHs and whose disproportionate patient percentage is greater than or equal to 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.

>=15% <20.2% 2.5% + [.65 x (DSH pct. - 15%)]

● For rural hospitals that are both RRCs and SCHs whose disproportionate patient percentage is greater than 20.2 percent:

(Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For rural hospitals that are both RRCs and SCHs there is no maximum DSH payment adjustment.

● For rural hospitals with fewer than 500 beds and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage − 15 percent) (65 percent) + 2.5 percent.

≥15% <20.2% 2.5% + [.65 x (DSH pct. - 15%)]

● For rural hospitals with fewer than 500 beds and whose disproportionate patient percentage is greater than 20.2 percent:

(Disproportionate patient percentage − 20.2 percent) (82.5 percent) + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For rural hospitals with fewer than 500 beds, the maximum DSH payment adjustment is 12 percent.

These revised formulae, which became effective for discharges occurring on or after April 1, 2004, were implemented through a CMS One-Time Notification (CR 3158), issued on March 26, 2004. The notice describes the changes required by section 402 of Pub. L. 108-173. In the May 18, 2004 proposed rule (69 FR 28284 through 28286) we described the changes to the DSH adjustment calculations required under section 402 of Pub. L. 108-173 as well as the required modifications to its regulations to implement section 402 of Pub. L. 108-173.

The following DSH formulae were not affected by the changes made by section 402 of Pub. L. 108-173 and remain in effect:

- For urban hospitals with 100 beds or more and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage – 15 percent) (65 percent) + 2.5 percent.

≥15% ≤20.2% 2.5% + [.65 x (DSH pct. - 15%)]

- For urban hospitals with 100 beds or more and whose disproportionate patient percentage is greater than 20.2 percent:

(Disproportionate patient percentage – 20.2 percent) (82.5 percent) + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For urban hospitals with 100 beds or more there is no maximum DSH payment adjustment.

- For rural hospitals with 500 beds or more and whose disproportionate patient percentage is equal to or greater than 15 percent and less than or equal to 20.2 percent:

(Disproportionate patient percentage – 15 percent) (65 percent) + 2.5 percent.

≥15% <20.2% 2.5% + [.65 x (DSH pct. - 15%)]

- For rural hospitals with 500 beds or more and whose disproportionate patient percentage is greater than 20.2 percent:

[(Disproportionate patient percentage – 20.2 percent) (82.5 percent)] + 5.88 percent.

≥20.2% 5.88% + [.825 x (DSH pct. - 20.2%)]

For rural hospitals with 500 beds or more there is no maximum DSH payment adjustment.

Comment: We received several comments in regard to section 402 of Pub. L. 108-173. One commenter requested that CMS clarify how the DSH percentage will be computed to implement these provisions for a provider whose year-end period overlaps with the April 1, 2004 date. Another commenter stated that when the DSH policy was developed, consideration was given to the financial condition of the hospitals providing a high level of care to low-income patients, and as a result of that consideration, a cap was placed on the size of DSH payments to rural hospitals. Additionally, the commenters believe that without any publicly articulated policy basis, Congress has called for raising this cap and increasing DSH payments, but only increasing them for rural hospitals, even though these hospitals are not treating more low-income patients and have not seen their financial condition deteriorate. The commenter believes that urban hospitals are in far worse and declining financial condition, and are to receive comparable benefit.

Response: As we stated in the May 18, 2004 proposed rule (69 FR 28285) hospitals whose DSH patient percentage exceeds 15 percent are eligible for a DSH payment adjustment (prior to April 1, 2001, the qualifying DSH patient percentage varied, in part, by the number of beds (66 FR 39882)). The DSH payment adjustment may vary based on the DSH patient percentage and the type of hospital. The revised formula increases the DSH add-on payment that a hospital receives because the cap has been increased. For example, effective for discharges occurring on or after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a DSH adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. The DSH adjustment for these hospitals, except RRCs will be capped at 12 percent instead of the 5.25 percent used prior to discharges occurring before April 1, 2004. We have determined that the revised formulae used to calculate the DSH payment adjustments for certain hospitals will result in making a change in the Medicare cost report. We will make two separate computations of the DSH percentage on the Medicare cost report for discharges occurring before April 1, 2004 and one after April 1, 2004.

In response to the comment regarding rural hospitals receiving a higher cap and DSH payment, as we stated previously, the statute allows a hospital that is not a large urban hospital that qualifies for a DSH adjustment to receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. Like large urban hospitals with 100 beds or more and rural hospitals with 500 beds or more, the revised formula removes the cap for RRCs and SCHs that are also RRCs.

Therefore, in this final rule, we are adopting as final the policy expressed in the May 18, 2004 proposed rule to revise the formulae used to calculate the DSH payment adjustment for certain hospitals that qualify for the adjustments, and amending our regulations at §412.106 accordingly. This policy is effective for discharges occurring on or after April 1, 2004.

3. Counting Beds and Patient Days for the IME and DSH Adjustments

In the May 19, 2003 IPPS proposed rule for FY 2004 (68 FR 27201), we proposed changes to our policy on counting beds and patient days for the purposes of the DSH and IME adjustments. We proposed changes to the way unoccupied beds are counted. We also proposed to clarify how observation beds and swing-beds are counted, as well as our policy regarding nonacute care (that is, a level of care that would not generally be payable under the IPPS) beds and days. In regard to patient days, we proposed changes to the way observation days, dual-eligible days and M+C days are counted. We recognize that section 101 of Pub.L. 108-173 changed the title of Medicare+Choice to Medicare Advantage. However, throughout this preamble and our regulations, we are continuing to use the title, Medicare+Choice (M+C). We will make a global change of this reference in a separate regulatory document.

As discussed earlier under section IV.N.1. of this preamble, the IME adjustment provided for under section 1886(d)(5)(B) of the Act applies to prospective payment hospitals that have residents in an approved GME program. These hospitals receive an additional payment to reflect the higher indirect costs of teaching hospitals relative to nonteaching hospitals and the level of the payment varies based in part on the applicable

IME adjustment factor. The IME adjustment factor is calculated using a hospital's ratio of residents to beds. As in the May 19, 2003 proposed rule (68 FR 45415), we are combining in this final rule our discussion of changes to the policies for counting beds and patient days in relation to the regulations at §§412.105(b) and 412.106(a)(1)(ii) because the underlying concepts are similar, and we believe they generally should be interpreted in a consistent manner for both purposes.

Due to the number and nature of the public comments received on the proposals regarding the counting of available beds and patient days in the May 19, 2003 proposed rule, we did not respond to the public comments on some of the proposals in the final rule for FY 2004 (August 1, 2003 final rule (68 FR 45415)). We indicated in that final rule that we would address public comments regarding unoccupied beds, observation beds, dual-eligible days, and M+C days in a separate document. In the May 18, 2004 proposed rule, we indicated that we planned to address the comments in this IPPS final rule for FY 2005.

a. Provisions of the FY 2004 Proposed Rule, Responses to Public Comments, and Provisions of the FY 2005 Final Rule

In the May 19, 2003, FY 2004 IPPS proposed rule (68 FR 27205), we discussed proposed changes to our policies for counting beds and patient days in relation to the IME and DSH adjustments. Specifically, we proposed to amend §412.105(b) and §412.106(a)(1)(ii) as they pertain to the counting of beds and patients days for determination of the IME adjustment and DSH payment adjustment. We proposed to amend §412.105(b) to indicate that the bed days in a unit that is unoccupied by patients

receiving a level of care that would be generally payable under the IPPS (IPPS level of care) for the 3 preceding months are to be excluded from the available bed day count for the current month. In addition, we proposed that the beds in a unit that was occupied by a patient(s) receiving an IPPS level of care during the 3 preceding months should be counted unless they could not be made available for patient occupancy within 24 hours, or they are used to provide outpatient observation services or swing-bed skilled nursing care (68 FR 27204). Regarding nonacute care beds and days, we proposed to revise §412.105(b) to clarify that beds in units or wards established or used to provide a level of care that is not consistent with what would be payable under the IPPS cannot be counted. We also proposed to revise the DSH regulations at §412.106(a)(1)(ii) to clarify that the number of patient days includes only those days attributable to patients that receive care in units or wards that furnish a level of care that would generally be payable under the IPPS (68 FR 27205).

In the May 19, 2003 proposed rule, we proposed to revise our regulations to specify our policy that observation and skilled nursing swing-bed days are to be excluded from the counts of both available beds and patient days, unless a patient treated in an observation bed is ultimately admitted, in which case the bed and patient days would be included in those counts.

The final categories of patient days addressed in the proposed rule of May 19, 2003 were the dual-eligible patient days and the Medicare+Choice (M+C) days. We proposed in the rule that the days of patients who are dually-eligible, (that is, Medicare beneficiaries who are also eligible for Medicaid) and have exhausted their

Medicare Part A coverage will not be included in the Medicare fraction. Instead, we proposed that these days should be included in the Medicaid fraction of the DSH calculation. In regard to M+C days, we proposed that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage. The patient days should be included in the count of total patient days in the denominator of the Medicaid fraction, and if the M+C beneficiary is also eligible for Medicaid, the patient's days would be included in the numerator of the Medicaid fraction as well.

In the August 1, 2003 final rule (68 FR 45346), we finalized some of these proposals. For the proposals we did not finalize, we indicated that we would address the comments in a separate document. The proposals for nonacute care beds and days, observation and swing-bed days, LDP beds and days, and days for 1115 demonstration projects were finalized in the August 1, 2003 final rule. However, due to the large number of comments we received on our proposals for unoccupied beds, observation beds for patients ultimately admitted as inpatients, dual-eligible patient days, and M+C days, we decided to address the comments on these proposed policies in a separate final document. In this IPPS final rule, we are addressing those comments, as well as some additional comments that we received in response to the May 18, 2004 proposed rule, and finalizing the policies.

As we did in the IPPS proposed rule of May 19, 2003 and the August 1, 2003 IPPS final rule, we are combining our discussion of policies for counting beds and patient days in relation to the calculations at §§412.105(b) and 412.106(a)(1) which relate to the

IME and DSH payment adjustments, because the underlying concepts are similar, and we believe they should generally be interpreted in a consistent manner for both purposes. Specifically, we clarified that beds and patient days that are counted for these purposes should be limited to beds or patient days in hospital units or wards that would be directly included in determining the allowable costs of inpatient hospital care payable under the IPPS on the Medicare cost reports. As a preliminary matter, beds, and patient days associated with these beds, that are located in units or wards that are excluded from the IPPS (for example, psychiatric or rehabilitation units, or outpatient areas), and thus from the determination of allowable costs of inpatient hospital care under the IPPS on the Medicare cost report, are not to be counted for purposes of §§412.105(b) and 412.106(a)(1)(ii).

The remainder of this discussion pertains to beds and patient days in units or wards that are not excluded from the IPPS and for which costs are included in determining the allowable costs of inpatient hospital care under the IPPS on the Medicare cost report.

As we noted in our FY 2004 proposed and final rules, our policies on counting beds are applied consistently for both IME and DSH although the incentives for hospitals can be different for IME and DSH. For purposes of IME, teaching hospitals have an incentive to minimize their number of available beds in order to increase the resident-to-bed ratio and maximize the IME adjustment. On the other hand, for DSH purposes, urban hospitals with under 100 beds and rural hospitals with under 500 beds may have an incentive to increase their bed count in order to qualify for the higher DSH payments for

urban hospitals with over 100 beds or rural hospitals with over 500 beds (although we recognize that, as a result of section 402 of Pub. L. 108-173, the DSH payment adjustment no longer varies based upon the hospital's number of beds effective for discharges on or after April 1, 2004). However, under section 402 of Pub. L. 108-173, urban hospitals under 100 beds and rural hospitals under 500 beds are subject to a 12 percent cap on the DSH payment adjustment.

While some of the topics discussed below pertain only to counting available beds (unoccupied beds) and some only to counting patient days (dual-eligible days and Medicare+Choice days), other topics are applicable to both bed-counting and day-counting policies (observation beds and days and swing-beds and days). Therefore, for ease of discussion, we have combined all topics pertaining to counting available beds and patient days together in the following discussion.

We received numerous comments on our May 19, 2003 and May 18, 2004 proposals and our responses and final polices are included in this preamble.

1. Unoccupied Beds

The existing regulations for counting hospital beds for IME and DSH are at §412.105(b). The bed count is based on total available bed days during the hospital's cost reporting period, divided by the number of days in the cost reporting period. The regulations specify certain types of beds to be excluded from this count (for example, beds or bassinets in the healthy newborn nursery, custodial care beds, and beds in excluded distinct part hospital units).

Further instructions for counting beds are detailed in section 2405.3, Part I, of the Medicare Provider Reimbursement Manual (PRM). That section states that a bed must be permanently maintained for lodging inpatients and it must be available for use and housed in patient rooms or wards. Thus, beds in a completely or partially closed wing of the facility are considered available only if the hospital can put the beds into use when they are needed.

Currently, if a bed can be staffed for inpatient care either by nurses on staff or from a nurse registry within 24 to 48 hours, the unoccupied bed is determined available.[2] In most cases, it is a straightforward matter to determine whether unoccupied beds can be staffed within this timeframe because they are located in a unit that is otherwise staffed and occupied (an unoccupied bed is available for patient care but it is not occupied by a patient on a particular day). The determination is not as simple in situations where a room in an otherwise occupied unit has been altered for other purposes, such as for a staff lounge or for storage.

Beds in unoccupied rooms or wards are to be excluded from the bed count if the associated costs are excluded from depreciable plant assets because the area is not available for patient use.[3] However, issues continue to arise with regard to how to treat entire units or even entire floors that are unoccupied over a period of time. For example, in a Provider Reimbursement Review Board (PRRB) decision, the hospital acknowledged that an entire floor was temporarily unoccupied for approximately 2 years. Rooms on the

[2] This policy was first articulated in correspondence to the Blue Cross and Blue Shield Association (BCBSA) on November 2, 1988, and published in BCBSA's Administrative Bulletin No.1841, 88.01, on November 18, 1988.
[3] Ibid.

floor were used for office space, storage, and outpatient services. The PRRB held that current rules allowed these beds to be counted. Specifically, the PRRB found the beds could reasonably be made ready for inpatient use within 24 to 48 hours, the rooms were counted on the hospital's cost report as depreciable plant assets available for patient care, and the hospital could adequately provide patient care in the beds using staff nurses or nurses from a nurse registry. Upon review, the Administrator also ultimately upheld this decision based on existing policies and instructions.

We do not believe that an accurate bed count should include beds that are essentially hypothetical in nature; for example, when the beds are on a floor that is not used for inpatient care throughout the entire cost reporting period (and, indeed, may have been used for other purposes). Followed to the extreme, a hospital could count every bed in its facility, even if it had no intention of ever using a bed for inpatient care, as long as it would be theoretically possible to place an inpatient in the bed. We do not believe such a result would accurately reflect a hospital's capacity to provide inpatient services. Although teaching hospitals have an incentive to minimize the bed count for IME payment purposes, some DSH hospitals have had an incentive to maximize the bed count for the same reason. Our current policy is intended to reflect a hospital's available bed count as accurately as possible, achieving a balance between capturing short-term shifts in occupancy and long-term changes in capacity. Therefore, we believe further clarification and refinement of our policies relating to counting available beds is necessary.

In the FY 2003 IPPS proposed rule published on May 9, 2002 (67 FR 31462), we proposed that, if a hospital's reported bed count results in an occupancy rate (average daily census of patients divided by the number of beds) below 35 percent, the applicable bed count, for purposes of establishing the number of available beds for that hospital, would exclude beds that would result in an average annual occupancy rate below 35 percent. However, at the time the FY 2003 IPPS final rule was published on August 1, 2002 (67 FR 50060), we decided not to proceed with the proposed changes as final and to reconsider the issue as part of a future comprehensive analysis of our bed and patient day counting policies.

In the May 19, 2003 proposed rule, we proposed to determine whether beds in a unit or ward are available based upon whether the unit or ward was used to provide patient care of a level generally payable under the IPPS ("IPPS level of care") at any time during the 3 preceding months, rather than propose to establish a minimum standard occupancy rate. If any of the beds in the unit or ward were used to provide an IPPS level of care at any time during the preceding 3 months, all of the beds in the unit or ward are considered available and are to be counted for purposes of determining available bed days during the current month. (However, individual bed days may be excluded from that count if the bed is used to provide other services such as observation bed or swing-bed service, as discussed below.) If no patient care of a type generally payable under the IPPS was provided in that unit or ward during the 3 preceding months, the beds in the unit or ward are to be excluded from the determination of available bed days during the current month (proposed §§412.105(b)(2) and 412.106(a)(1)(ii)(C)).

Comment: Many commenters objected to our proposals to amend our policy for counting unoccupied beds. Some commenters believed we should not apply an occupancy test, regardless of how long a hospital's beds sit idle. Other commenters believed the proposed 3-month test to show that a unit is unoccupied was unreasonable, and suggested that our policy should recognize small-scale, short-term renovations that take individual rooms out of service for less than 3 months.

A few commenters recommended the threshold for excluding an unoccupied unit should be reduced from 3 months to 1 month. Several commenters requested tangible evidence to support a 3-month threshold for excluding unoccupied beds.

Response: We believe that our proposal to amend our policy for counting unoccupied beds would provide a clear standard for both hospitals and fiscal intermediaries to use to determine whether otherwise unoccupied beds are to be counted. We note that if the required time period for excluding the unoccupied beds were set too low, hospitals could potentially manipulate their available bed count by not admitting any patients to a unit or ward during low occupancy periods, thereby distorting the measure of hospital beds. We believe that, 3 months (one quarter of a hospital's fiscal year), represents a reasonable standard for determining whether beds in a unit or ward are not being used to provide patient care and should be excluded from the hospital's available bed count.

Comment: One commenter stated that we should include the beds in the determination of the available bed count if they are located in an area that is included in the determination of allowable costs on the Medicare cost report. One commenter

suggested that a policy that does not recognize such beds for DSH payment purposes because they do not meet an occupancy standard contradicts the recognized allowable nature of the costs associated with those beds. This commenter also requested that we apply the same 24-hour availability standard, regardless of the reason a bed is unoccupied. The commenter expressed the opinion that, whether a bed is associated with an altered patient room or merely a bed in a unit housing unoccupied beds, if the bed can be staffed and readied to house a patient within a designated period of time, the bed should be counted for DSH payment calculations.

Another commenter stated that if a hospital can demonstrate its intent to remove beds from service, the beds should be excluded from the bed count on the first day they are removed from service without meeting the 3-month waiting period. Other commenters believed the proposal should allow hospitals to exclude specific rooms from the available bed count when the individual rooms are undergoing renovations (as opposed to the entire unit). Some commenters indicated that, instead of clarifying and simplifying our bed counting policy, our proposal would complicate the current policy.

Response: The range of comments on this proposal demonstrates the difficulty in administering our current policy, and the importance of a uniform bed-counting policy for purposes of determining the number of beds for IME and DSH.

We proposed to use a 3-month standard to determine whether beds in a unit or ward should be considered unoccupied and excluded from the count of available beds because we believed it would provide a clear standard for both hospitals and fiscal intermediaries to use to determine whether beds should be counted. We believed

3 months represents a reasonable timeframe to demonstrate whether beds within a unit or ward are or are not being used to provide an IPPS-level of patient care, and to determine whether beds in the unit or ward should be included in the determination of a hospital's available bed count.

We continue to believe that the 3 month standard is appropriate. As noted previously, there are conflicting views among hospitals over whether this timeframe is too long or too short. Some hospitals argue that there should be no limitation on a hospital's ability to count unoccupied beds. Others argue that hospitals should be able to exclude beds on a daily basis as they undertake renovations.

We believe our proposed policies generally provide a balance between these contrasting positions while establishing a clearer standard to follow. We also continue to believe our proposed policies will strike an appropriate balance between capturing short-term shifts in occupancy and reflecting long-term changes in capacity, which will result in a reasonable representation of the hospital's number of available beds. However, based on the comments, we recognize the need for some refinement and further elaboration upon our proposal. For example, we stated in the proposed rule of May 19, 2003, that the proposed policy to exclude from the count of available beds only the beds in units or wards that were not occupied by a patient receiving an IPPS level of care at any time during the 3 preceding months would be also be applicable to rooms undergoing renovations. However, we understand that many renovations do not involve entire units or wards, but do make individual rooms unavailable for patient care during the course of the renovation. Therefore, we are specifying in this final rule that beds in

individual rooms within units or wards that would otherwise be considered occupied and available, but that are actually unavailable due to renovations, will be excluded from the available bed count.

However, in order to avoid day-to-day fluctuations in available beds resulting from minor renovations, and to ensure consistent application of this policy, we continue to believe it is necessary to establish a uniform, minimum time period that a bed must be unavailable before it is excluded. Therefore, in order for any bed within a unit or ward that would otherwise be considered occupied to be excluded because it is unavailable, the bed must remain unavailable for 30 consecutive days. In other words, if an individual bed or group of beds within an otherwise occupied unit or ward could not be made available within a 24-hour period for whatever reason (for example, renovations, use as office space, use for provision of ancillary services) for 30 consecutive days, the beds should be excluded from the hospital's available bed count for those 30 consecutive days. This policy would apply to all situations that would render a bed unavailable, not just to the examples listed above. With respect to our proposal to exclude from the available bed count all of the beds in any unit or ward that is unoccupied for the 3 preceding months, we continue to believe that this is an appropriate standard to establish whether the beds in that unit or ward are available for use by the hospital for an IPPS level of care. At some point, the measure of a hospital's number of available beds must bear a relationship to its patient population. We believe the 3 month timeframe, which requires that the beds in a unit or ward are counted if an IPPS level of care is provided to even one

patient every 3 months, is a reasonable threshold that affords a good deal of flexibility to the hospital to maintain as available some beds in low occupancy units or wards.

Comment: One commenter requested that we postpone the proposal to decrease a hospital's total number of beds for purposes of calculating the IME and DSH payments if the hospital's occupancy rate falls below a threshold of 35 percent. Specifically, the commenter requested that we perform further analysis of the bed count methodology and determine the impact on smaller hospitals in rural areas.

Response: In the May 19, 2003 proposed rule, we made reference to the proposed rule published on May 9, 2002 (67 FR 31462) in which we proposed that if a hospital's reported bed count results in an occupancy rate (average daily census of patients divided by the number of beds below 35 percent), we would exclude from beds that would result in an average annual occupancy rate below 35 percent. However, in the August 1, 2002 IPPS final rule (67 FR 50060), we decided not to proceed with the proposed change as final and to reconsider the issue as part of a future comprehensive analysis of our bed and patient day counting policies. In the proposed rule of May 19, 2003 (68 FR 27203), we proposed to determine whether beds in a unit or ward are available based upon whether any bed in the unit or ward was used to provide ("an IPPS level of care") at any time during the 3 preceding months rather than to establish a minimum standard occupancy rate.

Comment: One commenter asked whether if an entire ward has been closed for 4 months, the beds should be excluded only for the fourth month, or whether after the

3-month period has been met, the beds would be excluded from the date that the ward closed.

Response: If any of the beds in a unit or ward were used to provide an IPPS level of care at any time during the preceding 3 months, all of the beds in the unit or ward would be counted for purposes of determining available bed days during the current month. If no IPPS level of care was provided within that unit or ward during the 3 preceding months, the beds in the unit or ward are to be excluded from the count of available bed days during the current month.

In the example given by the commenter, if an entire ward had been used to provide an IPPS level of care during December, but closed for the months of January, February, and March, the beds would be excluded from the available bed count for the month of April. However, the beds would be counted for the months of January through March if a bed in the ward had been used to provide an IPPS level of care in December. If a bed in the ward is occupied for even a portion of the month of April, all of the beds located in the ward would be considered available for the entire month of May. If no bed in the ward is occupied during the month of April, all of the beds would not be counted in the available bed count for May (because no IPPS level of care was provided in that ward for the months of February, March and April).

Comment: One commenter recommended that we reconsider our proposal to exclude unoccupied beds from the available bed count and rely on the hospital license as the definitive bed count for purposes of determining the applicable bed count.

Response: Our policy is not to rely on the hospital license as the definitive bed count for purposes of determining the applicable bed count. There are several reasons we do not believe it is appropriate to rely on a hospital's license to determine the applicable bed count. Hospitals often are licensed for many more beds than they currently occupy. Using a hospital's number of licensed beds as the measure of available beds would allow hospitals with excess capacity to show a higher number of beds which, could inappropriately allow some hospitals to meet the bed thresholds for DSH payment calculation purposes. We also note that the IME adjustment for teaching hospitals could be reduced significantly, and artificially, by including in a hospital's bed count the number of licensed beds that are not in use. In addition, individual states determine the number of licensed beds for hospitals. There is no consistent method from State to State on the requirements or standards for determining these licensed beds. Lack of a consistent method or standard for establishing the number of licensed beds could unfairly disadvantage hospitals in some states, and benefit hospitals in others; the inconsistency among States in bed-licensing methods or standards makes licensed beds an unreliable representation of a hospital's number of available beds.

Comment: Another commenter stated that, if the provider can document that a space is under evaluation as a future location for health care related services (although perhaps it is now only used for storage), the number of beds associated with these spaces should be considered allowable. If, in a year, the provider has not put beds into service or made the beds available by using them to provide an IPPS level of care, the fiscal

intermediary could consider the space as non-allowable, for purposes of determining a hospital's bed count.

Response: The purpose of our policy change is to provide clearer guidance, and to be more consistent in determining which beds should be considered available and included in a hospital's bed count. We believe that allowing hospitals to identify or document that a space is under evaluation as a location for future health care related services, and considering some number of beds associated with the space to be available would add significant vagueness and imprecision to the policy.

In summary, in this final rule, we are revising our regulations at §412.105(b) and §412.106(a)(1)(ii) to specify that bed days in a unit that was occupied to provide an IPPS level of care for at least one day during the 3 preceding months are included in the available bed day count for a month. In addition, bed days for any bed within a unit that would otherwise be considered occupied should be excluded from the available bed day count for the current month if the bed has remained unavailable (could not be made available for patient occupancy within 24 hours) for 30 consecutive days, or if the bed is used to provide outpatient observation services or swing-bed skilled nursing care. This policy will be effective for discharges occurring on or after October 1, 2004.

2. Observation Services and Swing-bed Skilled Nursing Services

Observation services are those services furnished by a hospital on the hospital's premises that include use of a bed and periodic monitoring by a hospital's nursing or other staff in order to evaluate an outpatient's condition or to determine the need for a possible admission to the hospital as an inpatient. When a hospital places a patient under

observation but has not formally admitted him or her as an inpatient, the patient is initially treated as an outpatient, and the services are reimbursed as outpatient services. Consequently, the observation days are not recognized under the IPPS as part of the inpatient operating costs of the hospital. However, if the patient is subsequently admitted as an inpatient, the observation services are reimbursed as inpatient services.

Observation services may be provided in a distinct outpatient observation bed area, (which is not a routine inpatient acute care unit or ward for which costs are included for purposes of the IPPS), but they may also be provided in a bed located within a routine inpatient care unit or ward. As we mentioned above, the discussion of our policies on counting beds and days in this final rule pertains to beds and patient days that occur in units or wards that are not excluded from the IPPS and for which costs are included in determining the allowable costs of inpatient hospital care under the IPPS on the Medicare cost report. However, we note that whether the observation services are provided in a separate outpatient observation area or in a bed within an inpatient acute care unit or ward, our general policy is that the days attributable to beds used for observation services are excluded from the counts of available bed days and patient days at (§§412.105(b) and 412.106(a)(1)(ii)). This policy was clarified in a memorandum that was sent to all CMS Regional Offices (for distribution to fiscal intermediaries) dated February 27, 1997. This memorandum stated that if a hospital provides observation services in beds that are generally used to provide hospital inpatient services, the days that those beds are used for observation services are to be excluded from the available bed day count (even if the patient is ultimately admitted as an acute inpatient).

A swing-bed is a bed that is available for use to provide acute inpatient care and is also available for use to provide SNF-level care. The requirements for a hospital to be considered a swing-bed hospital are located under existing regulations at §482.66, and for a swing -bed CAH, under existing regulations at §485.645. Under existing §413.114(a)(1), payment for posthospital SNF care furnished in swing-beds is made in accordance with the provisions of the SNF prospective payment system (effective for SNF services furnished in cost reporting periods beginning on and after July 1, 2002). Similar to beds and patient days, associated with observation services, when the swing-bed is used to furnish SNF care[4] those beds and patient days are excluded from the counts of available bed days and patient days (§§412.105(b) and 412.106(a)(1)(ii)).

Observation services and swing-beds skilled nursing services are both special, frequently temporary, alternative uses of acute inpatient care beds. Thus, the days a bed in an (otherwise occupied) acute inpatient care unit or ward is used to provide outpatient observation services are to be deducted from the available bed count under §412.105(b) and the patient day count under §412.106(a)(1)(ii). Otherwise, the bed would be considered available for IPPS-level acute care services (as long as it meets the other criteria to be considered available). This same policy applies to swing-beds for days the bed is used to provide SNF-level care. The policies to exclude observation days and SNF-level swing-bed days from the count of available bed days and patient days, as described above stem from the fact that although the services are provided in beds that would otherwise be available to provide an IPPS level of services, these days are not

[4] Ibid.

payable under the IPPS, except in the case of observation days when the patient is ultimately admitted as an inpatient).

In the proposed rule of May 19, 2003, we proposed to amend our policy with respect to observation days for patients who are ultimately admitted for inpatient acute care. As we noted previously, our current policy is that observation days are excluded from the available bed day and the patient day counts. (This policy was communicated in a memorandum to all CMS Regional Offices on February 27, 1997). Specifically, we proposed that, if a patient is admitted as an acute inpatient subsequent to receiving outpatient observation services, we would include the days associated with the observation services in the available bed day and patient day counts. We proposed this policy because it would be consistent with our policy generally to count beds and days when the costs associated with the beds and days would be considered inpatient operating costs under the IPPS.

In order to avoid any potential future misunderstandings about our policies regarding the exclusion of observation and swing-bed days under the regulations at §412.105(b) and §412.106(a)(1)(ii), we proposed to revise our regulations to specify our policy that observation and swing-bed days are to be excluded from the counts of both available beds and patient days, unless a patient, who receives outpatient observation services is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts.

Comment: One commenter indicated that the proposed change does not seem unreasonable, although it will require administrative changes for hospitals to count these

days as part of their reporting processes. However, the commenter suggested that, if the change is finalized, it should be included in all Medicare calculations of days and length of stay; for example, when determining the length of stay for patients subject to the per diem payment methodology for transfers.

Another commenter pointed out that the costs associated with these days would still be ancillary costs and treated as such on the Medicare cost report. Thus, it would be necessary to report these days separately from other inpatient routine care days so that the costs can be appropriately allocated.

Some commenters noted that the proposed change would result in Medicare treating these days inconsistently from other payers and, therefore, it would require a significant amount of a hospital's time and resources to track observation patients that ultimately become inpatients. On the other hand, some commenters asserted that this change would result in Medicare's policy becoming consistent with other payers' treatment of observation patient days attributable to patients who are admitted as inpatients.

Response: We recognize the issues raised by the commenters with regard to treating these days consistently for purposes of determining the length of stay in calculating per diem payments and for cost allocation purposes. We have determined that these days are similar to those days for patients who go to the emergency room and are ultimately admitted to the hospitals. Once a patient has been admitted into the hospital, the time and costs they incurred in the emergency room are also included in the inpatient stay. Including observation patients in the available bed and patient day count once they

are admitted as inpatients requires making a change in the Medicare cost report. On Worksheet S-3, of CMS Form 2552-96, we will include a line to show observation days for patients subsequently admitted as inpatients and a separate line for observation days for patients not admitted.

Comment: Some commenters objected to the general exclusion of observation bed days from the available bed day count on the grounds that it is a flawed premise that the size of a hospital's bed complement should be impacted by the payment policy classification of the services provided to the patient. That is, the commenter believed a bed should not be excluded from the available bed day count because it is used to provide services not payable under the IPPS on a particular day.

Response: When the application of IPPS payment policy hinges on a determination of a hospital's bed size, it seems reasonable to determine bed size based on the portion of the hospital that generates the costs that those IPPS payments are designed to compensate. In addition, we use available bed days as the basis to determine a hospital's the bed count for purposes of the IME adjustment. Therefore, we believe it is appropriate to consider how a bed is used on a given day. For example, if a bed is used for observation services on a given day, it is not available for inpatient services. As stated above, our bed counting policies start with the premise that the treatment of beds should be generally consistent with the treatment of the patient days and the costs of those days on the Medicare cost report. Therefore, we continue to believe it is appropriate to exclude outpatient observation days, even when the beds used to provide that service are located in an otherwise available routine inpatient care unit or ward.

In determining whether a bed should be considered available, our policy has been to treat the bed in the same manner as we treat the patient days and costs associated with the bed. For example, we include intensive care unit beds in the available bed count because patient days in these units are included in total patient days and the costs are included in the calculation of allowable costs under the IPPS. If a patient is placed for observation in a bed generally used to provide inpatient services, and is then admitted to the hospital, the patient days that occurred before the inpatient admission are included in the inpatient stay, the costs prior to the admission are included in allowable inpatient costs, and the bed days are included in the available bed day count. However, if the patient placed for observation is released from the hospital without being admitted, then the observation days and costs are excluded from the calculation of inpatient days and costs, and the bed days are excluded from the available bed day count.

A change in the Medicare cost report is required in order to include observation days for patients that are subsequently admitted as inpatients in the available bed and patient day counts. Therefore, on Worksheet S-3, of CMS Form 2552-96, we will include a line, to show observation days for patients subsequently admitted as inpatients and a separate line for observation days for patients not admitted. This policy change will be applied to all cost reporting periods beginning on or after October 1, 2004.

In summary, in this final rule we are adopting the proposed changes to §412.105(b) and §412.106(a)(1)(ii), which specify that observation and swing-bed days are to be excluded from the counts of both available bed days and patient days unless a patient receiving outpatient observation services in a bed that is generally used to provide

hospital inpatient acute care services is ultimately admitted, in which case the beds and days associated with the observation services would be included in those counts. This policy will be effective for cost reporting periods beginning on or after October 1, 2004.

3. Dual-Eligible Patient Days

As described above, the DSH patient percentage is equal to the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and SSI benefits, and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A benefits. If a patient is a Medicare beneficiary who is also eligible for Medicaid, the patient is considered dual-eligible and the patient days are included in the Medicare fraction of the DSH patient percentage but not the Medicaid fraction. This is consistent with the language of section 1886(d)(5)(F)(vi)(II) of the Act, which specifies that patients entitled to benefits under Part A are excluded from the Medicaid fraction.

It has come to our attention that we inadvertently misstated our current policy with regard to the treatment of certain inpatient days for dual-eligibles in the proposed rule of May 19, 2003 (68 FR 27207). In that proposed rule, we indicated that a dual-eligible beneficiary is included in the Medicare fraction even after the patient's Medicare Part A hospital coverage is exhausted. That is, we stated that if a dual-eligible patient is admitted without any Medicare Part A hospital coverage remaining, or the patient exhausts Medicare Part A hospital coverage while an inpatient, the non-covered patient days are counted in the Medicare fraction. This statement was not accurate. Our policy has been that only covered patient days are included in the Medicare fraction

(§412.106(b)(2)(i)). A notice to this effect was posted on CMS's website **(www.cms.hhs.gov/providers/hipps/dual.asp)** on July 9, 2004.

Comment: We received numerous comments that commenters were disturbed and confused by our recent website posting regarding our policy on dual-eligible patient days. The commenters believed that this posting was a modification or change in our current policy to include patient days of dual-eligible Medicare beneficiaries whose Medicare Part A coverage that has expired in the Medicaid fraction of the DSH calculation. In addition, the commenters believed that the information in this notice appeared with no formal notification by CMS and without the opportunity for providers to comment.

Response: The notice that was posted on our website was not a change in our current policy. Our current policy is, if a patient is a Medicare beneficiary who is also eligible for Medicaid, the patient is considered dual-eligible and the patient days are included in the Medicare fraction of the DSH patient percentage but not the Medicaid fraction. This is consistent with the language of section 1886(d)(5)(F)(vi)(II) of the Act, which specifies that patients entitled to benefits under Medicare Part A are excluded from the Medicaid fraction.

The website posting is a correction of an inadvertent misstatement made in the May 19, 2003 proposed rule (68 FR 27207). This website posting was not a new proposal or policy change. As a result, we do not believe it is necessary to utilize the rule making process in correcting a misstatement that was made in the May 19, 2003 proposed rule regarding this policy.

In the proposed rule of May 19, 2003 (68 FR 27207), we proposed to change our policy to begin to count in the Medicaid fraction of the DSH patient percentage the patient days of dual-eligible Medicare beneficiaries whose Medicare coverage has expired. We note that the statutory provision referenced above stipulates that the Medicaid fraction is to include patients who are eligible for Medicaid. However, the statute also requires that patient days attributable to patients entitled to benefits under Medicare Part A are to be excluded from the Medicaid fraction.

Comment: Numerous commenters opposed our proposal to begin to count in the numerator of the Medicaid fraction of the DSH patient percentage, the patient days of dual-eligible Medicare beneficiaries whose Medicare inpatient coverage has expired. They objected that the proposal would result in a reduction of DSH payments when the exhausted coverage days are removed from the Medicare fraction and included in the Medicaid fraction. According to these commenters, any transfer of a particular patient day from the Medicare fraction (based on total Medicare patient days) to the Medicaid fraction (based on total patient days) would dilute the value of that day and, therefore, reduce the overall patient percentage and the resulting DSH payment adjustment.

One commenter observed that a patient who exhausts coverage for inpatient hospital services still remains entitled to other Medicare Part A benefits. This commenter found it difficult to reconcile the position that these patients are not entitled to Medicare Part A benefits when they can receive other covered Part A services, such as SNF services.

In addition, some commenters stated that these days should not be included in either the Medicare or Medicaid fraction. They indicated that the days should not be included in the Medicare fraction because that computation includes the number of patient days actually furnished to patients who were entitled to both Medicare Part A and SSI benefits. The commenters stated that the days should also be excluded from the Medicaid fraction because that computation excludes hospital patient days for patients who, for those days, were entitled to benefits under Medicare Part A.

Commenters also indicated that the proposal would put an increased administrative burden on the hospitals to support including these patient days in the Medicaid fraction. They recommended that if we finalize this policy, the requirement that hospitals submit documentation justifying the inclusion of the days in the Medicaid fraction should be removed.

Response: We proposed this change to facilitate consistent handling of these days across all hospitals, in recognition of the reality that, in some States, fiscal intermediaries are reliant upon hospitals to identify days attributable to dual-eligible patients whose Medicare Part A hospitalization benefits have expired. We believe it is important that all IPPS policies be applied consistently for all hospitals around the country.

However, we acknowledge the point raised by the commenter that beneficiaries who have exhausted their Medicare Part A inpatient coverage may still be entitled to other Part A benefits. We also agree with the commenter that including the days in the Medicare fraction has a greater impact on a hospital's DSH patient percentage than including the days in the Medicaid fraction. This is necessarily so because the

denominator of the Medicare fraction (total Medicare inpatient days) is smaller than the denominator of the Medicaid fraction (total inpatient days). However, we note that we disagree with the commenter's assertion that including days in the Medicaid fraction instead of the Medicare fraction always results in a reduction in DSH payments. For instance, if a dual-eligible beneficiary has not exhausted Medicare Part A inpatient benefits, and is not entitled to SSI benefits, the patient days for that beneficiary are included in the Medicare fraction, but only in the denominator of the Medicare fraction (because the patient is not entitled to SSI benefits). The inclusion of such patient days in the Medicare fraction has the result of decreasing the Medicare fraction in the DSH patient percentage.

For these reasons, we have decided not to finalize our proposal stated in the May 19, 2003 proposed rule to include dual-eligible beneficiaries who have exhausted their Part A hospital coverage in the Medicaid fraction. Instead, we are adopting a policy to include the days associated with dual-eligible beneficiaries in the Medicare fraction, whether or not the beneficiary has exhausted Medicare Part A hospital coverage. If the patient is entitled to Medicare Part A and SSI, the patient days will be included in both the numerator and denominator of the Medicare fraction. This policy will be effective for discharges occurring on or after October 1, 2004. We are revising our regulations at §412.106(b)(2)(i) to include the days associated with dual-eligible beneficiaries in the Medicare fraction of the DSH calculation.

4. Medicare+Choice (M+C) Days

Under existing §422.1, an M+C plan means "health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan." Generally, each M+C plan must provide coverage of all services that are covered by Medicare Part A and Part B (or just Part B if the M+C plan enrollee is only entitled to Part B).

We have received questions whether the patient days associated with patients enrolled in an M+C Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation. The question stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C.

We note that, under existing regulations at §422.50, an individual is eligible to elect an M+C plan if he or she is entitled to Medicare Part A and enrolled in Part B. However, once a beneficiary has elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A. In the proposed rule of May 19, 2003 (68 FR 27208), we proposed that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DSH patient percentage. Under our proposal, these patient days would be included in the Medicaid fraction. The patient days of dual-eligible M+C beneficiaries (that is, those also eligible for Medicaid) would be included in the count of total patient days in both the numerator and denominator of the Medicaid fraction.

Comment: Several commenters indicated that they appreciated CMS's attention to this issue in the proposed rule. The commenters also indicated that there has been insufficient guidance on how to handle these days in the DSH calculation. However, several commenters disagreed with excluding these days from the Medicare fraction and pointed out that these patients are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program.

Response: Although there are differences between the status of these beneficiaries and those in the traditional fee-for-service program, we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A. We agree with the commenter that these days should be included in the Medicare fraction of the DSH calculation. Therefore, we are not adopting as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction. Instead, we are adopting a policy to include the patient days for M+C beneficiaries in the Medicare fraction. As noted previously, if the beneficiary is also an SSI recipient, the patient days will be included in the numerator of the Medicare fraction. We are revising our regulations at §412.106(b)(2)(i) to include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation.

M. Payment Adjustments for Low-Volume Hospitals (§412.101)

Section 406 of Pub. L. 108-173 amended section 1886(d) of the Act to add a new subclause (12) to provide for a new payment adjustment to account for the higher costs per discharge of low-volume hospitals under the IPPS. Section 1886(d)(12)(C)(i) of the

Act, as added by section 406, defines a low-volume hospital as a "subsection (d) hospital . . . that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year." Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term "discharge" refers to total discharges, and not merely to Medicare discharges. Specifically, the term refers to the "inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A." Finally, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the "empirical relationship" between "the standardized cost-per-case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges." The statute thus mandates the Secretary to develop an empirically justifiable adjustment formula based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

MedPAC has published an analysis of the financial performance and cost profiles of low-volume hospitals (MedPAC June 2001 Report to Congress, page 66). Its analysis indicated that hospitals with 500 discharges or less generally have negative Medicare margins. Specifically, hospitals with 200 discharges or less have margins of -16.4 percent, and hospitals with 201 to 500 discharges have margins of –2.1 percent. MedPAC's analysis further revealed that hospitals with a small volume of discharges have higher costs per discharge than larger facilities, after controlling for the other cost factors recognized in the payment system. MedPAC's analysis thus indicates that

low-volume providers are disadvantaged by payment rates based on average volume. In analyzing the relationship between costs per case and discharges, MedPAC also found that this relationship begins to level off and reaches zero variation at around 500 discharges. Therefore, MedPAC recommended an adjustment formula in the form of:

1.25 -(.0005*D), if D<500 discharges

Where 1.25 represents the maximum 25-percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and "D" is the number of discharges.

Using FY 2001 cost report data, we found an even larger disparity than MedPAC found between low-volume providers and their higher-volume counterparts. Although Medicare margins remain healthy overall at 9.32 percent, the Medicare margin for providers with 200 or less discharges is –46.26 percent, and the margin for providers with 201 to 500 discharges is –11.74 percent. For the May 18, 2004 proposed rule, we employed a bivariate regression analysis to determine the fit between total hospital discharges and operating costs from FY 2001.

As discussed in the proposed rule, we found a very strong correlation between costs and the total number of discharges. We then examined the variation in cost-per-case among subsection (d) hospitals, using both log and nonlog functions. When the analysis was limited to hospitals with fewer than 1,000 discharges, we found a strong relationship between cost per case and low volume. We found that the greatest variation from the mean costs per case exists between 1 and 150 discharges, indicating (as

MedPAC also found) that hospitals with the lowest case volume generally experience greater costs per case than hospitals with higher volume. However, after about 150 discharges, the trend line begins to level off rapidly. The trend line reaches zero variation from mean cost per case at approximately 450 discharges (cost per case in log form) or 500 discharges (nonlog form). Immediately after that point, the trend line in both forms becomes negative, while still maintaining a very smooth line. Both because of where the trend line crosses zero and because there is very little variation from the mean after this point, we believed that 500 discharges was the appropriate cutoff for an add-on payment under this provision.

Based on these results, we proposed to adopt a slightly revised version of MedPAC's recommended formula for an add-on payment to low-volume hospitals:

Adjustment = **1.25 - (.0005*D), if 0<D≤500 discharges**

Where 1.25 represents the maximum 25 percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and "D" is the number of discharges. We proposed to revise the MedPAC recommended formula by adding the condition that "D>0" in order to avoid the anomalous result that a hospital without any discharges would qualify for the maximum 25-percent adjustment.

However, these proposals were based only on our univariate analysis conducted before publication of the proposed rule. In the proposed rule, we indicated our concerns about whether we had sufficient information (for example, total hospital case-mix) to support valid multivariate analyses. We also noted our plan to conduct more detailed multivariate analyses for the final rule.

We also noted that, under our proposed formula, some hospitals that meet the statutory definition of low-volume hospital would receive no adjustment. Specifically, hospitals with more than 500 but fewer than 800 total discharges for the fiscal year would receive no adjustment under this formula. Despite the statutory definition of a low-volume hospital as a subsection (d) hospital that has less than 800 discharges during the fiscal year, the statutory provision mandating this adjustment also requires the Secretary to determine the empirical relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs associated with the number of discharges. In addition, the provision requires that the applicable percentage increase shall be "based upon such relationship in a manner that reflects . . . such incremental costs." We believe that the statutory language thus gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs.

Comment: Many commenters objected to our proposal to provide an adjustment for only some hospitals that meet the statutory definition of a low-volume hospital. Some of these commenters contended that such a proposal was contrary to the statute. Other commenters stated that the proposal neglected to provide additional payments for many small hospitals that may be struggling financially.

Response: We continue to believe that the statutory language gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs. Indeed, we believe that the statutory language implies that no adjustment would be warranted for any hospitals that meet the definition of "low-volume hospital" if the requisite empirical analysis of the "relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs associated with the number of discharges" does not support an adjustment. We also note MedPAC's agreement with our proposal to limit the adjustment to the level supported by the empirical analysis.

While the statute defines low-volume hospitals in terms of total inpatient acute care discharges and mandates that the adjustment be based upon the amount of incremental costs associated with the number of discharges, it does not specify whether the count of discharges, either for purposes of the definition or the payment adjustment formula, should be based on the payment year or some previous year. Specifically, the statute defines low-volume hospital as "for a fiscal year, a subsection (d) hospital . . . [that] has less than 800 discharges during the fiscal year" (emphasis added).

As we indicated in the proposed rule, we believe that this statutory language gives us the flexibility to define which fiscal year to use in determining the number of discharges, both for purposes of the definition of "low-volume hospital" and the payment

adjustment formula. Prospective payment systems place substantial value on providing hospitals with predictability regarding payments. If the determination of whether hospitals qualify for low-volume payment adjustments and the computation of the payment adjustment amount are based on the number of discharges in the current fiscal year, neither CMS nor the hospital will know with certainty whether a hospital qualifies for the adjustment, or what the amount of the adjustment would be, until after the end of the payment year (probably not until the time of final cost report settlement for the year). In such circumstances, CMS could be faced with the prospect of recouping large overpayments in some cases or reimbursing for large underpayments in others. Hospitals would face similar uncertainties. On the other hand, if these determinations are based on discharge counts from a prior fiscal year, hospitals will know in advance whether they will be receiving a payment adjustment and what the size of the adjustment will be. Both hospitals and CMS will be able to plan accordingly.

Therefore, in the proposed rule, we proposed to base the count of discharges, for purposes both of meeting the qualifying definition and determining the amount of the payment adjustment, on the number of inpatient acute care discharges occurring during the cost reporting period for the most recent submitted cost report. We recognize that this policy may temporarily disadvantage certain hospitals. For example, a hospital that had more than 500 discharges in its most recent submitted cost report may have fewer than 500 discharges during the first fiscal year in which this low-volume payment adjustment is available. Such a hospital would not qualify for the low-volume adjustment during the first fiscal year of the adjustment under the proposed policy, but it would qualify under an

alternative policy of basing the discharge count on the fiscal year for which payment is made. However, even in such cases, the hospital would not be certain about whether it would receive an adjustment until its cost report for the payment year is settled. In addition, under the proposed policy, the hospital would still be certain of receiving a low-volume adjustment for any fiscal year in which it had 500 or fewer discharges. The hospital would receive the adjustment during the fiscal year after the cost report is submitted for any fiscal year in which the hospital had 500 discharges or less.

Comment: MedPAC recommended that we consider employing a 3-year moving average of discharges in determining the adjustment and they noted that a 3-year moving average would better track a hospital's underlying patient volume.

Response: We appreciate and understand the basis for this recommendation. However, we believe that the text of the statute, which defines a low-volume hospital as one that has "less that 800 discharges during the fiscal year," precludes taking a multiyear approach to the number of discharges.

Comment: MedPAC recommended that we revise this proposed policy, and consider basing the adjustment on the actual number of discharges in the payment year, rather than relying on 2-year old cost report data. MedPAC noted that our proposed approach would delay recognition of changes to a hospital's actual volume in determining the adjustment, and that reconciliation of the final discharge count for the payment year could be carried out less than a year from the end of the cost reporting period.

Response: We appreciate MedPAC's recommendation and will take it into consideration for future years. However, we are not adopting the recommendation at this time for several reasons. The recommendation to employ the current year count of discharges would require establishment of a reconciliation process, which would probably be implemented by means of revisions to the Medicare cost report form. As we discuss later in this section of the preamble, we are significantly modifying the proposed low volume adjustment on the basis of the empirical analysis that we have conducted since the proposed rule. In the light of this analysis, we will be reanalyzing the empirical data in the FY 2006 rulemaking process and reexamining whether an adjustment is warranted based on the statutory requirement that the adjustment be empirically justified. Until we have determined whether a low-volume adjustment is warranted by the empirical data over the long term, we do not believe that it would be prudent to establish a new reconciliation process and revise the Medicare cost report form.

A further implication of our proposed policy was that a new hospital would not receive an adjustment during its first year of operation, even if it has fewer than 500 total discharges during that year. While this approach is somewhat disadvantageous for hospitals in their first year of existence, we believe that it is justified in order to avoid establishing a settlement process to finalize payments under this new proposed adjustment. Therefore, we proposed that new hospitals that meet the distance requirement would not be eligible for the adjustment until data become available to determine that the annual number of discharges is 500 or less. Under this approach, new hospitals would not receive a low-volume adjustment during at least the first 2 years of

their existence. (This is generally the amount of time that elapses before submission of a cost report.) This policy is consistent with the treatment of some existing hospitals, for example, hospitals that have declining numbers of discharges, and would not be eligible for the adjustment until their data show 500 or fewer discharges.

Comment: Several commenters encouraged us to provide a mechanism for new hospitals to qualify to receive an adjustment without waiting for settlement of the hospital's first cost report.

Response: Providing for new hospitals to receive an adjustment during the first year of operation would require establishment of a reconciliation process, probably through revision of the Medicare cost report. For the reasons discussed previously, we do not believe that it would be prudent to revise the cost report and establish a reconciliation process at this time.

As we noted previously, the statute defines a low-volume hospital as a subsection (d) hospital that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. In order to enforce the requirement that a qualifying hospital be located more than 25 miles from another subsection (d) hospital, we proposed that a hospital that wishes to qualify for the adjustment must provide its fiscal intermediary with evidence that it meets this distance requirement. The intermediary will then certify, on the basis of the evidence presented by the hospital and any other relevant evidence that it may be able to develop, that the hospital meets this requirement. Other relevant evidence may include maps,

mapping software, and inquiries to State and local police, transportation officials, or other government officials.

As discussed previously, we indicated in the proposed rule that for the final rule we planned to conduct more detailed multivariate analysis on the empirical basis for a low-volume adjustment. We have expanded and refined our analysis in several significant ways and, as a result, are revising our proposal in this final rule.

In order to further evaluate the low volume proposal, we empirically modeled the relationship between hospital costs-per-case and total discharges in several ways. We used both regression analysis and straight-line statistics to examine this relationship. We conducted three different regression analyses. For all of the analyses, we simulated the FY 2005 cost environment because the low-volume policies would be applied during that year. We also analyzed the relationship between costs and discharges based purely on FY 2001 and FY 2002 data. The FY 2005 models were given the most weight in our conclusions as payments have undergone several changes between FY 2001 and FY 2005, making the results of the earlier data less relevant. Furthermore, many of these policy changes may already have helped increase payments to low-volume hospitals.

In the first regression analysis, we used a dummy variable approach to model the relationship between standardized costs and total discharges. We standardized costs to remove the effects of differences in area wage levels, case-mix, outliers, and, for hospitals in Alaska and Hawaii, the applicable cost-of-living adjustment. This model was similar to that used by MedPAC on 1997 data. The results of these regression models on the earlier years of data, FY 2001 and FY 2002, provided support for giving

hospitals with less than 200 total discharges positive payment adjustments, as they were found to have higher Medicare costs per Medicare discharge in comparison to high-volume hospitals. These results are somewhat consistent with the similar analysis performed by MedPAC, as MedPAC found that hospitals with up to 200 discharges were in most need of a payment adjustment. However, MedPAC also found evidence for providing an adjustment to hospitals with up to 500 discharges, which the data for FYs 2001 and 2002 do not show. Furthermore, the analysis revealed no statistically significant relationship between standardized costs and total discharges when modeling under the FY 2005 environment. These results suggest that the relationship between standardized costs and total discharges is becoming less significant over time, which may indicate that changes to the payment structure (for example, changes in the labor share, and the equalization of standardized amounts) over time have already had some positive impact on low-volume hospital payments.

We also used a descriptive analysis approach to understand the empirical relationship between costs and total discharges. We grouped all hospitals by their total discharges and compared the mean Medicare per discharge payment-to-Medicare per discharge cost ratios. Hospitals with less than 800 total discharges were split into 24 cohorts based on increments of 25 discharges. For the most part, the mean payment-to-cost ratios were below one (implying that Medicare per discharge costs exceeded Medicare per discharge payments), for cohorts of hospitals with less than 200 discharges. However, consistent with the regression findings, the point at which the ratio seemed to transition from consistently being below 1 to above 1 decreased over time from

approximately 225 discharges in 2001 to 150 discharges in 2005. There was also no obvious increasing trend in the ratios, from which it would be possible to infer a formula to generate adjustments for hospitals based upon the number of discharges. Because nearly 70 percent of hospitals with less than 200 discharges had ratios below 0.80, this analysis supports applying the highest payment adjustment to all providers with less than 200 discharges that are eligible for the low volume adjustment. This finding also raises concerns that the large variation in costs relative to payments and the low sample sizes for low-volume hospitals may bias the regressions toward insignificant results.

The second regression analysis modeled the Medicare per discharge cost-to-Medicare per discharge payment ratio as a function of total discharges. The cost-to-payment ratio model more explicitly accounts for the relative values of per discharge costs and per discharge payments. These models provided some evidence for a statistically significant negative relationship between the cost-to-payment ratio and total discharges. However, that result was limited to FY 2001 and FY 2002 data and no significant relationship between the cost-to-payment ratio and total discharges was found with simulated FY 2005 data. These results also lend support to the notion that the relationship between the cost-to-payment ratio and total discharges has become less significant over time, and that changes to the payment structure have had some positive impact on low-volume hospital payments.

The third regression analysis employed per discharge costs minus per discharge payments as the dependent variable and total discharges as an explanatory variable. The results of this analysis were similar to the other regression analyses: some evidence was

provided for an adjustment with the FY 2001 and FY 2002 data, but not with the simulated FY 2005 data. In fact, the 2005 results suggest (with a positive intercept and positive coefficient on total discharges) that payments are greater than costs for all hospitals, including the low-volume hospitals. Again, these results are consistent with the notion of previous changes to the payment structure having already had positive impacts on low-volume hospital payments.

In conjunction with this third regression analysis, we also examined the straight-line statistical relationship between per discharge costs minus per discharge payments and total discharges. The results of this analysis indicate that this relationship is negative for the majority of hospitals with less than 200 discharges.

The declining trend in the significance of the relationship between hospital costs and discharges and, in particular, the statistically insignificant relationship with the simulated FY 2005 results may provide some case for not making a low-volume adjustment. However, we are persuaded by the earlier data and the descriptive statistics that hospitals with less than 200 discharges have sufficiently higher costs relative to payments to justify an adjustment, although more modest in scope than the adjustment we proposed. Therefore, in this final rule we are providing a low-volume adjustment for hospitals with less than 200 discharges. As noted above, the descriptive data do not reveal any pattern that could provide a formula for calculating an adjustment in relation to the number of discharges. However, the descriptive analysis of the data does indicate that, for a large majority of the hospitals with less than 200 discharges, the maximum adjustment of 25 percent would be appropriate. This is because, for example, the

payment-to-cost ratios for more than 70 percent of these hospitals are 0.80 or less. The maximum adjustment of 25 percent would therefore leave most of these hospitals with payment-to-cost ratios still below 1.00. Because a large majority of hospitals with less than 200 discharges have payment-to-cost ratios below 1.00, we are providing that hospitals with less than 200 total discharges in the most recent submitted cost report will receive an adjustment of 25 percent on each Medicare discharge. Therefore, we are revising §412.101(a) and (b) to implement these changes.

We believe that, in the light of all the analysis that we have conducted, extending a 25 percent low-volume adjustment to all hospitals with less than 200 discharges is most consistent at this time with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of discharges. However, we acknowledge that the empirical evidence does not provide robust support for this conclusion. Therefore, we will thoroughly reexamine the empirical evidence next year, and propose to modify or even eliminate the adjustment if the empirical evidence indicates that it is appropriate to do so at that time. Our analysis indicates that there are fewer than 100 hospitals with less than 200 total discharges. We are unable to determine how many of these hospitals also meet the requirement that a low-volume hospital be more than 25 road miles from the nearest subsection (d) hospital in order to qualify for the adjustment. However, the majority of the low-volume hospitals that we have been able to identify are located in urban areas. Some indications suggest that a number of these hospitals may be specialty hospitals, which are generally small institutions concentrating in one area of surgical practice, such

as orthopedics or heart surgery. It is not entirely clear that it is the intent of this statutory provision to provide additional payment to this type of hospital. Others may be eligible to apply to become CAHs. We will monitor the numbers and types of hospitals that receive the low-volume adjustment as the intermediaries make determinations concerning which facilities meet all the requirements for the adjustment.

N. Medicare Geographic Classification Review Board (MGCRB) Reclassifications (§§412.230, 412.234, and 412.236)

1. Background

With the creation of the MGCRB, beginning in FY 1991, under section 1886(d)(10) of the Act, hospitals could request reclassification from one geographic location to another for the purpose of using the other area's standardized amount for inpatient operating costs or the wage index value, or both (September 6, 1990 interim final rule with comment period (55 FR 36754), June 4, 1991 final rule with comment period (56 FR 25458), and June 4, 1992 proposed rule (57 FR 23631)). Implementing regulations in Subpart L of Part 412 (§§412.230 et seq.) set forth criteria and conditions for redesignations for purposes of the wage index or the average standardized amount, or both, from rural to urban, rural to rural, or from an urban area to another urban area, with special rules for SCHs and rural referral centers.

Effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act provides that the MGCRB must use the average of the 3 years of hourly wage data from the most recently published data for the hospital when evaluating a hospital's request for reclassification. The regulations at §412.230(e)(2)(ii) stipulate that the wage

data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes. To evaluate applications for wage index reclassifications for FY 2005, the MGCRB used the 3-year average hourly wages published in Table 2 of the August 1, 2003 IPPS final rule (68 FR 50135). These average hourly wages are taken from data used to calculate the wage indexes for FY 2002, FY 2003, and FY 2004, based on cost reporting periods beginning during FY 1998, FY 1999, and FY 2000, respectively.

2. Standardized Amount Reclassification Provisions

As specified in §412.230(d)(1), to be reclassified to an adjacent area for the purpose of using that area's standardized amount, an individual hospital seeking redesignation must demonstrate that its incurred costs are comparable to hospital costs in the adjacent area (that is, hospitals must demonstrate that their costs exceed their current payments by 75 percent of the additional payments they would receive through reclassification) and that it has the necessary close proximity to that area (that is, an urban hospital must be no more than 15 miles and a rural hospital no more than 35 miles from the adjacent area; or at least 50 percent of the hospital's employees must reside in the adjacent area).

Under section 402(b) of Pub. L. 108-7, Congress provided that all inpatient PPS hospitals be paid at the large urban average standardized amount for discharges occurring on or after April 1, 2003 and before October 1, 2003. Under Pub. L. 108-89, Congress extended section 402(b) of Pub. L. 108-7 to discharges occurring through March 31, 2004. Section 401 of Pub. L. 108-173 further extended the equalization of

urban and rural operating standardized payment amounts. (See section IV.B. of this preamble for a more detailed discussion.) Section 401 also equalized the Puerto Rico-specific urban and other area rates by requiring that the Puerto Rico-specific urban and other area rates be made retroactive to October 1, 2003. The Puerto Rico-specific equalization of the urban and rural operating standardized amounts became effective for discharges beginning on or after April 1, 2004.

As a result of these legislative changes, the standardized amount reclassification criterion is no longer necessary or appropriate. Therefore, in the May 18, 2004 proposed rule (69 Fr 28288), we proposed to revise §412.230 and §412.234 to remove all standardized amount criteria provisions. We proposed to remove the provisions of §412.230(d) (existing paragraph (e) would be redesignated as paragraph (d)), and to remove §412.234(c) and (d)(2) (existing paragraph (d)(1) would be redesignated as paragraph (c) and revised), which contain the criterion requiring individual hospitals and urban hospital groups to demonstrate that their costs are more comparable to the average amount they would be paid if they were reclassified than the amount they would be paid under their current classification.

With the implementation of the equalization of the national adjusted operating standardized amount for large urban and other areas provision of Pub. L. 108-173, we also proposed the following technical revisions to several sections under Subpart L of Part 412, which set forth the criteria and conditions for redesignations.

- We proposed to delete the cross-reference to "§412.230(d)(2)" cited in §412.230(a)(4) and to make redesignation changes for the existing cross-reference changes to paragraph (e), which was proposed to be redesignated as paragraph (d).

- We proposed to delete §412.230(a)(5)(ii) (the existing paragraphs (a)(5)(iii), (a)(5)(iv), and (a)(5)(v) was proposed to be redesignated as paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(5)(iv), respectively. Under existing §412.230(a)(5)(ii), we defined, for fiscal years 1997, 1998, and 2002, the limitation for redesignation for purposes of the standardized amount. Our policy has been that a hospital may not be redesignated for purposes of the standardized amount to an area that does not have a higher standardized amount than the standardized amount the hospital currently receives.

Comment: Many commenters agreed with our proposed revisions. One commenter stated that, as a RRC approved for reclassification, the hospital should be allowed to retain its reclassification to the MSA with which it competes, as opposed to assignment to an area that does not include any other "academic tertiary care hospitals". The commenter also stated that by allowing hospitals to maintain reclassification to the selected MSA, CMS would be adhering to the original intent of the geographic reclassification provision. In addition, the commenter advises that through CMS's recognition that "rural hospital's continued financial viability is necessary in order to preserve access to needed services for Medicare beneficiaries in these providers' service areas" and acknowledgement of the "need to maintain access to tertiary care for Medicare beneficiaries in relatively isolated areas," rural referral centers and other similar teaching hospitals have in the past been insulated from the adverse financial consequences that

result from changes in rules and regulations. In light of its concerns, the commenter recommends that CMS establish a separate exception for major rural teaching hospitals by revising §412.230 to add two provisions. The commenter believes that adoption of the suggested rules would allow a major teaching hospital to reclassify to an MSA where a substantial number of its competing hospitals are located within the same census region, thus affording them the flexibility to reclassify to an appropriate MSA.

The first revision recommended by the commenter is to revise §412.230(a)(4) to add a new title, "Special Rule for Major Rural Teaching Hospital," to revise the text to read as follows:

"A hospital that is a major teaching hospital located in a rural area does not have to demonstrate a close proximity to the area to which it seeks redesignation. The hospital may seek redesignation to a large urban area (as defined in §412.63(c)(6)) that includes five or more major teaching hospitals and that is located in the same census region as the applicant. For purposes of this section, a major teaching hospital is a hospital that (i) has a documented affiliation agreement with a medical school accredited by the Liaison Committee on Medical Education ("LCME"), and (ii) sponsors, or participates significantly in residency programs in Medicine, Surgery, Obstetrics/Gynecology, Pediatrics, Family Practice, or Psychiatry."

The second recommendation is that §412.230(e)(4) be retitled, "Major Rural Teaching Hospital Exception, and revised to read " If a hospital was a major teaching hospital in a rural area as of September 30, 2004, it does not have to demonstrate that it

meets the criterion set forth in paragraph (e)(1)(iii) of this section concerning its average hourly wage."

Response: We appreciate the opportunity to consider the revisions recommended by the commenter. In response to the commenter's concern regarding the proposal to assign reclassified hospitals to the nearest county, because we have addressed similar concerns in this final rule, we are not readdressing that response here. We encourage the commenter to refer to section III.H of this final rule for a more detailed response to this issue.

With respect to the recommendation that §412.230 be revised to establish a separate exception for major rural teaching hospitals we are not persuaded that there is a need to establish the suggested exception for several reasons. First, this hospital, while defined as a major rural teaching hospital, is also a rural referral center. Given its status as a rural referral center, it is not subject to the proximity criteria because it already has a special status as a rural referral center. As a result of this special status the hospital has an advantage over other reclassifying hospitals in that it can utilize a larger radius in seeking reclassification opportunities (§412.230(a)(3)). In addition, rural referral centers (and SCHs) may also reclassify to any MSA to which they qualify under §412.230(b). With respect to the hospitals ability to reclassify based on its status as a rural referral center, we believe these criteria provide adequate opportunity for reclassification.

Second, while we understand the commenter's point about its competitors, we do not believe that this justifies establishing such broad exceptions as exempting a specific type of rural hospital from meeting the proximity requirement or from having to

demonstrate that it meets any wage comparability test for reclassification purposes. Therefore, we are not adopting either of the recommended revisions.

In the May 18, 2004 proposed rule, we proposed to delete existing §412.236. Section 412.236 sets forth the redesignation criteria for hospitals in a NECMA. Under the new CBSAs, OMB has defined the MSAs and Micropolitan areas in New England on the basis of counties. As discussed in section III.B. of the May 18, 2004 proposed rule, to maintain consistency in the definition of labor market areas between New England and the rest of the country, we proposed to use the New England MSAs under the new CBSA definition. Proposing to adopt the New England MSAs requires not only that we delete the reference to NECMAs in existing definitions, but that we also delete reference to criteria applicable to hospitals located in a NECMA that apply for reclassification. In keeping with the proposal to define labor market areas as MSAs, including those in New England, the criteria and conditions for redesignation set forth in §412.230 will be applicable to New England hospitals seeking to reclassify.

In an effort to refine the reclassification guidelines, we established §§412.234 and 412.236 in the existing guidelines to allow for reclassification of urban groups and New England groups, respectively (56 FR 25458). Under §412.232(a) and §412.234(a), we set forth similar criteria for rural and urban hospitals to be reclassified as a group, respectively. Prior to the implementation of legislation to eliminate the differential in the standardized amount, urban county groups that were interested in applying for purposes of the wage index submitted applications to the MGCRB for consideration. Many urban county group applications were unable to reclassify solely because they failed to meet the

standardized amount criteria. In light of the fact that the standardized amount criteria are no longer appropriate, we believe it would be appropriate to make an adjustment to the hospital's wage index by assigning, to hospitals that were unable to reclassify in applications for both FY 2004 and FY 2005, the wage index for the MSA requested in the FY 2004 and FY 2005 group application. Section 1886(d)(5)(I)(i) of the Act provides the Secretary with broad authority to make adjustments and exceptions under the IPPS. Specifically, the section provides that the "Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." Under this unique circumstance, in the May 18, 2004 proposed rule, we proposed to exercise the broad authority under section 1886(d)(5)(I)(i) of the Act, to make an exception to the assignment of wage index value for certain hospitals that failed to reclassify as a group under §412.234 for FY 2004 and FY 2005. Specifically, effective with discharges occurring during the 3-year period beginning October 1, 2004 through September 30, 2007, any hospital whose urban county group application under §412.234 would have been approved by the MGCRB but for the failure to meet the requirements in §412.234 (c), would be assigned the wage index for the MSA identified in the FY 2004 and FY 2005 group application (in cases where the group identified more than one preference, the hospital would be assigned the wage index that is most advantageous). In the proposed rule, we indicated that hospitals that wish to receive the wage index of the area identified in their FY 2004 and FY 2005 group applications under this provision would need to only notify CMS in writing, at the

address provided under the "Addresses" section of the proposed rule, before the close of the comment period. We further stated that the notification should only contain:

- The hospital's name and street address.
- The hospital's provider number.
- The name, title, and telephone number of a contact person for communications.
- The area (name and MSA number) identified in their FY 2005 group application.
- Copies of any and all MGCRB decision notification letters for FY 2004 and FY 2005.

Comment: Several commenters stated that the requirement that hospitals needed to have failed to reclassify as an urban group under §412.234 for "FY 2004 and FY 2005" is "unreasonable and arbitrary." The commenters recommended that the criteria be modified to provide relief to all urban group hospitals that applied in FY 2005, irrespective of whether they applied for consideration in FY 2004.

Response: We proposed to exercise the Secretary's authority to provide for "exceptions and adjustments" to payments under the IPPS. To assign a different wage index to a group of hospitals that were unable to reclassify because of a reclassification criterion that is no longer appropriate due to a statutory change. We do not believe it was "unreasonable and arbitrary" to restrict the extraordinary exercise of this exceptions authority to a small group of hospitals that had persisted in seeking reclassification as an urban county group over two consecutive years. Several hospitals notified us that they have met the requirements that we announced in the proposed rule. In this final rule, we

are providing for these hospitals to be assigned to the wage index of the MSA identified in their FY 2004 and FY 2005 group applications.

We do not agree with the commenters that we should extend this exception to all hospitals that were unable to reclassify as a group solely because they failed to meet the standardized amount criterion in either FY 2004 or FY 2005. However, we have been persuaded by the factual situations described by several commenters to extend this exception modestly beyond what we proposed. In several cases, some hospitals that were parties to group reclassification applications in FY 2004 or FY 2005 have been able to reclassify as individual hospitals, either through the regular MGCRB process or through the special one-time wage index appeal process under section 508 of MMA. In cases where a significant proportion of the group applicants have been able to reclassify otherwise, the remaining hospitals in the group can be placed at a significant competitive disadvantage. Therefore, we are providing in this final rule, to provide for an adjustment to the wag e index of the hospitals that meet the following criteria:

• The hospital was part of an urban county group reclassification application for FY 2004 or FY 2005 that failed solely on the basis of the standardized amount criterion;

• At least one-third of the hospitals that had been parties to the urban county group reclassification application have subsequently been reclassified for FY 2005 either through the regular MGCRB reclassification process or the special one-time wage index appeal process under section 508 of MMA;

• The hospitals can demonstrate that the hospitals that have since reclassified to another area, have a wage index at least 10 percent higher than the wage index of the MSA where the hospital is located.

A hospital that meets all of these criteria will be assigned the wage index of the area identified in their FY 2004 or FY 2005 urban county group reclassification application.

Hospitals will have 30 days after the publication date of this final rule to notify us of their eligibility on the basis of the criteria described above.

Comment: Several commenters expressed concern that the proposed adoption of CBSA designations will require urban hospital groups seeking reclassification to be located within a CBSA, and to seek reclassification to another area within that CBSA (that is, another Metropolitan Division). They stated that if the proposal is implemented the opportunity for reclassification will not be available to urban hospital groups located in states such as California, Connecticut, New Hampshire, North Carolina, and New York. In other words, the proposal limits hospital group reclassification to hospitals located in CBSAs with multiple Metropolitan Divisions. Several of the commenters recommended that if CMS adopts the new CBSAs, it should modify the urban group proximity criteria to require that hospitals that are located in counties located in the same CSA under the new MSAs would meet the proximity requirement. Other commenters expanded on this recommendation by recommending that CMS "grandfather" counties where a group reclassification is in place and "deem" those counties as eligible for future group reclassifications to contiguous Metropolitan Divisions included in the same CSA.

Response: Section 1886(d)(10)(D)(i)(II) of the Act requires the Secretary to publish guidelines "for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area." The statute does not specify the particular criteria to be used, but instead confers broad authority on the Secretary in establishing guidelines. Under current regulations, hospitals seeking group reclassification must be located within a CMSA, and they may seek reclassification only to another area within that CMSA. As we stated in the May 18, 2004 proposed rule, we proposed to adopt the new CBSA designations as announced by OMB to define labor market areas, specifically, the MSA category as defined by the standards. Given that the implications of implementing the new labor market areas as proposed result in the unintended restriction of reclassifications for some urban county groups, we have been persuaded that there is a need to modify our urban group reclassification policy so as to preserve the reclassification opportunities for these urban county groups. Therefore, in this final rule we are modifying the urban county group reclassification criteria set forth in §412.234(a)(3) to specify that "hospitals located in counties that are, under the new MSA designations, in the same CSA under the new MSA designations and the same CMSA under the former MSA designations qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation." We thank the commenters for bringing this issue to our attention.

3. Reclassification of Urban Rural Referral Centers

Under existing regulations at §412.230(e)(3), rural referral centers (RRCs) (including hospitals that were ever RRCs) are exempt from one of the average hourly

wage criteria that apply to other hospitals seeking reclassification. Specifically, an RRC is exempt from the requirement under §412.230(e)(1)(iii) that the hospital's 3-year average hourly wage meet a threshold percentage in relation to the average hourly wage of all the hospitals in the area in which the hospital is located. These threshold percentages are 108 percent for hospitals located in urban areas, and 106 percent for hospitals located in rural areas. However, an RRC is not exempt from another threshold requirement, namely the requirement under §412.230(e)(1)(iv) that the hospital's 3-year average hourly wage must meet a threshold percentage of the 3-year average hourly wage of the hospitals located in the area to which the hospital seeks reclassification. As in the case of the first threshold, this threshold percentage is different for urban and rural hospitals. An urban hospital's 3-year average hourly wage must be at least 84 percent of the average hourly wage of the hospitals located in the area to which the hospital seeks reclassification, while a rural hospital's 3-year average hourly wage must be at least 82 percent of the average hourly wage of the hospitals located in the area to which the hospital seeks reclassification.

In the May 18, 2004 proposed rule (69 FR 28289), we indicated that it had come to our attention that the requirement of §412.230(e)(1)(iv) places RRCs located in urban areas on a different footing than RRCs located in rural areas. In some cases, urban RRCs that have been denied reclassification because they failed to meet the 84-percent threshold would have been able to meet the 82-percent threshold that would have applied if they were located in a rural area. RRCs play a significant role in treating Medicare beneficiaries from rural areas, whether or not a particular RRC is physically located in a

rural area or an urban area. Thus, we believe that it would be more appropriate for all RRCs, whether they are actually located in urban or rural areas, to be treated on an equal basis with respect to the qualifications for geographic reclassification. Therefore, we proposed to revise §412.230(e)(1)(iii) of the regulations to provide that RRCs, including RRCs located in urban areas, must meet the 82-percent threshold that applies to rural hospitals rather than the 84-percent threshold that applies to urban hospitals.

Furthermore, we had become aware of at least one case in which an RRC was reclassified by the MGCRB for FY 2004, but upon applying to the MGCRB for FY 2005, was found to be ineligible for reclassification because its 3-year average hourly wage was now less than 84 percent of the hospitals located in the MSA to which it applied for reclassification. In this case, the hospital's 3-year average hourly wage was still greater than 82 percent of the MSA to which it had applied for reclassification. In such a case, we believe that it would be appropriate to make an accommodation for one year, so that the hospital is not subjected to the financial strain that may be caused by receiving a lower wage index for one year until it qualifies to apply for reclassification under the revised threshold criterion that we are proposing here. Therefore, we proposed that, in such a case, we would exercise our authority under section 1886(d)(5)(I)(i) of the Act to make an exception by assigning to the hospitals for one additional year the wage index that applied to the hospital in FY 2004 through FY 2005. We proposed to use this authority to provide, under this unique circumstance, special protection to a small number of hospitals that would otherwise be subject to a temporary, but serious, disadvantage. Specifically, we would assign an RRC that meets the conditions described above, the

wage index value of the MSA to which it was reclassified by the MGCRB in FY 2004. In order to be eligible for this exception, the hospital may not qualify for any geographic reclassification for discharges effective October 1, 2004 (under the regular rules or the special one-time appeal provision). This assignment would be valid only for FY 2005, after which the hospital would have the opportunity to apply for reclassification under the proposed new threshold for all RRCs in the proposed rule.

We proposed to revise proposed redesignated §412.230(d)(3) and add a new §412.64(j) to incorporate this proposal.

Comment: A number of commenters expressed support for our proposal to revise §412.230(e)(1)(iii) of the regulations to require that the 3-year AHW of RRCs, including those located in urban areas, must be at least 82 percent of the AHW of the hospitals in the targeted area and to allow an urban RRC which did not qualify for reclassification for FY 2005 to receive the wage index of the MSA to which it was reclassified in FY 2004. One commenter, questioned the rationale for extending the reclassification exception for only 1 year while other hospitals qualifying for reclassification are reclassified for 3 fiscal years. The commenter stated that the proposed 1-year extension impairs the hospital's ability to make plans regarding financial status more than 1 year in advance. The commenter recommended that the exception allowing qualifying urban RRCs to be reclassified be applicable for 3 years. Other commenters recommended that "CMS continue to allow a 35 mile proximity requirement for urban RRCs."

Response: We appreciate the commenter's support for our proposal that RRCs, including those located in urban areas must, meet the 82 percent threshold that applies to

rural hospitals rather than the 84 percent threshold applicable to urban hospitals. The premise behind the development of the proposal and the exception was to put urban RRCs on an equal footing with RRCs located in rural areas. As the commenter noted, a 1-year exception, even in light of their ability to apply for reclassification in FY 2006, does not provide the equal footing they would realize if the exception were extended for 3 years. We agree with the commenter and, in this final rule, we are modifying the reclassification exception for urban RRCs and therefore will allow qualifying urban RRCs to be reclassified for 3 years.

With respect to the recommendation that "CMS continue to allow a 35 mile proximity requirement for urban RRCs", it is important to note that under the special access guidelines at §412.230(a)(3), we exempt RRCs and SCHs from the adjacency and proximity requirements in §412.230(a)(2), therefore, RRCs and SCHs are not required to demonstrate a close proximity to the area to which it seeks to reclassify.

Comment: A commenter recommended that CMS consider, for purposes of geographic reclassification, designating as RRCs these urban hospitals that reflect characteristics similar to urban RRCs. The commenter advised that failure to do so will continue to "significantly disadvantage" urban hospitals that play a significant role in treating Medicare rural beneficiary populations. As one way to accomplish this, the commenter recommended that CMS designate any hospital as an urban RRC if it meets the criteria of §412.103(a)(3) as it relates to RRCs.

Response: Under Medicare law, the location of a hospital can affect its payment as well as whether the facility qualifies for special treatment both for operating and

capital payments. The commenter recommends that CMS designate urban hospitals that reflect characteristics similar to urban RRCs as RRCs and advises that §412.103 provides the means to accomplish this. Section 401(a) of Public Law 106-113, which amended section 1886(d)(8) by adding paragraph (E), directs the Secretary to treat any subsection (d) hospital located in urban areas as being located in the rural area of the State in which it is located if the hospital files an application and if it meets one of the established criteria set forth on §412.103. (We provided a detailed discussion of this policy in the August 1, 2000 interim final rule with comment period (65 FR 47029) and the August 1, 2001 final rule (FR 66 39884).) Because there are several provisions of the of Social Security Act that provide procedures under which a hospital can apply for reclassification from one geographic area to another, we still do not believe, as we stated in the aforementioned final rules, that there is a need to specify further qualifying criteria for reclassifications governed by §412.103 guidelines. Therefore, as discussed above, we are adopting the change requiring all RRCs, regardless of location in an urban or rural area, to meet the 82- percent threshold. In addition, we are modifying our proposal for those RRCs that were reclassified to an urban area in FY 2004 and that failed to be reclassified in FY 2005 in order to provide a reclassification for 3 years using our authority under section 1886(d)(5)(i)(I) of the Act.

4. Special Circumstances of Sole Community Hospitals (SCHs) in Low Population Density States

Medicare program policy has long provided special treatment for hospitals in rural areas. For many years, rural hospitals have experienced lower margins than other

hospitals, and Congress has created several special measures to address the unique issues of hospitals in rural areas. For example, Congress created the CAH program in 1997 to ensure that beneficiaries in isolated areas had access to emergency services and certain essential inpatient services. To qualify for CAH designation, a hospital must be located more than 35 miles from the nearest similar hospital and have an average length of stay not exceeding 4 days. A CAH must provide 24-hour emergency care services and have no more than 25 acute care beds. CAHs are currently paid 101 percent of their current Medicare allowable costs for inpatient and outpatient services. Similarly, the SCH program has long served to maintain access to needed health services for beneficiaries in isolated communities. SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; or the updated hospital-specific rate based on FY 1996 costs per discharge.

Many rural hospitals have taken advantage of the opportunity to participate in the CAH program in recent years. We expect the number of hospitals to increase because of the changes made to the CAH program under recently enacted Pub. L. 108-173 (for example, increasing the reasonable cost payment rate from 100 percent to 101 percent and increasing the qualifying bed size limitation from 15 to 25). Because CAHs are paid on the basis of their reasonable costs, the wage index is not a factor in their payments, and geographic reclassification is thus not an issue for these hospitals. However, for many rural hospitals that cannot qualify for CAH status, the wage index remains an

important factor in their payment, even in the case of SCHs paid on their hospital-specific rate, for which the only impact of the wage index may be on their inpatient capital and outpatient payments. The regulations governing reclassifications by the MGCRB provide special treatment for SCHs by exempting them from the normal rules that require hospitals to demonstrate a close proximity (15 miles in the case of urban hospitals; 35 miles for rural hospitals), and allowing these hospitals to reclassify to the urban area or the rural area that is the closest to the hospital.

Wage index assignment is an especially pressing issue for hospitals in States with low population densities. In such States, employees are likely to commute greater distances to work. More distant areas are thus likely to compete for labor than is the case in more densely populated States. Because of this concern, and the program's longstanding recognition of these hospitals, we exercised our discretion in implementing the special one-time wage index reclassification appeal provision of section 508 of Pub. L. 108-173 to provide special consideration for SCHs in States with fewer than 10 people per square mile, based on 2000 census data (Alaska, Montana, North Dakota, South Dakota, and Wyoming). Specifically, we provided that SCHs in such a State could reclassify to an MSA within its State. More than 20 SCHs in those States were able to reclassify under this provision.

However, a number of SCHs from those States were precluded from reclassifying under the terms of section 508. In the May 18, 2004 proposed rule (69 FR 28289), we indicated that we were concerned that these hospitals could now be placed at a serious disadvantage in comparison to other SCHs in their States and regions. Under the

authority of section 1886(d)(5)(I)(i) of the Act, we proposed to provide, under these unique and temporary circumstances, special protection to a small number of hospitals that would otherwise be subject to a temporary, but serious, disadvantage. Specifically, we proposed to allow an SCH in one of the States with fewer than 10 people per square mile (Alaska, Montana, North Dakota, South Dakota, and Wyoming) to adopt the wage index of another geographic area within its State for 3 years.

Under the proposal, such wage index assignments would become effective for FY 2005 through FY 2007. Because the wage index assignments would be made in order to remedy a temporary disadvantage, the assignments would be for the 3-year period only and would not be available thereafter. In order to receive the wage index of another area under this proposal, we proposed that a SCH may not qualify for reclassification (under the regular rules or the special one-time appeal provision) effective for discharges on or after October 1, 2004. SCHs in the identified States will not be required to meet proximity or access requirements similar to those required for reclassification in order to qualify for change in wage index under this provision. Under this proposal, SCHs that wished to receive the wage index of another area within their State under this provision needed only to notify CMS in writing, at the address in the "Addresses" section provided for comments on the proposed rule, before the close of the comment period. The notification should have contained:

- The hospital's name and street address.
- The hospital's provider number.
- The name, title, and telephone number of a contact person for communications.

- A statement certifying the SCH status.

- The name of the area within the State whose wage index the hospital wishes to adopt.

Comment: Many commenters expressed their support of our proposal and providing us with notification that they meet the conditions for receiving this exception.

Response: We will adjust the wage indexes of these hospitals accordingly. We have listed these hospitals, and their wage index assignments, in Table 9B of the Addendum to this final rule.

Comment: One commenter expressed support for the provision and noted that it would have qualified for the exception, except that it had been designated as a CAH effective July 1, 2004. This hospital requested that we provide the exception retroactively back to April 1, 2004, the date on which the commenter would have begun to receive an adjustment under section 508 of the MMA if it had been able to qualify.

Response: We do not believe that it would be appropriate to provide this adjustment retroactively. Doing so runs counter to the basis for payment in a prospective payment system. We would note that the hospital is now receiving payment on a favorable basis at 101 percent of cost as a CAH.

Comment: One commenter expressed concern regarding CMS's proposal to allow an SCH located in one of 5 identified low-population density States to adopt the wage index of another geographic area within its State for 3 years. The commenter objected to the proposal on the basis that because CMS is not proposing a broader exception, hospitals such as the SCHs and other hospitals who met criteria under section

508 in the commenter's State, are being disadvantaged given the fact that hospitals in neighboring States will be reclassified.

Response: As we noted in the proposed rule, we believe that given the pressing issues associated with wage index assignment issues for hospitals in States with low population densities, the likelihood that, in such States, employees are likely to commute greater distances to work, and the fact that more distant areas are thus likely to compete for labor than is the case in more densely populated States. Given these circumstances, we continue to believe that such an exception for these SCHs is warranted. Therefore, in this final rule, we are finalizing the special exception provision, as proposed, by adjusting the wage indexes of those SCHs that provided notification that they met the conditions for receiving this exception.

5. Possible Reclassifications for Dominant Hospitals and Hospitals in Single-Hospital MSAs

In the May 18, 2004 proposed rule (69 FR 28290), we indicated that representatives of individual hospitals had expressed concern about the special circumstances of dominant hospitals and hospitals in single-hospital MSAs in relation to the wage index and the rules governing geographic reclassification. The term “dominant hospital” generally refers to a hospital that pays a substantial proportion of all the wages paid by hospitals geographically located in the hospital’s area. A dominant hospital necessarily has a preponderate influence on the wage index calculation for the area in which it is located. As a result, dominant hospitals find it difficult to meet the threshold requirements for wage index reclassification; for example, the requirement that an urban

hospital's average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located (§412.230(e)(1)(iii)(B)). Indeed, a dominant hospital would find it difficult to meet any threshold based on the ratio of the hospital's average hourly wage to the average hourly wage of hospitals in the area, unless the dominant hospital's wage data were removed from the denominator for purposes of the comparison. Dominant hospitals have argued that this places them in an unfair situation. While the lower wages of other, smaller hospitals in the area can still have the effect of holding down their wage index, their dominant position makes it difficult, or even impossible, to reclassify to another area where the wage index may more closely reflect their costs.

Hospitals in single-hospital MSAs face a situation that is similar in certain respects, but quite different in others. By definition, the wage index for the sole hospital in an MSA is based completely on that hospital's wage data. Such a hospital receives, in effect, its own unique wage index, reflecting the hospital's exact position in relation to the national average hourly wage. As a result, these hospitals cannot qualify for reclassification, unless they are exempt from the wage threshold requirements due to rural referral center status. By definition, the ratio of such a hospital's average hourly wages to the area average hourly wage is always 100 percent, and these hospitals thus cannot meet either the 108 percent threshold for urban hospitals or the 106 percent threshold for rural hospitals (§412.230(e)(1)(iii)(B)). Unlike dominant hospitals, hospitals in single-hospital MSAs cannot argue that they are disadvantaged by the effect that lower wage hospitals can have on the area wage index. However, these hospitals

have contended that they are sometimes in the position of competing for labor with hospitals in nearby MSAs with higher wage indexes. Under these circumstances, these hospitals cannot reclassify to the higher wage index area even if they meet the relevant distance requirements. These hospitals also contend that they cannot afford to compete with hospitals that are paid under a higher wage index, and the 3-year lag in the data used to compute the wage index can place them in a permanent position of playing catch up. On the other hand, it is also true that such a disadvantage may be only temporary because increasing wages may eventually equalize wage index values despite the temporary financial disadvantage that would accrue to these hospitals during the 3-year lag period.

In the proposed rule, we invited comment on the concerns raised by hospitals in these two situations and on possible methods of addressing these concerns. We indicated that a number of measures might be considered to address the concerns of these hospitals. In the case of dominant hospitals, the threshold requirements for reclassification could be revised to provide that a hospital's average hourly wage is at least 108 percent (in the case of urban hospitals) or 106 percent (in the case of rural hospitals) of the average hourly wages of <u>all other</u> hospitals in the area. Removing a dominant hospital's wages from the denominator of the ratio would remove the current disadvantage imposed by their dominant status, and make it more realistic for a dominant hospital to meet the threshold requirement. An existing provision under §412.230(e)(4) provides this treatment for certain dominant hospitals, specifically those that were approved for reclassification each year from 1992 through 1997. We could develop a parallel provision that applies to dominant hospitals generally. The use of this revised ratio could

be restricted to the special circumstances of dominant hospitals, or extended to all hospitals. We could also adopt a revised threshold for dominant hospitals, as we did in the notice setting forth the criteria for reclassification under the one-time wage index appeal provision of section 508 of Pub. L. 108-173 (69 FR 7342). Consistent with the criteria from that notice, a dominant hospital might be defined for this purpose as a hospital that pays at least 40 percent of all the wages paid by hospitals geographically located in the hospital's area. We indicated that we were considering adopting one of these measurers in the final rule, and invited comments on the advisability of doing so.

In the case of hospitals in single-hospital MSAs, we cited one new provision that that we had proposed to implement in this proposed rule that might address some of their concerns (see section III.G.3.2. of the preamble of the proposed rule). Section 505 of Pub. L. 108-173 provides for a new wage index adjustment for hospitals in lower wage areas in cases where significant numbers of hospital workers commute from the lower wage area to higher wage areas nearby. The statute requires that at least 10 percent of the hospital workers in a county must be commuting to a higher wage area, or areas, in order for the hospitals in the county to receive the adjustment. The adjustment formula provides for an increase to the wage index for hospitals in the county, based on the differences between the wage index that applies to the county and the higher wage indexes of nearby areas, in proportion to the percentages of hospital workers commuting to the higher wage index areas. To the degree that hospitals in single-hospital MSAs experience disadvantages in competing for hospital workers with hospitals in higher wage index areas, we expect that the counties in which these hospitals are located would

qualify for this adjustment. We also indicated that we were actively considering whether to address the concerns of these hospitals more directly. At the same time, we intended to analyze the extent to which this provision would alleviate the concerns of these hospitals. We welcomed comments on the special circumstances of hospitals in single-hospital MSAs and whether their special circumstances should be addressed by revisions to the regulations governing reclassification, or other measures.

Comment: A number of commenters expressed support for adopting a provision to address the concerns of dominant hospitals. Several commenters supported defining a dominant hospital as a hospital that pays at least 40 percent of all wages paid by hospitals geographically located in the hospital's MSA, and providing that any hospital so defined should be "given the same reclassification options as rural and urban rural referral centers." One of these commenters further recommended that dominant hospitals should be entitled to the full implementation of the occupational mix adjustment. Other commenters recommended that we consider revising §412.230(e)(4) to eliminate the requirement that the applicant hospital "was approved for redesignation…for each year from fiscal year 1992 through fiscal year 1997." The effect of this revision would be that the test for dominant hospitals would be that the three-year AHW be at least 108 percent (106 percent for rural hospitals) of the three-year AHW of all the other hospitals in the area. Other commenters supported the idea that, for purposes of determining the AHW of the area where the hospital is located, the 108/106 percent test should be revised for *all* hospitals so that applicant hospitals are required to compare their AHWs to all the other hospitals in the area. One of these commenters argued that including a hospital's own

AHW in the equation does not support the underlying purpose of the 108/106 percent test, which is for the hospital to demonstrate that its wage costs are disproportionately high when compared to its neighbors. Other commenters recommended that we exempt dominant hospitals altogether from the 108/106 percent threshold requirement or consider a new threshold requirement for reclassification that would be at least 110 percent of all other hospitals in the MSA. One commenter recommended that CMS consider establishing criteria that would give special consideration to these hospitals by, for example, allowing a dominant hospital to reclassify to MSAs that are "less than 55 miles" from the MSA where the hospital is located. Finally, some commenters expressed opposition or hesitation about providing any special provision to address the concerns of the dominant hospitals. Med PAC, for example, suggested that the new out-commuting adjustment is a promising approach, observing that the blended formulation of that adjustment, which generally yields a lower wage index than traditional reclassification, might be appropriate since these hospitals have an above-average degree of influence on the wage indexes of the areas where they are located.

Response: We are persuaded that it is equitable, as a matter of general policy for all hospitals, to revise the wage comparison formula for all hospitals in the manner recommended by some of the commenters. Specifically, in this final rule we are revising the regulations at §412.230(e)(1)(iii)(B) to provide that, in order to qualify for reclassification, the hospital's average hourly wage is at least 106 percent (in the case of a hospital located in a rural area) or at least 108 percent (in the case of a hospital located in an urban area), of the average hourly wage of all other hospitals in the area in which the

hospital is located. While this revision addresses, at least in part, the concerns of the dominant hospitals, and while it will allow some dominant hospitals to qualify for reclassification, this is not the primary consideration in favor of this revision to the regulations. The predominant consideration is rather the general point that the purpose of the comparison test is to distinguish whether a hospital is sufficiently different in terms of the wages it pays from other hospitals in its geographic region. Defining the ratio in terms of all other hospitals in the area captures the appropriate comparison more precisely. Therefore, we are also not adopting any of the other alternatives suggested.

Comment: A number of commenters also expressed support for adopting a provision to address the concerns of hospitals that are the only hospitals in an MSA. Several commenters recommended that CMS consider exempting hospitals in single hospital MSAs from the 108/106 percent threshold requirement. One commenter suggested that CMS consider using its discretion to either eliminate or significantly reduce the number of single hospital MSAs by, merging into the nearest MSA only those single hospital MSAs whose hospitals meet the 84 percent threshold requirement, merging all single hospital MSAs into the closest MSA, for purposes of the wage index, or allowing hospitals in single hospital MSAs to reclassify to the closest MSA if they satisfy all of the RRC criteria except for the rural location requirement. One commenter recommends that CMS exercise its discretion to implement a 4-year transition period for hospitals in single hospital MSAs. The transition period would, in addition to protecting these hospitals from financial hardship, allow them the opportunity to equalize their wage index without experiencing any temporary adverse financial impact. The commenter

further suggests that during the transition period these hospitals should be afforded the same exemption as RRCs under §412.230(e)(3). The commenter argued that, by allowing these providers to be paid at a higher wage index they will, in turn, be in a better position to raise wage levels and compete with neighboring urban hospitals. As in the case of the dominant hospitals, MedPAC suggested that the new out-commuting adjustment is a promising approach for addressing this issue.

Response: We have decided not to adopt any of the policy changes proposed by commenters concerning the issue of single hospital MSAs at this time. We agree with MedPAC that the new out-commuting provision is a promising vehicle for addressing the concerns raised by hospitals in single-hospital MSAs. To the degree that hospitals in single-hospital MSAs experience disadvantages in competing for hospital workers with hospitals in higher wage index areas, we would expect that the counties in which these hospitals are located would exhibit rates of commuting by hospital workers to the higher wage index areas that might meet the threshold for receiving the adjustment. We also agree with MedPAC that the adjustment under this provision, which generally yields a lower wage index than traditional reclassification, may be appropriate since the wage indexes for these hospitals are calculated solely on the basis of the hospitals' own wage data. Although certain of the hospitals in single-hospital MSAs that have contacted us about their situations do not qualify for the adjustment this year, we believe that it is appropriate to gain more experience with the workings of this new provision before we adopt any policy revisions designed to address separately reclassification by these hospitals.

6. Special Circumstances of Hospitals in All-Urban States

Section 4410 of Pub. L. 105-33 (BBA) provides that, for the purposes of section 1886(d)(3)(E) of the Act, for discharges occurring on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in the State. This provision, commonly referred to as the "rural floor," affects the payments received by 150 hospitals in 49 MSAs in FY 2004. For these 150 hospitals, the applicable wage index and overall payment amounts under the IPPS are higher than they would be if their wage indexes were computed solely on the basis of the wage data from their MSAs. The wage index floor is applied in a budget neutral manner, so that aggregate IPPS payments each year are not greater or less than those that would have been made in the absence of this provision.

In the May 18, 2004 proposed rule (69 FR 28291), we discussed the fact that the "rural floor" under section 4410 of Pub. L. 105-33 does not apply in the two States that have no rural areas under the labor market definitions that apply within the IPPS. In the past, hospitals in those two States had commented that the absence of a rural floor disadvantages them for wage index purposes compared to hospitals in States where the "rural floor" provision can apply. Specifically, some hospitals contend that they would have higher wage indexes, and higher payments overall, if there were a rural area in their State to set a floor under the wage indexes within the State.

In the proposed rule, we indicated that we were considering whether it would be appropriate to adopt some measure to address the concerns of these hospitals. For

example, we indicated that we were examining the ratios between the lowest and highest wage index values in States where the "rural floor" affects the wage indexes of some hospitals. We further indicated that we might consider employing the average ratio of highest-to-lowest wage indexes in those States to set an imputed "rural floor" for all-urban States. For example, assume the average "lowest-to-highest" ratio of States with rural floors is 0.9500. Assume further that the lowest wage index in an all-urban State is 1.0000, and the highest is 1.1000. The "lowest-to-highest" ratio for that State is 0.9091. If we apply the average "lowest-to-highest" ratio to the highest wage index in the all-urban State, we would multiply 0.9500 by 1.1000, which yields 1.0450. The imputed analogue to the "rural floor" for the all-urban State would then be 1.0450. Any hospital with a regular wage index value less than 1.0450 would then receive the new imputed floor.

In the proposed rule, we welcomed comments on the position of hospitals in all-urban States relative to hospitals that receive the "rural floor" in other States. We also welcomed comments on whether it would be advisable to adopt an imputed floor measure or some alternative measure to address the concerns of hospitals in these States. We noted that, in order to be consistent with the statutory provision establishing the rural floor, we would apply any such measure in budget neutral manner, that is, we would adjust the standardized amount so that aggregate IPPS payments each year are not greater or less than those that would have been made in the absence of this provision.

Comment: We received a number of comments in favor of proceeding with a provision to establish an imputed floor in all-urban states. These commenters asserted

that the absence of a rural floor does disadvantage them for wage index purposes compared to hospitals in States where the "rural floor" provision can apply.

While generally supportive of our proposal, these commenters offered alternative suggestions to the example we had provided about how the formula for determining such an imputed floor might work. For example, one commenter suggested using the median, instead of the average, ratio of the highest to lowest wage indexes in the States where a rural floor could potentially affect the wage indexes of some hospitals. This formulation, according to the commenter, would provide more predictability and would be subject to less distortion as situations change in the States with rural floors. Other commenters recommended expanding any provision for an imputed rural floor to at least one additional State, which has geographic rural areas, but no hospitals actually classified as rural.

Response: We agree with the commenters that any provision to provide an imputed floor for States without rural areas should also apply to any State which has geographic rural areas but no hospitals actually classified as rural. Using this definition, there are three States that can be considered all-urban for the purposes of this provision. As discussed in more detail below, we also agree with the commenters that a variation of the methodology that we suggested in the final rule is more appropriate for determining the level of the imputed floor. Specifically, we believe that the most appropriate methodology is to compare the average ratio of lowest-to highest wage indexes of the three all-urban States to the ratio of the lowest-to-highest wage index of each of those States individually. For each State, we would base the imputed floor on the higher of

these two ratios. Therefore, in this final rule, we are revising the regulations at §412.64(h) to describe the methodology for computing the minimum wage index value for all-urban states and to define an all-urban State.

Comment: Some commenters objected to the establishment of an imputed floor in all-urban States. These commenters contended that any special provision for urban-only States should be subject to legislative action.

Response: Although we appreciate the commenters' observation, we would note that the Secretary has broad authority under section 1886(d)(3)(E) of the Act to "adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates . . . for area differences in hospital wage levels by a factor (**established by the Secretary**) . . ." (Emphasis added). Therefore, we believe that we do have the discretion to adopt a policy that would adjust wage areas in the stated manner.

Comment: Some commenters also pointed out that other States, including those with rural floors, face various inequities in the wage index system, and recommended that a more general solution would be preferable to piecemeal approaches such as an imputed floor for only a few States. Finally, some commenters objected because they were not persuaded that the problem described was sufficiently serious to justify a special protection for a few States that would require a reduction in the rates paid to all hospitals.

Response: We appreciate the reservations expressed by the comments opposing the policy that we discussed in the May 18, 2004 proposed rule. While we are adopting a policy that establishes an imputed floor for the three all-urban States in this final rule, we

are limiting this policy change to 3 years (that is, FYs 2005, 2006, and 2007). During that time, we will monitor the operation of this policy in these all urban States and determine whether to make additional changes to the policy or eliminate it.

In this final rule, we are adopting a variation of the policy that we discussed in the May 18, 2004 proposed rule. We note first that there are similarities among the three States that are not impacted by the rural floor. Obviously, they are urban States. In addition, each of the three States has one predominant labor market area. That, in turn, forces hospitals that are not located in the predominant labor market area to compete for labor with hospitals that are located in that area. However, because there is no "floor" to protect those hospitals not located in the predominant labor market area from facing continued declines in their wage index, it becomes increasingly difficult for those hospitals to continue to competed for labor. In the BBA, Congress spoke of an "anomaly" in States where hospitals located in urban areas had a wage index that was below the wage index applicable for hospitals located in rural areas. (See H.R. Rep. No. 149, 105th Cong., 1st Sess. At 1305.) We think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or "floor," from declines in their wage index. Therefore, we are adopting the logic similar to that articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period.

In the proposed rule, we suggested a policy option that would have developed a ratio of the lowest-to-highest wage index for all States that had a rural wage index and therefore, had the potential to be impacted by the rural floor. Based on the comments that

we have received, and based on the similarities between the three all-urban States, we think that it is more appropriate to compare the three individual all-urban States to those three States as a class. Under the proposed rule, we suggested that we would analyze the average ratio of the lowest-to-highest wage indexes of all States potentially affected by the rural floor. Under the policy are adopting in this final rule, we compare the average ratio of the lowest-to-highest wage indexes (occupational mix-adjusted, both prereclassification and postreclassification) of the three all-urban States to the ratio of the lowest-to-highest wage index (occupational-mix adjusted, both prereclassification and postreclassification) of each of those States individually. We note that in doing so, we consider only the wage indexes of all-urban States in the mainland United States. The Commonwealth of Puerto Rico is also an urban area that does not benefit from the rural floor because there are no hospitals located in rural areas in Puerto Rico. However, there are sufficient differences between Puerto Rico and the three mainland all-urban states. For example, the highest area wage index in the Commonwealth of Puerto Rico is 0.5230; by contrast, the lowest wage index in the three mainland all-urban States is almost twice as high. Moreover, the lowest-to-highest ratio of wage indexes in Puerto Rico is significantly less than the lowest-to-highest ratio of wage indexes of any State on the mainland United States. Moreover, Puerto Rico hospitals are paid on a blended Federal/Commonwealth-specific rate. We therefore, do not believe that it is appropriate to consider the wage indexes of Puerto Rico hospitals in the development of this policy.

Under our final rule, we would then take the higher of those two numbers (that is, the State-specific ratio and the average ratio of the three all-urban States) and multiply it

by the highest area wage index applicable in a State (again, we would look at the postreclassification wage indexes). The product is the imputed "floor," below which no wage index in the State could fall. In order to account for the fact that some hospitals receive a blended wage index (see section III.B.3.d. of this final rule), we computed these ratios, and the corresponding imputed floors, separately using the old labor market definitions and the new labor market definitions. We then compared the blended wage indexes (that is, the wage index determined on the basis of the old labor market areas, and the wage index determined on the basis of the new labor market areas) separately with the corresponding imputed floors.

As a result, hospitals receiving a blended wage index could be at the floor for neither wage index, for their old labor market wage index alone, for their new labor market wage index alone, or for both wage indexes. After this determination, we blended the two wage indexes (including the effects of the imputed floor on each side): 50 percent of the wage index determined on the basis of the old labor market areas (whether at the floor level or above), and 50 percent of the wage index determined on the basis of the new labor market areas (whether at the floor level or above).

7. Geographic Reclassifications for SNFs

Several SNFs indicated support for our proposal to implement the new CBSA designations for IPPS hospitals. They also commented that our continued delay in implementing a reclassification system for SNFs, as authorized by section 315 of BIPA, places Medicare SNFs at an unfair disadvantage in competing with reclassified hospitals for professional staff.

We appreciate the commenters' support for our proposed adoption of the new CBSA designations for IPPS hospitals. With respect to the comment regarding the implementation of a SNF reclassification system, section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates for SNFs to account for differences in area wage levels using a wage index that we find appropriate. Since the inception of a PPS for SNFs, we have used hospital wage data in developing a wage index to be applied to SNFs. Section 315 of the BIPA does authorize us to establish a reclassification system for SNFs, similar to the hospital methodology. However, the statute makes this change contingent upon the collection of the data necessary to establish an area wage index for SNFs based on SNF wage data. As part of our ongoing program analysis, we periodically reevaluate the suitability of establishing an SNF-specific wage index and a provider reclassification methodology. However, we note that, in order to effect such changes, we must first be able to provide reasonable assurance as to the accuracy of the underlying cost report data and the equitable distribution of funds under the new methodology.

O. Payment for Direct Graduate Medical Education (Existing §413.86)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99-272) and implemented in regulations at existing §413.86, establishes a methodology for determining payments to hospitals for the costs of approved GME programs. Section 1886(h)(2) of the Act, as added by COBRA, sets forth a payment methodology

for the determination of a hospital-specific, base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable costs of GME for a base period by its number of residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, the period of October 1, 1983 through September 30, 1984). The PRA is multiplied by the weighted number of full-time equivalent (FTE) residents working in all areas of the hospital (and nonhospital sites, when applicable), and the hospital's Medicare share of total inpatient days to determine Medicare's direct GME payments. In addition, as specified in section 1886(h)(2)(D)(ii) of the Act, for cost reporting periods beginning on or after October 1, 1993, through September 30, 1995, each hospital-specific PRA for the previous cost reporting period is not updated for inflation for any FTE residents who are not either a primary care or an obstetrics and gynecology resident. As a result, hospitals that train primary care and obstetrics and gynecology residents, as well as nonprimary care residents in FY 1994 or FY 1995, have two separate PRAs: one for primary care and obstetrics and gynecology and one for nonprimary care.

The BBRA (Pub. L. 106-113) amended section 1886(h)(2) of the Act to establish a methodology for the use of a national average PRA in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. The BBRA established a "floor" for hospital-specific PRAs equal to 70 percent of the locality-adjusted national average PRA. In addition, the BBRA established a "ceiling" that limited the annual adjustment to a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average PRA. Section 511 of

the BIPA (Pub. L. 106-554) increased the floor established by the BBRA to equal 85 percent of the locality-adjusted national average PRA. Existing regulations at §413.86(e)(4) specify that, for purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and the ceiling to determine whether a hospital-specific PRA should be revised.

Section 1886(h)(4)(F) of the Act established caps on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments. For most hospitals, the caps were the number of allopathic and osteopathic FTE residents training in the most recent cost reporting period ending on or before December 31, 1996.

Comment: Several commenters noted that policy experts are beginning to forecast shortages in physician supply in the near future. One commenter stated: "[a]s presented at the Federal [Council on Graduate Medical Education] meeting, the physician workforce analysis indicated that while the supply of physicians is expected to increase over the next two decades, demand for services is likely to grow even more rapidly. According to the analysis, the three major factors driving the increase in demand will be the projected U.S. population growth of 18 percent between 2000 and 2020, the aging of the population as the number of Americans over 65 increases from 35 million in 2000 to 54 million in 2020, and the changing age-specific per capita physician utilization rates, with those under age 45 using fewer services and those over age 45 using more services. The analysis notes that changing work patterns of physicians, such as decreases in

working hours, could lead to greater shortfalls, while increases in productivity could moderate any shortfalls."

In response to the projected physician shortfall, one commenter urged CMS to work with Congress "to explore expansion of physician training opportunities if research demonstrates a need for more U.S. medical school graduates." These commenters argued that Congress should lift the statutorily mandated 1996 FTE caps for direct GME and IME. Stated another commenter: "[i]t is time for the Medicare resident caps to be lifted. While Medicare has periodically imposed other types of regulatory 'freezes,' these have always been temporary. The current caps have been in place for over six years—far exceeding what typically would be viewed as reasonable."

Response: We appreciate the commenters' concern about the statutory 1996 caps on the count of FTE residents for purposes of direct GME and IME payments, particularly in light of the alleged national physician shortage. If the Congress considers further legislation regarding the cap on the number of residents that may be counted for Medicare payment purposes, CMS would provide assistance to Congress and the provider industry on this issue.

Note to Readers: This final rule includes a major redesignation of the contents of §413.86. As a result of the numerous amendments we have made over the years, the size of §413.86 has become voluminous and difficult to follow because of the multiple levels of coding. We are taking a first step to split the one section (§413.86) into nine individual sections (§§413.75 through 413.83). We are designating each first level paragraph under existing §413.86 as a separate new section and vacate §413.86. At this

time, we are not making any changes in the language of these new redesignated sections, except for the changes that are discussed in section IV.O. of this preamble (which conform to the existing language of §413.86) and any appropriate cross-reference and conforming changes. We are providing a detailed crosswalk of the existing paragraphs of §413.86 to the new §§413.75 through 413.83. In addition, in any discussion of changes we are making, we are providing both the existing citation under §413.86 and the redesignated section and paragraph. At a later date, we may further refine the contents of the redesignated sections to improve readability.

2. Reductions of and Increases in Hospitals' FTE Resident Caps for GME Payment Purposes under Section 422 of Pub. L. 108-173 (redesignated §413.79 (a redesignation of §413.86(g))

a. General Background on Methodology for Determining the FTE Resident Count

As we explain earlier in this preamble, Medicare makes both direct and indirect GME payments to hospitals that train residents in approved medical residency training programs. Direct GME payments are made in accordance with section 1886(h) of the Act, based generally on hospital-specific PRAs, the number of FTE residents a hospital trains, and the hospital's Medicare patient share. IME payments are made in accordance with section 1886(d)(5)(B) of the Act, based generally on the ratio of the hospital's FTE residents to the number of hospital beds. Accordingly, the calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count; generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will

receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes under the provisions of section 1886(h)(4)(F) of the Act for direct GME and section 1886(d)(5)(B)(v) of the Act for IME. Dental and podiatric residents were not included in this statutorily mandated cap.

b. Reduction of Hospitals' FTE Resident Caps under the Provisions of Section 422 of Pub. L. 108-173

Medicare makes direct GME and IME payments based only on the number of FTE residents that is within a hospital's FTE resident cap. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps. Other hospitals have reduced their resident counts to some level below their FTE resident caps. Section 422 of Pub. L. 108-173 added a new section 1886(h)(7) to the Act to provide for reductions in the statutory resident caps under Medicare for certain hospitals and authorize a "redistribution" of the FTE resident slots resulting from the reduction in the FTE resident caps to other hospitals.

The new section 1886(h)(7)(A) of the Act provides that a hospital's FTE resident cap will be reduced if its reference resident level, as described below, is less than its otherwise applicable FTE resident cap. Rural hospitals with less than 250 acute care inpatient beds are exempt from these reductions. For other hospitals, any such reduction will be equal to 75 percent of the difference between the hospital's otherwise applicable FTE resident cap and its reference resident level.

Under the new section 1886(h)(7)(B) of the Act, the Secretary is authorized to increase the otherwise applicable FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2005, by an aggregate number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(7)(A). A single hospital may receive an increase in its FTE resident cap of no more than 25 additional FTEs. In determining which hospitals would receive an increase in their FTE resident caps, section 1886(h)(7)(B) of the Act directs us to--

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2005.

- Establish a priority order to distribute resident slots first to programs in hospitals located in rural areas; second, to urban hospitals that are not in large urban areas; and third, to other hospitals operating a training program in a State where there is no other training program for a particular specialty in the State.

In summary, section 422 of Pub. L. 108-173 added a new section 1886(h)(7) of the Act that prescribes a methodology for determining reductions to certain hospitals' FTE resident caps based on unused FTE resident slots, provides for certain exceptions to the FTE resident cap reductions, and includes general criteria that CMS must consider in making a "redistribution" to other hospitals of the estimated number of FTE resident positions resulting from the reductions in the FTE resident caps. In this final rule, we are establishing procedures for determining whether, and by what amount, a hospital's FTE

resident cap is subject to a reduction under section 1886(h)(7) of the Act. We also are specifying an application process for hospitals that seek to receive increases in their FTE resident caps and the specific criteria that we will use to determine which hospitals will receive the increases in their FTE resident caps under section 1886(h)(7)(B) of the Act.

c. Hospitals Subject to the FTE Resident Cap Reduction

As indicated earlier, section 1886(h)(7)(A) of the Act, as added by section 422 of Pub. L. 108-173, provides that if a hospital's "reference resident level" is less than its "otherwise applicable resident limit," its "otherwise applicable resident limit" will be reduced by 75 percent of the difference between its "otherwise applicable resident limit" and its "reference resident level." Under the amendments made by section 422, the "reference resident level" generally refers to the number of unweighted allopathic and osteopathic FTE residents who are training at a hospital in a given cost reporting period. The "otherwise applicable resident limit" refers to a hospital's FTE resident cap established under sections 1886(h)(4)(F)(i) and (h)(4)(H) of the Act. A hospital's permanent FTE cap under section 1886(h)(4)(F)(i) of the Act is based on (1) for an urban hospital, the number of unweighted allopathic or osteopathic FTE residents in the hospital's most recent cost reporting period ending on or before December 31, 1996 (the "1996 cap"), adjusted as specified under existing regulations at §413.86(g)(4) (redesignated §413.79(c)(2)), and, if applicable, the 1996 cap adjusted for new programs as specified under existing §413.86(g)(6) (redesignated §413.79(e)); or (2) for a rural hospital, 130 percent of the 1996 cap, adjusted as specified under existing §413.86(g)(4) and, if applicable, 130 percent of the 1996 cap adjusted for new programs as specified

under §413.86(g)(6), or 130 percent of the 1996 cap with both adjustments. We also note that a hospital's 1996 cap may be adjusted in other instances (such as temporary adjustments for program or hospital closure) if the hospital is a member of a Medicare GME affiliated group under existing §413.86(b) (redesignated §413.75(b)), but we will discuss the applicability of affiliations under section 1886(h)(7)(A) of the Act in more detail at section IV.O.2.f.(5) of this preamble.

In our discussion of the provisions of section 422 of Pub. L. 108-173 under this section of this final rule, we will generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as a hospital's "resident level." We will also refer to a hospital's resident level in the applicable "reference period," as explained further below, as the hospital's "reference resident level." In addition, we will refer to the "otherwise applicable resident cap" as the hospital's FTE resident cap that is applicable during a particular cost reporting period. Thus, as we proposed in the May 18, 2004 proposed rule (69 FR 28293), we are providing that if a hospital's resident level is less than the hospital's otherwise applicable resident cap in the "reference period" (as explained below), effective for portions of cost reporting periods occurring on or after July 1, 2005, we will permanently reduce the hospital's FTE resident cap by 75 percent of the difference between the reference resident level and the otherwise applicable FTE resident cap. For example, if a hospital's otherwise applicable FTE resident cap for the reference period is 100, and its resident level for that period is 80 FTEs, we will reduce the hospital's FTE resident cap by 15 FTEs [0.75 (100 – 80)] = 15). (Redesignated §413.79(c)(3)).

Comment: One commenter expressed concern that the reduction to the FTE resident cap of a hospital that has had trouble filling vacancies in certain specialty programs may jeopardize the funding available for residents training in programs that the hospital has been able to fill. The commenter asked that CMS further analyze the impact that "slot re-allocations" could have on other specialties at a particular hospital, and should consider the effect that such reductions may have on the overall availability of services to patients.

Response: Although the commenter may be concerned about the impact that cap reductions may have on a hospital's ability to provide patient care and maintain its residency programs at historical levels, we do not believe we have the authority to design and implement a "re-allocation" process that considers such factors. Rather, as explained in response to other comments, under section 1886(h)(7)(A)(i), the Secretary is directed to reduce the FTE resident caps of hospitals in instances where the resident levels were below the FTE resident caps in the reference cost reporting period. There is no statutory provision that authorizes CMS to consider the overall impact on patient care delivery or on residency training in making reductions to FTE resident caps.

d. Exemption from FTE Resident Cap Reduction for Certain Rural Hospitals

Section 1886(h)(7)(A)(i)(II) of the Act, as added by section 422 of Pub. L. 108-173, specifically exempts rural hospitals (as defined in section 1886(d)(2)(D)(ii) of the Act) with less than 250 acute care inpatient beds from the possible 75 percent reduction to their FTE resident caps. Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA).

Under the existing regulations at §413.62(f)(ii), an "urban area" means (1) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA); or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing §413.62(f)(iii), a "rural area" means any area outside an urban area. In addition, we note that under section III. of this preamble, which discusses wage areas, we are no longer recognizing NECMAs as a distinct category of wage areas. Thus, for purposes of the amendments made by section 422, we are providing that any hospital located in an area that is not in a MSA is a rural hospital, regardless of any reclassification under §412.102 or §412.103. We note that this definition of "rural" is consistent with our policy under section III. of this preamble concerning designation of wage index areas.

A hospital's bed size is based on its number of available beds, as determined for IME payment purposes under §412.105 of the regulations. For purposes of determining whether a rural hospital has less than 250 beds, in the May 18, 2004 proposed rule (69 FR 28293), we proposed to use data from the rural hospital's most recent cost reporting period ending on or before September 30, 2002. (This information may be found on Worksheet S-3, Part I of the Medicare cost report, CMS-2552-96, the sum of lines 1 and 6 through 10 in column 2, minus line 26 in column 6, divided by the number of days in the cost reporting period.) This is the cost reporting period under section 1886(h)(7)(A)(ii)(I) of the Act that is to be used in determining a hospital's reference resident level (the unweighted allopathic and osteopathic FTE resident count) (unless a

hospital makes and CMS grants a timely request under section 1886(h)(7)(A)(ii)(II) of the Act). We proposed that if a rural hospital has less than 250 beds in its most recent cost reporting period ending on or before September 30, 2002, the hospital would not be subject to a possible reduction to its FTE resident cap under section 1886(h)(7)(A) of the Act. However, if a rural hospital has at least 250 beds in its most recent cost reporting period ending on or before September 30, 2002, we proposed that the rural hospital would be subject to a possible reduction to its FTE resident cap. (Proposed redesignated §413.79(c)(3)(i).)

Comment: Several commenters inquired as to whether our proposed changes for wage areas, if finalized, would affect a teaching hospital's status as urban or rural for purposes of section 422. Specifically, the commenters asked how a hospital that is currently located in a rural area (that is, non-MSA), but under our proposals for wage areas, would be located in an MSA effective October 1, 2004, would be treated for purposes of determining if and by much its FTE resident cap would be reduced. The commenter also questioned whether it would be considered a rural hospital under the first and second level priority categories under the criteria for determining whether the hospital will receive increases in its FTE resident caps. Several commenters believed that any hospital that was considered rural during the most recent cost reporting period ending on or before September 30, 2002 should be considered rural for purposes of section 422 and if reporting less than 250 beds, any resident positions below its FTE resident cap should be exempt from redistribution.

Response: Under section 1886(h)(7) of the Act, there are two instances in which a hospital's rural or urban designation could affect determinations made under this section for that hospital. First, under section 1886(h)(7)(A)(i)(II) of the Act, rural hospitals with less than 250 acute care inpatient beds are exempted from the possible 75 percent reduction to their FTE resident caps. Second, section 1886(h)(7)(B)(iii)(I) of the Act, established "hospitals located in rural areas" as the first priority category for CMS to determine which hospitals will receive increases in their FTE resident caps. In both instances, we proposed that, for purposes of the amendments made by section 422, any hospital located in an area that is not in an MSA is a rural hospital, regardless of any reclassification under §412.102 or §412.103. However, we did not specify as of what date a hospital must be located in an area that is not an MSA in order to be a rural hospital. That is, a hospital may be located in an area that is not currently in an MSA, but will become an MSA effective October 1, 2004. (Alternatively, a hospital may be located in an area that is currently an MSA, but will become rural effective October 1, 2004.) We believe it is reasonable and consistent with the July 1, 2005 effective date for both reductions and increases in FTE resident caps under section 1886(h)(7) of the Act, to use the urban or rural designation that is in effect on July 1, 2005. Therefore, we are requiring that, for purposes of section 1886(h)(7) of the Act (that is, both for purposes of determining if a hospital is a rural hospital with less than 250 beds, and also whether a hospital qualifies to receive higher priority to receive an increase in its FTE resident caps), a hospital located in an area that is not in an MSA effective October 1, 2004, is a rural hospital. Any hospital that is located in an area that

is not currently in an MSA, but will become an MSA effective October 1, 2004, will not be considered a rural hospital for the purpose of applying section 1886(h)(7) of the Act. Alternatively, a hospital located in an area that is currently an MSA, but will become rural effective October 1, 2004, will be considered a rural hospital for the purpose of applying section 1886(h)(7) of the Act.

In section IV.O.2.i. of the preamble to the May 18, 2004 proposed rule, we proposed six priority categories (derived from the priorities established by section 1886(h)(7)(B) of the Act) to determine the order in which hospitals would be eligible to receive increases in their FTE resident caps. The first three priority categories are reserved for rural hospitals (hospitals that are located outside of an MSA as of July 1, 2005). The fourth level priority category is reserved for hospitals located in a "small" urban MSA (defined as an MSA with a population of less than 1,000,000). And the fifth and sixth level priority categories are reserved for hospitals located in "large" urban areas (defined by section 1886(d)(2)(D) of the Act as an MSA with a population of more than 1,000,000). For purposes of determining the order in which hospitals would be eligible to receive increases in their FTE resident caps under section 1886(h)(7)(B) of the Act, we are requiring that a hospital located in an MSA with a population of less than 1,000,000 effective October 1, 2004, is a "small" urban hospital and that a hospital located in an MSA with a population of more than 1,000,000 effective October 1, 2004 is a "large" urban hospital.

We note that there may be hospitals with less than 250 beds that are currently located outside of an MSA that will be redesignated as of October 1, 2004, to be located

within an MSA. As such, these hospitals do not qualify for exemption from FTE resident cap reductions under section 1886(h)(7)(A)(i)(II) of the Act. As stated above, we did not specify in the proposed regulations the date on which a hospital must be in an area that is not an MSA in order to be a rural hospital. Hospitals located outside of an MSA with fewer than 250 beds may have believed that the hospital is exempt from section 1886(h)(7) of the Act and, therefore, failed to consider whether to file a timely request (by June 14, 2004) to use the cost report containing July 1, 2003 (to reflect an expansion of an existing program) or to request that its reference resident level be adjusted to include residents in certain newly approved programs. Therefore, we are allowing hospitals that are redesignated as of October 1, 2004 to be located within an MSA to make a timely request by August 23, 2004 to use the cost report containing July 1, 2003, as the reference cost report if the requirements of 1886(h)(7)(A)(ii)(II) of the Act (expansion of existing programs) are met. Furthermore, we are allowing hospitals that meet the requirements of section 1886(7)(A)(ii)(III) of the Act (expansions under newly approved programs) to request by August 23, 2004 that their reference resident levels be adjusted to include residents in certain newly approved programs.

Comment: One commenter noted that the proposed rule stated that CMS would be addressing, in the IPPS FY 2005 final rule, issues related to determining a hospital's bed count, such as observation beds and unused beds, some of which may be clarifications of existing policy. The commenter asked for clarification as to whether these policies concerning the bed count will be applied in determining whether a rural hospital with less than 250 beds.

Response: In the May 18, 2004 proposed rule, we proposed that, for purposes of determining whether a rural hospital has less than 250 beds, we would use data from the rural hospital's most recent cost reporting period ending on or before September 30, 2002. We proposed that if a rural hospital has less than 250 beds in its most recent cost reporting period ending on or before September 30, 2002, it would not be subject to a possible reduction to its FTE resident cap under section 1886(h)(7)(A) of the Act. We separately indicated that we plan to address comments concerning unoccupied beds, observation beds, and some other patient day issues that were proposed in the May 19, 2003 IPPS proposed rule in the IPPS final rule for FY 2005. As planned, in §412.105(b) of this final rule, we have finalized a new policy concerning unoccupied beds, which has a prospective effective date of October 1, 2004. Therefore, the new policy concerning unoccupied beds would not impact the determination of a rural hospital's bed size based on its most recent cost report ending on or before September 30, 2002. We have also amended our policy in this final rule with respect to observation days for patients who are ultimately admitted as inpatients. This policy is a revision of existing policy, the effective date is prospective (October 1, 2004), and consequently, this policy would not impact the determination of a rural hospital's bed size based on its most recent cost report ending on or before September 30, 2002. The other policies that we have finalized concerning dual-eligible days and Medicare+Choice days do not apply to the determination of a hospital's bed size. However, we note that in the August 1, 2003 IPPS final rule, we clarified at 42 CFR 412.105(b)(3) that beds otherwise countable for IME purposes when used for outpatient observation services,

skilled nursing swing-bed services, or ancillary labor/delivery services, are excluded from the allowable count of available bed days. Because this policy was a clarification of existing policy, it would apply to the determination of a hospital's bed size in its most recent cost reporting period ending on or before September 30, 2002.

Comment**:** Some commenters expressed "deep concern" over what they believed is an the unintended consequence of section 422 in that rural hospitals with at least 250 beds face possible reductions to their current FTE resident caps, when those caps were increased by previous legislation that was intended to encourage the growth of residency training in rural areas. The commenters were specifically referring to section 407(b) of Pub. L. 106-113 (the Balanced Budget Refinement Act (BBRA) of 1999), which provided for a 30 percent increase to rural hospitals' direct GME and IME FTE resident caps, effective April 1, 2000. The commenters explained that the extensive plans they had set in motion to expand their residency programs were nowhere near completion as of their reference cost reporting period under section 886(h)(7)(A). They stated that this "sudden reversal" of the 30 percent increase to their caps would prevent them from meeting their educational and patient care missions in rural communities, and asked that the final rule contain a provision excepting these larger rural hospitals from cap reductions under section 1886(h)(7)(A) of the Act.

Response**:** We understand that the commenters are in a somewhat unique situation, but we note that Congress specifically limited the exception from the application of section 1886(h)(7)(A) of the Act to rural hospitals with less than 250 beds. We do not believe we have the authority to expand the exception to rural hospitals with

250 beds or more from reductions under section 1886(h)(7)(A) of the Act. However, we believe that if these hospitals have been in the process of increasing the number of residents training in existing programs, they will likely qualify to request that their cost reporting period that includes July 1, 2003 be used as the reference cost reporting period. We believe that, between the effective date of section 407(b) of the BBRA and the cost report that includes July 1, 2003, these hospitals had several years to increase their resident counts. Therefore, a sizeable portion of this increase should be reflected on the cost report that includes July 1, 2003, thereby limiting the amount of slots lost under section 1886(h)(7)(A)(i) of the Act. In addition, because these hospitals are located in a rural area, they would be among those to receive first priority to obtain additional slots if they apply for increases to their FTE resident caps under section 1886(h)(7)(B) of the Act.

e. Determining the Estimated Number of FTE Resident Slots Available for Redistribution

Under section 1886(h)(7)(A) of the Act, we will determine the number of resident positions available for redistribution by estimating possible reductions to hospitals' FTE resident caps. We believe that section 422 allows us to distinguish between the FTE counts that are used to determine the number of FTE resident slots that are available for redistribution (that is, the "resident pool"), and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced. In the May 18, 2004 proposed rule (69 FR 28293), we proposed to estimate the reduction to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act for purposes of determining the

number of FTEs that a hospital might contribute to the resident pool. This interpretation was based on the language at section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3), which states that the "aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits . . ." (emphasis added). We proposed to interpret this language to mean the aggregate number of FTE residents by which we increase the FTE resident caps of qualifying hospitals under section 1886(h)(7)(B) of the Act must not be more than the estimate of the aggregate number of FTE residents by which we would reduce the FTE resident caps of hospitals whose reference resident levels are less than their otherwise applicable FTE resident caps. However, we could subsequently perform an audit, as described further in section IV.O.2.f.(3) of this preamble, in order to make a final determination regarding any reductions to a hospital's FTE resident cap.

To ensure that we will begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2005, in the May 18, 2004 proposed rule, we proposed to set a date by which we will have estimated a hospital's resident level and compared it to the hospital's otherwise applicable resident cap to estimate whether, and by how much, the hospital's FTE resident cap would be reduced. We did not propose to commit to make a final determination as to whether, and by how much, a particular hospital's FTE resident cap should be reduced as of this date, nor did we propose to commit to inform any hospital that it will receive an increase to its FTE resident cap by this date. Rather, we only proposed to use this date as an internal "deadline" to ensure

that we will have sufficient time to distribute the resident pool and begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2005. We proposed that this date be May 1, 2005, and that the date would apply for all hospitals for purposes of determining an estimate of whether and by how much their FTE resident caps should be reduced.

Accordingly, in the event that the fiscal intermediaries have not completed an audit (explained further under section IV.O.2.f.(3) of this preamble) by May 1, 2005, we proposed that CMS may estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced by May 1, 2005. For example, a fiscal intermediary may estimate by May 1, 2005, that Hospital A's FTE resident cap should be reduced by 10 FTEs. Thus, we would place 10 FTEs into the resident pool. It is possible that even after May 1, 2005, the fiscal intermediary may continue to audit Hospital A's relevant cost report(s) to determine if, in fact, 10 FTEs is the appropriate amount by which to reduce Hospital A's FTE resident cap, and could ultimately conclude that Hospital A's FTE resident cap should only be reduced by 8 FTEs. If the fiscal intermediary makes this final determination by May 1, 2005, we would change the number of FTE residents in the resident pool attributable to Hospital A from 10 FTEs to 8 FTEs. If the fiscal intermediary does not make this determination by May 1, 2005, based on the audit, we would only reduce Hospital A's FTE resident cap by 8 FTEs effective July 1, 2005, but the number of FTE residents in the resident pool attributable to Hospital A would remain at 10 FTEs (the estimated number as of May 1, 2005). Similarly, if the fiscal intermediary ultimately concluded that Hospital A's FTE resident cap should be reduced

by 12 FTEs, but this final determination is not made by May 1, 2005, Hospital A's FTE resident cap would be reduced by 12 FTEs effective July 1, 2005, but the number of FTE residents in the resident pool attributable to Hospital A would remain at 10 FTEs.

As we stated above, because we believe that section 422 allows us to distinguish between the FTE counts that are used to determine the size of the resident pool, and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced, we proposed in the May 18, 2004 proposed rule, to use preliminary information in certain instances to estimate possible reductions to hospitals' FTE resident caps. As described further below, sections 1886(h)(7)(A)(ii) and (h)(7)(A)(iii) of the Act direct CMS to adjust the determination of a hospital's reference resident level in certain instances, due to an expansion of an existing program that is not reflected on the most recent settled cost report, or to include the number of residents for which a new program was accredited, or for hospitals that are members of the same Medicare GME affiliated group as of July 1, 2003. We note that, in adjusting the determination of the reference resident level in these instances, the reference resident level established for purposes of determining possible reductions to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act may not be the actual or audited number of FTE residents that we would otherwise use for direct GME or IME payment purposes. For example, for expansions under newly approved programs (as explained in more detail in section IV.O.2.f.(3) of this preamble), we proposed to adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital even though, at the time the fiscal intermediary is determining possible reductions to a

hospital's FTE resident cap, the hospital may not be training the full complement of residents for which the program was accredited. Thus, the number of FTE residents (including those training in the newly accredited program) for purposes of IME and direct GME payment would be dependent upon the actual number of FTE residents the hospital is permitted to count in a particular cost reporting period, as determined in accordance with the regulations at §412.105 for IME and §413.86 for direct GME.

In addition, in the proposed rule we stated that we realize that there may be instances where a hospital's FTE resident cap or a hospital's FTE resident count for the reference cost reporting period might be under appeal. We believed that appeals related to these issues should be resolved through the normal course of business. In the event that an appeal that may affect determinations made under section 1886(h)(7)(A) of the Act is not resolved by May 1, 2005, we proposed that we would estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced (or not reduced, as applicable) by May 1, 2005.

Comment: One commenter requested a waiver from the FTE resident cap reduction provisions of section 422 for a special circumstance. The commenter detailed a situation where a hospital, because of financial difficulties, had discontinued its residency program and had submitted a plan to the state in which the hospital is located to close the hospital. Through action of the state's Supreme Court, the hospital's petition for authorization to close the Hospital was denied. A committee appointed by the state Supreme Court selected another hospital as a sponsor that lent financial support to the subject hospital. A formal merger between the two hospitals has been opposed by the

state's Attorney General. The subject hospital's residency programs have not grown to the level maintained prior to the petition for closure and the hospital was training residents well below its FTE resident cap during the reference cost reporting period. As such, the hospital believes that its FTE resident caps will be reduced pursuant to section 422. The commenter requests that the hospital be exempt from FTE resident cap reductions and that this exemption extend to the Medicare GME affiliated group of which the hospital is a part of to preserve the group's future ability to build their teaching programs.

Response: We sympathize with the commenter and believe that the particular circumstances experienced by this hospital are unusual and not specifically addressed by the Act or the proposed regulations. However, as we noted above, the statute provided for only a limited exemption from the provisions of section 1886(h)(7)(A)(i) of the Act for small rural hospitals. Therefore , we cannot grant the commenter's request. As we stated above, hospitals that believe they will receive a reduction to their FTE resident cap are not precluded under section 1886(h)(7)(B) of the Act from applying for an increase in their FTE resident cap.

Comment: Numerous commenters were concerned about how to determine possible cap reductions in instances where a hospital's FTE resident count for the reference cost reporting period is under appeal. One commenter was concerned that the number of FTE residents by which a hospital's FTE resident cap would be reduced would not reflect the final settlement of the cost report, which could unfairly harm hospitals whose FTE resident counts in the reference period were ultimately increased through the

cost report appeal process. Another commenter emphasized that if appeals for payment purposes are made completely independently of the FTE resident count determinations for purposes of section 422, "it could potentially result in the rather bizarre situation of a hospital's resident cap being permanently lowered by an amount that is later found to be based on an erroneous resident count determination." The commenter continued that the result would "undermine the credibility of CMS, its fiscal intermediaries, and the process for making determinations under section 422, and therefore, CMS should ensure that it will not occur."

One commenter noted that CMS proposed to estimate the aggregate reduction in FTE resident caps under section 1886(h)(7)(A) of the Act based on available data as of May 1, 2005, which means that, for some hospitals, the hospital-specific actual reduction in the FTE resident cap can be based on further audit and appeal activity that may take place at any time after May 1, 2005. Thus, according to CMS' proposal, the number of FTEs in the resident pool attributable to a specific hospital might be higher than or lower than the actual number by which that hospital's FTE count will be reduced as of July 1, 2005. The commenter objected to this proposal and urged a more "budget neutral" approach that would promote finality for section 422. The commenter claimed that not only might this proposal lead to an improper increase or reduction in the estimated aggregate reduction in FTE resident caps, but it would also generate undue uncertainty about whether, and by how much, any given hospital's FTE cap will be reduced as of July 1, 2005. The commenter proposed that, to avoid this uncertainty and to promote finality, each hospital's FTE resident count should be permanently reduced by

the same number of FTEs attributable to that hospital that are added to the pool for redistribution as of May 1, 2005. Under the commenter's proposal, fiscal intermediaries will need to conduct and attempt to complete audit activity by May 1 (or perhaps a later deadline if CMS so chooses). Whether those audits are complete or not, CMS would use the best available data as of the deadline so that the aggregate total of increases to the "redistribution pool" would equal the total of the permanent decreases to the hospitals' FTE resident caps effective July 1, 2005. Appeals and audits of the reference period that continue after May 1, 2005, would ultimately only impact that particular fiscal year's direct GME and IME reimbursement, but would have no impact on FTE resident cap adjustments under section 1886(h)(7)(A) of the Act. As such, the commenter agreed with CMS' statement in the proposed rule that the actual FTE resident count used for purposes of direct GME or IME payment in the reference period need not equal the FTE resident count used for purposes of determining possible reductions to a hospital's FTE resident cap under section 1886(h)(7)(A) of the Act. Finally, the commenter stated that since, under its proposal, all hospitals would know prior to the start of an impacted fiscal year precisely by how many FTEs their caps would be reduced, this advance knowledge would aid hospitals in deciding whether and to what extent they would enter into Medicare GME affiliation agreements as of July 1, 2005.

Response: In the May 18, 2004 proposed rule (69 FR 28294), we stated that we realize there may be instances where a hospital's FTE resident cap or a hospital's FTE resident count for the reference cost reporting period might be under appeal. We further stated that we believe appeals related to these issues should be resolved through the

normal course of business. In the event an appeal that may affect determinations made under section 1886(h)(7)(A) of the Act is not resolved by May 1, 2005, we proposed that we would estimate the number of FTE residents by which a hospital's FTE resident cap should be reduced (or not reduced, as applicable) by May 1, 2005.

Since the publication of the proposed rule, and after considering the detailed and thoughtful comments we received on the issue of cost reports that are under appeal, we believe that it is in the best interest of the Medicare program, CMS, the fiscal intermediaries, and the hospitals, to adopt an approach that allows for finality as early as possible during the process of implementing this provision. We believe that Congress gave some consideration to the challenges we would encounter in implementing a provision as complex as section 422 in such a short timeframe by providing the Secretary with the discretion to distinguish between the FTE counts that are used to estimate the number of FTE resident slots that are available for redistribution (that is, the "redistribution pool"), and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced. We therefore had proposed to interpret the language at section 1886(h)(7)(B)(i) of the Act to mean that the aggregate number of FTE residents by which we increase the FTE resident caps of qualifying hospitals under section 1886(h)(7)(B) of the Act must not be more than the estimated aggregate number of FTE residents by which we would reduce the FTE resident caps of hospitals whose reference resident levels are less than their otherwise applicable FTE resident caps.

We also believe the Congress expected and provided for administrative expediency under section 1886(h)(7)(A)(ii)(I) of the Act by stating that a possible

reduction in a hospital's FTE resident cap would, generally, be based upon "the reference resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report *has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary*" (emphasis added). As stated in the May 18, 2004 proposed rule (69 FR 28295-28296), we proposed to interpret this language to mean that, if a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled, then, unless the hospital submits a timely request to use the cost reporting period that includes July 1, 2003, we would use the hospital's settled cost report without further audit to determine possible reductions to the FTE resident caps. Furthermore, the fact that the Congress took the unusual step of including the language at section 1886(h)(7)(D) of the Act which provides that, "There shall be no administrative or judicial review . . . with respect to determinations made under this paragraph," supports the position advocating for finality. If we were to delay determinations concerning hospital-specific FTE cap determinations until all affected cost reports are settled, audited, and appealed through the various channels normally available to providers, the language at section 1886(h)(7)(D) of the Act would be rendered meaningless. Therefore, despite its complexity and potential for profound and long-term GME payment ramifications, we believe that the Congress did not expect the implementation of this provision to linger indefinitely. Rather, by limiting appeal rights, and instituting an effective date of July 1, 2005 (which requires implementation in a relatively short timeframe), the Congress expected section 1886(h)(7) of the Act to be implemented with expediency and finality.

Consistent with Congressional intent and in response to comments, we believe it would be disruptive to CMS, the fiscal intermediaries, and the hospitals if we do not establish a framework that encourages determinations under section 1886(h)(7)(A)(i) of the Act to be made final by July 1, 2005. Therefore, we are not finalizing our proposed policy to wait for reference period cost reports that are under appeal to be resolved before making a final determination as to whether and by how much a hospital's FTE resident cap will be reduced. We do, however, perceive the need in certain instances to continue audit work for a limited time period past July 1, 2005 to promote the accuracy of FTE resident cap determinations. In this final rule, we are adopting a policy that will require the fiscal intermediaries to use the latest available cost report or audit data at the time they make their determinations. That is, if a hospital's reference period cost report has been settled, then the fiscal intermediary will make a final determination as to whether and by how much a hospital's FTE resident cap would be reduced based on the FTE resident level in that settled cost report. If the hospital's reference period cost report is under appeal and a final decision has not been rendered at the time the fiscal intermediary makes the determination, then the fiscal intermediary would not wait until a decision is rendered, but instead, would use the reference resident level from the settled (per the Notice of Program Reimbursement (NPR)) cost report. If the settled reference period cost report had been appealed and the final decision is rendered in time for the fiscal intermediary to make the FTE resident cap determination, then the fiscal intermediary would use the FTE resident level that will be used in issuing the subsequent NPR as established through the appeal. However, if the reference period cost report has never

been settled at the time the fiscal intermediary is making the determination as to whether and by how much a hospital's FTE resident cap should be reduced, then, whether the reference period cost report is the as-submitted most recent cost report ending on or before September 30, 2002, or the cost report that includes July 1, 2003, the reference resident level is subject to audit by the fiscal intermediary, and the final determination regarding any possible reduction to the hospital's FTE resident cap is not subject to appeal. Although we will make every effort to provide fiscal intermediaries with the resources and funding they need to complete as many audits as possible in time to notify each hospital by July 1, 2005 of their FTE cap determinations under section 1886(h)(7)(A) of the Act, there may be instances where the audits of the reference resident levels may not be completed by July 1, 2005. However, we anticipate that the fiscal intermediaries will be able to complete audits related to section 1886(h)(7)(A) of the Act by December 2005, which is six months into the July 1, 2005—June 30, 2006 academic year. All determinations made after July 1, 2005 and through December 2005 will be effective retroactively to July 1, 2005.

Comment: One commenter noted that some hospitals' 1996 FTE resident caps have yet to be finalized, or have been finalized only recently. The commenter requested that CMS consider these situations when comparing caps to resident counts. The commenter gave an example in which some hospitals may have an FTE resident count in the reference period cost report that once matched their corresponding FTE resident cap, but that cap was later increased during the audit and appeal process. If the settled (post-audit and/or appeal) FTE resident cap is used in the cap and count comparison, the

hospital's FTE resident cap would be reduced, "even though the hospital was at its cap as it knew it to be as of 2002." The commenter asserted that such a result would be "patently unfair" and should be addressed in the final rule.

Response: The commenter's point is well taken, but we note that the reverse situation could also occur in that a hospital's 1996 FTE resident cap may later be *reduced* as the result of an appeal. If the reduced settled FTE resident cap were to be used in the cap and count comparison under section 1886(h)(7)(A) of the Act, the reduction in the hospital's FTE resident cap would be lessened (or there could be no reduction at all), even though the hospital's FTE resident count was *below* its cap "as it knew it to be as of 2002." Accordingly, where the hospitals' FTE resident cap used in its reference cost report is revised on an appeal, some hospitals could benefit by using the *original* FTE resident cap while other hospitals would not. We do not believe it is appropriate to decide our policy based on the possible occurrence of a circumstance that could produce favorable results for some and unfavorable results for others. Therefore, as stated in response to the previous comment regarding situations where the FTE resident count in the reference cost reporting period is under appeal, in the interest of finality, we will instruct the fiscal intermediaries to use the latest determined 1996 FTE resident caps for direct GME and IME that are available as of the time the determination regarding any possible FTE resident cap reduction is being made. If, as of the time the fiscal intermediary makes the determination as to whether and by how much a hospital's FTE resident cap should be reduced, an appeal of the FTE resident cap for the reference cost reporting period has not been resolved (that is, a final decision has not been rendered),

then the fiscal intermediary would use the FTE resident cap amount from the initially settled (per the NPR) reference period cost report. However, if, as of the time that the fiscal intermediary makes the determination as to whether and by how much a hospital's FTE resident cap should be reduced, the FTE resident cap appeal has been resolved, we would use the FTE resident cap as established by the appeal.

We are, however, sympathetic to the commenter's point that there could be instances where, as the result of an appeal of the 1996 FTE resident cap that was resolved at the time the fiscal intermediary makes the determination, the hospital's FTE resident cap would be reduced, "even though the hospital was at its cap as it knew it to be as of 2002." Such a hospital may apply for an increase in its FTE resident cap under section 1886(h)(7)(B) of Act. In this final rule, under section IV.O.2.m. of this preamble, we are adding an Evaluation Criterion to address this situation where a hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) of the Act because the resident level in its reference period cost report equaled or was above its FTE resident cap in effect at that time, but as a result of the resolution of an appeal concerning the FTE resident cap (for example, the 1996 FTE resident cap, as adjusted for new programs, if applicable), the FTE resident cap was later increased to an amount that is greater than the reference resident level.

Comment: Several commenters acknowledged CMS' need to estimate the aggregate reduction in FTE resident caps in order to "redistribute" positions to other hospitals by the July 1, 2005 implementation deadline, but expressed concern that if the finalized number of FTE resident cap reductions exceeds the number of redistributed cap

slots, the result would be a permanent reduction in the national total number of resident positions eligible for Medicare program support. The commenters asserted that this was not the intent of Pub. L. 108-173. Rather, one commenter believed that, while the Congress was permitting the use of estimate in administering the redistribution, the Congress was not "sanctioning" aggregate additions or reductions to the number of FTE residents counted for purposes of Medicare direct GME and IME reimbursement. Another commenter noted that Pub. L. 108-173 requests that CMS submit a report to the Congress by July 1, 2005, that contains recommendations regarding whether to extend the application deadline for hospitals seeking to increase their resident limits. The commenter stated that, because of audit and appeal timeframes, CMS may not know the final aggregate number of FTE resident cap reductions by July 1, 2005, urged CMS to address this situation in its report, and recommended that the application process be extended or reopened in the event that the final resident limit reductions exceed distributed slots.

Response: We acknowledge the commenters' concern that, to the extent the number of slots in the "resident pool" attributable to certain hospitals is based on estimates of the amount by which those hospitals' FTE residents caps will be reduced, and the finalized number of FTE resident cap reductions exceeds the number of redistributed cap slots, the result would be a permanent reduction in the total number of resident positions that would be counted for purposes of Medicare direct GME and IME payments. As explained in response to previous comments, we will make every effort to provide fiscal intermediaries with the resources and funding they need to complete as

many audits as possible in time to notify each hospital by July 1, 2005, of their determinations under section 1886(h)(7)(A) of the Act. Therefore, we anticipate that by May 1, 2005, the number of hospitals for which we believe additional audit work is required (and, therefore, we "estimated" the amount by which their FTE resident caps would be reduced) will be relatively small. However, we acknowledge that, as a result of the possibility of some remaining audits (which we believe will be completed by the end of calendar year 2005), there is a slight possibility that the final number of FTE cap reductions could be more than the estimated size of the "resident pool" as of July 1, 2005. To address this concern, in drafting the report to Congress due by July 1, 2005, we will consider ways in which this potential situation may be addressed, and, if appropriate, would request that Congress extend the deadline for increases in resident limits.

Comment: One commenter agreed with CMS that, given the short timeframe for implementation of section 422 and the complexity involved in determining the number of positions available for redistribution, it is reasonable for CMS to exercise its discretion to make a "best estimate" of the aggregate number of FTE cap reductions under section 1886(h)(7)(A) of the Act by a particular date and proceed with the "redistribution" under section 1886(h)(7)(B) of the Act. However, the commenter was "extremely concerned" that CMS ensure that hospitals at risk of having their FTE resident cap reduced have ample opportunities to submit additional documentation to the fiscal intermediary so that the hospital's residents are not "undercounted". The commenter noted that section 1886(h)(7)(D) of the Act specifies that "There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made

under this paragraph." The commenter urged CMS to not interpret this statement to mean that a determination of the fiscal intermediary with regard to FTE resident cap reductions will be final, without any external appeal mechanism. Rather, the commenter suggested CMS should appoint an ombudsman who would be available to adjudicate hospital-specific issues as they arise.

Response: As stated in response to the previous comment, we believe the fact that Congress included the language at section 1886(h)(7)(D) of the Act stating that "There shall be no administrative or judicial review . . . with respect to determinations made under this paragraph," clearly means that the Congress did intend for the determination of the fiscal intermediary with regard to FTE resident cap reductions to be final, without any external appeal mechanism. Because of this statutory language, together with the requirement that all reductions and increases in FTE resident caps be made effective July 1, 2005, we do not believe it is appropriate to allow hospitals (or CMS) to appeal determinations concerning the FTE cap reductions (or the FTE cap increases, for that matter) under section 1886(h)(7) of the Act. In addition, as indicated previously, we believe that Congress intended this provision to be implemented fairly, but efficiently, avoiding the delays and uncertainty that would be produced by an appeals process. Furthermore, we note that, as with any audit and cost report settlement process, the fiscal intermediaries will provide the hospitals with an opportunity to review and respond to the audit adjustments before they are finalized.

Comment**:** One commenter said the proposed regulations are unclear as to whether the policy to ensure that the aggregate number by which FTE resident caps are

increased through the redistribution provisions at section 1886(h)(7)(B) of the Act, does not exceed the estimated aggregate number by which FTE resident caps are reduced under section 1886(h)(7)(A) of the Act would be applied individually to each hospital that requests additional residency slots, or whether the policy would be applied to the national aggregate amounts. The commenter stated that if a hospital loses resident positions as part of the reductions under section 1886(h)(7)(A) of the Act, it could be due to a number of factors that have "nothing to do with the ability of a program to recruit and retain residents" in other programs. The commenter requested that if CMS intended that the rule requiring that aggregate increases not exceed aggregate decreases be applied on a hospital-specific basis, it should be eliminated.

Response**:** The commenter is referring to our proposal relating to the language at section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3) of the MMA, which states that the "aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's *estimate* of the aggregate reduction in such limits . . ." (emphasis added). As explained in response to previous comments, we proposed to interpret this language to mean that the *aggregate* number of FTE residents by which we increase the FTE resident caps of qualifying *hospitals* under section 1886(h)(7)(B) of the Act may not exceed the estimate of the *aggregate* number of FTE residents by which we would reduce the FTE resident caps of *hospitals* whose reference resident levels are less than their otherwise applicable FTE resident caps. As is evident from the use of the word "aggregate" and the plural form of "hospital," we intended that this principle be applied on a national aggregate basis, and *not* to each

hospital individually. Rather, as long as the *total* number of FTE residents by which we increase the FTE resident caps of *all* hospitals nationally is not more than the estimated number of FTE residents by which we reduce the FTE resident caps of *all* hospitals nationally, we will have complied with the statute at section 1886(h)(7)(B)(i) of the Act.

f. Determining the Possible Reduction to a Hospital's FTE Resident Cap

(1) Reference Resident Level--General

In order to determine if a hospital's resident level is less than the hospital's otherwise applicable FTE resident cap, section 1886(h)(7)(A)(ii) of the Act, as added by section 422 of Pub. L. 108-173, directs the Secretary to use one of two reference cost reporting periods. Section 1886(h)(7)(A)(ii)(I) of the Act directs CMS to use a hospital's most recent cost reporting period ending on or before September 30, 2002, "for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary," as the reference period, unless we grant the hospital's timely request to use a later cost report under section 1886(h)(7)(A)(ii)(II) of the Act, as described under section IV.O.2.f.(2) of this preamble. Generally, if the hospital's resident level for either direct GME or IME is less than the hospital's otherwise applicable resident cap for direct GME or IME, respectively, for the most recent cost reporting period ending on or before September 30, 2002, the hospital's FTE resident cap for direct GME or IME will be reduced by 75 percent of the difference between the resident level and the otherwise applicable FTE resident cap. On April 30, 2004, we issued a One-Time Notification (OTN) (Transmittal 77, CR 3247), "Instructions Related to 'Redistribution of Unused Resident Positions', Section 422 of the Medicare Modernization Act of 2003 (MMA),

Pub. L. 108-173, for Purposes of Graduate Medical Education (GME) Payments" that prescribed certain requirements related to the implementation of section 422 and established a deadline by which a hospital must exercise its option to request that we use a later cost report as the reference cost report. If the hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, is settled by April 30, 2004, the date on which the OTN was issued, we proposed in the May 18, 2004 proposed rule to use that cost report to determine if, and by how much, a hospital's FTE resident cap should be reduced. We noted that the "settled" cost report does not necessarily mean the initial cost report settlement. The fiscal intermediary may have previously settled the cost report, reopened it to audit it, and then settled the cost report again, issuing a revised Notice of Program Reimbursement (NPR). Thus, we would refer to the more recently issued NPR. When a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled by April 30, 2004, we proposed to use the most recently settled cost report as of April 30, 2004, to determine any reduction to the hospital's FTE resident cap under section 1886(h)(7)(A)(ii)(I) of the Act (unless we grant the hospital's timely request under section 1886(h)(7)(A)(ii)(II) of the Act to use a later cost report, as described in section IV.O.2.f.(2) of this preamble). If the hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002 has not yet been settled as of April 30, 2004, we proposed that the as-submitted cost report would be used to determine any reduction in the FTE resident cap, subject to audit by the fiscal intermediary. If the cost report was initially settled, but then reopened, and the fiscal

intermediary has not issued a revised NPR prior to April 30, 2004, the data from the initially settled cost report will be used to determine the possible reductions to the FTE resident caps. (Discussion and comments on this portion of the proposed rule are located at section IV.O.2.f.(3) of this preamble.)

(2) Expansion of an Existing Program

Section 1886(h)(7)(A)(ii)(II) of the Act, as added by section 422(a) of Pub. L. 108-173, provides that if a hospital's resident level increased due to an expansion of an existing program, and that expansion is not reflected on the hospital's most recent settled cost report, a hospital may make a timely request to CMS that, rather than using its most recent cost reporting period ending on or before September 30, 2002, to determine if its FTE resident cap should be reduced, CMS should use the cost report for the hospital's cost reporting period that includes July 1, 2003. For example, assume a hospital's most recent settled cost report is September 30, 2000 (that is, no NPRs were issued for subsequent year cost reports). The hospital increased its resident level due to an expansion of an existing program in its fiscal year ending September 30, 2001. The hospital may submit a timely request that CMS use its cost report that includes July 1, 2003 (which would be its cost report for the fiscal year ending September 30, 2003), to determine if and by how much the hospital's FTE resident cap should be reduced. (Proposed redesignated §413.79(c)(3)(ii)(A)(2)). As explained on page 3 of the April 30, 2004 OTN, to be considered a timely and proper request, a hospital's request to use its cost reporting period that includes July 1, 2003, must be signed and dated by the hospital's chief financial officer (or equivalent) and submitted to

its fiscal intermediary on or before June 4, 2004 (later revised to June 14, 2004). In its timely request, the hospital must include the following:

(1) The FTE resident caps for direct GME and IME and the number of unweighted allopathic and osteopathic FTE residents for direct GME and IME in its most recently settled cost report (that is, its cost report that is more recently settled as of April 30, 2004.

(2) The FTE resident caps for direct GME and IME and the unweighted allopathic and osteopathic FTE residents for direct GME and IME for each cost report after its most recently settled cost report, up to and including its cost reporting period that includes July 1, 2003. If the cost reporting period that includes July 1, 2003, has not ended as of June 4, 2004, the hospital must report the estimated number of unweighted allopathic and osteopathic residents for that cost reporting period.

(3) If not already reported in accordance with steps 1 and 2 above, the FTE resident caps for direct GME and IME and the number of unweighted allopathic and osteopathic FTE residents for direct GME and IME in its most recent cost reporting period ending on or before September 30, 2002.

In addition, as we stated in the April 30, 2004 OTN, a hospital should refer to its most recently settled cost report as of the issuance of the OTN (that is, April 30, 2004) to determine whether the hospital believes it has expanded an existing program in a cost reporting period subsequent to the one for the most recently settled cost report.

In the May 18, 2004 proposed rule, we also proposed that, for purposes of this provision, an "expansion of an existing program" means that, except for expansions due

to newly approved programs, as described below in section IV.O.2.f.(4) of this preamble, the hospital's total number of unweighted allopathic and osteopathic FTE residents training in existing programs in a cost reporting period up to and including the hospital's cost report that includes July 1, 2003, is greater than the resident level in the hospital's most recent settled cost report. (Proposed redesignated §413.79(c)(3)(ii)(A)(3)). In other words, generally, we proposed that as long as a hospital trained more unweighted allopathic and osteopathic FTE residents in a cost reporting period after its most recent settled cost report in programs that were existing during the cost reporting period for the most recently settled cost report, it may submit a timely request that its cost report that includes July 1, 2003, be used for purposes of determining any FTE resident cap reduction under section 1886(h)(7)(A)(i) of the Act. We noted that if a hospital expanded an existing program after its most recent settled cost report, and then subsequently reduced its FTE resident count to the extent that it actually trained fewer unweighted allopathic and osteopathic FTE residents in its cost report that includes July 1, 2003, than in its most recent cost reporting period ending on or before September 30, 2002, the hospital would not benefit from, and would likely not make, a timely request that its cost report that includes July 1, 2003, be used for purposes of determining a possible reduction to its FTE resident cap.

Comment: One commenter stated that, even though the current deadline of June 14, 2004, for timely requests has passed, because the process was included in the proposed rule and is subject to comment and possible revisions, CMS should reopen the timely request deadline for all hospitals. Another commenter was "extremely dismayed"

that CMS stated that the timely requests are "binding" even if the reduction to the hospital's FTE resident cap would have been less had the hospital not submitted a timely request to use the cost report that includes July 1, 2003. The commenter declared that it is "absolutely not reasonable for CMS to make a [hospital's] request such as this 'binding' in full knowledge that inherent in making such a request, there must be at least a small element of estimation, and an incorrect estimate might eventually work to a hospital's disadvantage when the data and documentation issues are reviewed more thoroughly." The commenter recommended that if it is found that a hospital's reduction to its FTE resident cap would be less if the hospital had not made the timely request, the request should be "null and void," and the hospital should either be allowed to withdraw its request, or CMS should use the hospital's most recent cost report ending on or before September 30, 2002, as the reference cost report.

Response: We acknowledge the unique circumstances surrounding implementation of section 1886(h)(7) of the Act in that it requires hospitals to supply, and CMS and the fiscal intermediaries to review, a large amount of technically difficult information regarding FTE resident counts and caps in a relatively short timeframe, in order to assess and make modifications effective July 1, 2005. If we had more time to implement section 1886(h)(7) of the Act, we would have waited until after publication of this final rule to establish a deadline for all hospitals to submit timely requests due to expansions of existing programs not reflected on the most recent settled cost report, (or due to expansions under newly approved programs). We note that many of the reference cost reporting periods are subject to audit under section 1886(h)(7)(A)(ii) of the Act. Given

our limited time and audit resources, we believe it would be inefficient for the fiscal intermediaries to audit the cost reporting period that includes July 1, 2003, for a hospital that submitted a timely request, and then, in the event that the hospital regrets having submitted that request, audit the cost report ending on or before September 30, 2002. Therefore, due to the extremely tight timeframe mandated by the statute, and considering that GME audits can be lengthy and complicated processes, we believe that we needed to issue the OTN on April 30, 2004, establish June 4, (later changed to June 14) 2004, as the deadline for a hospital's "timely request" under section 1886(h)(7)(A)(ii) of the Act, and make submissions of timely requests "binding". We note that, to allow hospitals more time to evaluate their FTE resident data, we reissued this OTN (CR 3247, Transmittal 87) on May 26, 2004 with a revised "timely request" deadline of June 14, 2004. In those OTNs, we explained that, "In the Fiscal Year (FY) 2005 Hospital Inpatient Prospective Payment System (PPS) proposed rule, we will be proposing procedures for determining the number of "unused" residency positions, as well as an application process for hospitals that seek additional residency slots, and specific criteria that we will use in determining which hospitals will receive the additional residency positions. However, since the procedures would not be finalized before publication of the FY 2005 Hospital Inpatient PPS final rule (by August 1, 2004), and the provisions of that final rule would not become effective until October 1, 2004 (at least 60 days after publication of the final rule), we are notifying you and your providers in this OTN of certain information that we will need in order to determine in a timely fashion the number of unused resident positions available for redistribution" (emphasis added).

In issuing the OTNs, and in conjunction with the additional information provided in the proposed rule, we believe that we provided enough information for hospitals to determine whether their FTE residents caps would be subject to reduction, whether the hospital had an expansion of an existing program, and whether it would be advantageous for the hospital to submit a timely request to use the cost report that includes July 1, 2003 as the reference period. Furthermore, we believe that, as a general proposition, a hospital should know the validity of its FTE resident count, and be able to assess whether its FTE count is below its FTE resident cap. Therefore, the issuance of proposed and final regulations should have had little, if any, impact, on a hospital's decision to submit a timely request. However, we do accede that this may not be the case for hospitals located in areas for which the urban or rural status will change as of October 1, 2004, as described previously in section IV.O.d. of this preamble. Accordingly, we are providing another limited opportunity after publication of this final rule only for hospitals located in areas whose rural status will change to urban as of October 1, 2004, as stated in section IV.O.d. of this preamble, to make a timely request under section 1886(h)(7)(A)(ii) of the Act.

Comment: One commenter noted that because the June 14, 2004 deadline for submitting a timely request was prior to the issuance of the final rule, the enforcement of that deadline could be problematic, even though CMS issued a One-Time Notification (CR 3247) instituting this deadline. The commenter recommended that CMS use the deadline of June 14, 2004, issued in the OTN as a guideline, rather than a firm deadline, with respect to allowing a hospital to use an alternative cost report.

Response: We disagree with the commenter's suggestion that the June 14, 2004 deadline for submission of a timely request should be used as a guideline, and not a firm deadline. We note that sections 1886(h)(7)(A)(ii)(II) and (III) of the Act specifically hinge a hospital's ability to use its cost report that includes July 1, 2003, or to adjust its reference resident level due to newly approved programs, on the submission of a *timely* request, and clearly gives the Secretary the discretion to establish what a timely request should be. As we explained in the OTN and in response to the previous comment, if the modifications under section 1886(h)(7) of the Act had not been made effective July 1, 2005, we could have waited until after publication (or perhaps even the effective date) of this final rule to establish a deadline for all hospitals to submit timely requests. However, because we have a limited amount of time in which to implement section 1886(h)(7) of the Act, and the provisions of this final rule will not be effective until October 1, 2004, we chose to exercise our discretion and subregulatory authority to issue the OTN and require that timely requests must be submitted by June 14, 2004. Accordingly, all requests submitted after June 14, 2004 (except for those for which a new deadline is established under this final rule) are *not* timely, and may not be used by the fiscal intermediaries to allow for use of the cost report that includes July 1, 2003, or to adjust the reference resident level to reflect newly approved programs.

Comment: One commenter was concerned that hospitals "must choose" between two reference cost reporting periods, regardless of whether those cost reports have been settled. The commenter believed that there is too much uncertainty surrounding cost reports that are not settled, and requested that hospitals be given an opportunity to make

or withdraw a timely request once both its most recent cost report ending on or before September 30, 2002, and its cost report that includes July 1, 2003 is settled.

Response: We are not accepting the commenter's request, because it is possible that a hospital's most recent cost report ending on or before September 30, 2002, and its cost report that includes July 1, 2003, will not be settled until well after the effective date of section 1886(h)(7) of the Act of July 1, 2005. Waiting until all reference cost reports are settled would prevent this provision from being implemented in a timely fashion, and would generally be disruptive to fiscal intermediaries and to hospitals.

Comment: One commenter noted that there may be hospitals that have increased their resident levels in the reference period due to new programs that do not qualify as a "newly approved program" under section 1886(h)(7)(ii)(III) of the Act because they were either accredited after January 1, 2002, or they were in operation during the providers' reference periods, or both. The commenter asked whether increases in resident counts due to these new programs can be considered expansions of existing programs, and, if so, whether the commenter could request that its cost report that includes July 1, 2003 be used to determine if and by how much its FTE resident cap would be reduced. The commenter believed that CMS should not deny such a hospital the ability to use the cost report that includes July 1, 2003, and CMS should not reduce the hospital's FTE resident caps based on a lower FTE resident count on the cost report ending on or before September 30, 2002 if its FTE resident level has subsequently increased due to the addition of the new program(s) not addressed under section 1886(h)(7)(A)(ii)(III) of the Act.

Response: Section 1886(h)(7)(A)(ii)(II) of the Act, as added by section 422(a) of Pub. L. 108-173, provides that if a hospital's resident level increased due to an expansion of an existing program, and that expansion is not reflected on the hospital's most recent settled cost report, a hospital may make a timely request to CMS that, rather than using its most recent cost reporting period ending on or before September 30, 2002, to determine if its FTE resident cap should be reduced, CMS should use the cost report for the hospital's cost reporting period that includes July 1, 2003. In the May 18, 2004 proposed rule (69 FR 28295), we proposed that "expansion of an existing program" means that the hospital's total number of unweighted allopathic and osteopathic FTE residents in existing programs in a cost reporting period up to and including the hospital's cost report that includes July 1, 2003, is greater than the resident level in the hospital's most recent settled cost report. In other words, generally, as long as a hospital trained more unweighted allopathic and osteopathic FTE residents in a cost reporting period after its most recent settled cost report in programs that were existing during the cost reporting period for the most recently settled cost report, it may submit a timely request that its cost report that includes July 1, 2003, be used for purposes of determining any FTE resident cap reduction under section 1886(h)(7)(A)(i) of the Act. We believe this definition of an existing program is consistent with the language and intent of section 1886(h)(7)(A)(ii)(II) of the Act, which specifically addresses expansions of existing programs not reflected on the hospital's most recent settled cost report. Therefore, in order for a hospital to qualify to submit a timely request to use its cost report that includes July 1, 2003, the increase in its overall resident level must be due to an increase

in the number of residents that were in residency programs in which the hospital was training residents in its most recent settled cost report. For the purposes of this provision, a hospital first must determine whether the total unweighted allopathic and osteopathic FTE count (not program-specific, but for all allopathic and osteopathic programs combined) in a cost reporting period subsequent to its most recent settled cost reporting period up to and including the cost report that includes July 1, 2003, is greater than the total unweighted allopathic and osteopathic FTE count in its most recent settled cost report. If there has been an increase in the total unweighted allopathic and osteopathic FTE resident count since the last settled cost report, the hospital must determine if that increase is due to expansion of a program(s) in which that hospital trained FTE residents in its most recent settled cost report, or whether the increase is due to a new or a different specialty program for which the hospital did not train FTE residents in its most recent settled cost report. For example, assume that a hospital's most recent settled cost report ending on or before September 30, 2002, is the cost reporting period ending December 31, 2000, and the hospital only trained 10 FTE internal medicine residents in that period. The hospital began training 2 FTE residents in a pediatrics program in 2001, so that the hospital's total unweighted allopathic and osteopathic resident level on its FYE December 31, 2001 cost report increased by 2 FTEs to equal 12. Because the increase in the resident level is entirely attributable to the residents in the pediatrics program, a specialty program in which the hospital did not train FTE residents in its FYE December 31, 2000 cost report, this hospital would not qualify to use the cost report that includes July 1, 2003, as its reference period because the increase in the resident level is

due to residents in a new program rather than an expansion of an existing program not reflected on the last settled cost report. On the other hand, if any of the additional residents counted in FYE December 31, 2001 (using the same example) would be internal medicine residents, a program in which the hospital did participate and train FTE residents in FYE December 31, 2000 (its last settled cost report), the hospital may qualify to make a timely request to use the cost reporting period that includes July 1, 2003 due to an expansion of an existing program that was not reflected on the last settled cost report of FYE December 31, 2000.

(3) Audits of the Reference Cost Reporting Periods

As mentioned under section IV.O.2.f.(1) of this preamble, to determine a possible reduction to a hospital's FTE resident cap, section 1886(h)(7)(A)(ii)(I) of the Act, as added by section 422(a) of Pub. L. 108-173, directs CMS to use a hospital's most recent cost reporting period ending on or before September 30, 2002, "for which a cost report has been settled (or, if not, submitted (subject to audit), as determined by the Secretary" (emphasis added). In the May 18, 2004 proposed rule (69 FR 28295), we proposed to interpret this language to mean that, if a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has been settled, then, unless the hospital submits a timely request to use the cost reporting period that includes July 1, 2003, we would use the hospital's settled cost report without further audit to determine possible reductions to the FTE resident caps. We also proposed to interpret this language to mean that if a hospital's cost report for the most recent cost reporting period ending on or before September 30, 2002, has not been settled, the hospital's

as-submitted cost report for the most recent cost reporting period ending on or before September 30, 2002, would be subject to audit by the fiscal intermediary. In addition, as stated under section 1886(h)(7)(A)(ii)(II) of the Act, use of a hospital's cost report that includes July 1, 2003 is made "after audit and subject to the discretion of the Secretary." A hospital's cost report that includes July 1, 2003 may be at various stages of settlement, or may not even be submitted at the time this proposed rule is published. For example, if a hospital has a fiscal year end of June 30, its cost reporting period that includes July 1, 2003 would not end until June 30, 2004. This cost report is not required to be submitted until 5 months after the cost reporting period closes, which would be by December 1, 2004. In any case, the fiscal intermediary would need to make a determination as to whether a hospital has actually increased its resident level due to an expansion of an existing program that is not reflected on the most recent settled cost report. Further, the FTE resident counts that are included (or would be included) in the cost report that includes July 1, 2003, are subject to audit by the fiscal intermediary to ensure that an appropriate determination is made as to whether, and by how much, a hospital's FTE resident cap will be reduced. To facilitate these determinations, in the May 18, 2004 proposed rule, we proposed that the fiscal intermediaries may audit the FTE resident counts as necessary in the most recently settled cost reports and in the cost reports up to and including the cost report for the cost reporting period that includes July 1, 2003.

Fiscal intermediaries will perform desk or onsite audits related to section 422, using instructions that will be issued in a separate document. As we explained in the

OTN, Transmittal No. 77, CR 3247, in the interest of time and the most efficient use of audit resources, we have required that if a hospital would like CMS to use its cost report that includes July 1, 2003, as its reference period due to an expansion of an existing program, the hospital must notify the fiscal intermediary in accordance with the instructions provided in the OTN by June 4, 2004 (later revised to June 14, 2004). If a hospital submits a timely request that its cost report that includes July 1, 2003, be used, we proposed that the fiscal intermediary would audit that cost report and previous cost reports as necessary to determine if the hospital increased its resident level due to an expansion of an existing program that is not reflected on the most recent settled cost report. If a hospital does not submit a timely request to the fiscal intermediary that its cost report that includes July 1, 2003, be used, we proposed that the fiscal intermediary would use the cost report for the most recent cost reporting period ending on or before September 30, 2002, to determine if, and by how much, a hospital's FTE resident cap should be reduced, as specified under section 1886(h)(7)(A)(ii)(I) of the Act. If the cost report that is used to determine the possible reduction to a hospital's FTE resident count is for a period of less than or more than 12 months, we proposed that the fiscal intermediary would prorate the FTE resident caps and unweighted FTE residents to equal 12-month counts.

Comment: Some commenters urged CMS to keep in mind that Congress' intent is to redistribute only "unused" slots, and requested that a hospital's FTE resident cap should not be reduced on account of FTEs that were disallowed because the hospital did not fulfill paperwork or other requirements associated with receiving direct GME or IME

payments. The commenters believed that the legislation dictates that the hospital's FTE resident cap not be reduced as a consequence of technical lapses because the slots are unquestionably being "used", despite the fact that for cost report payment purposes, a lower FTE count may be used. One commenter added that, in the case where there is a discrepancy between a hospital's submitted FTE resident count and the audited FTE resident count, and the audited count would result in a (more substantial) lowering of the hospital's FTE resident cap, then the determination should be made on the basis of the as-submitted FTE resident count.

Response: We are sympathetic to the commenter's point that it was not the intention of Congress to reduce a hospital's FTE resident cap solely because the hospital failed to comply with certain paperwork requirements necessary for receiving direct GME and IME payment with respect to FTE residents that a hospital actually trained.. Nevertheless, we believe that Congress was aware that there could be certain anomalies in a hospital's FTE count in a given year, and therefore, provided for some flexibility in determining the reference resident levels by granting hospitals the option to use the cost report that includes July 1, 2003 due to expansions of existing programs that were not reflected on the most recent settled cost report under section 1886(h)(7)(A)(ii)(II) of the Act, or to adjust the reference resident level to include the number of residents in newly approved programs under section 1886(h)(7)(A)(ii)(III) of the Act, rather than only using the most recent cost report that ended on or before September 30, 2002. We believe that Congress in fact intended that CMS use only allowable FTE resident counts in determining any applicable reductions to a hospital's FTE resident cap under this

provision. Furthermore, in directing CMS to use "resident levels", or FTE data from the hospital's cost reporting period ending on or before September 30, 2002 or the cost reporting period that includes July 1, 2003, the statute directs that the cost reports to be used are "subject to audit".

Comment: One commenter stated that the proposed rule does not provide an indication of how or when audits under section 422 will be performed or what standards will be used to determine a hospital's unused resident slots. The commenter asked that CMS provide specific, detailed information about such audits and then review and respond to providers' comments prior to finalizing the audit protocols.

Response: We believe it is inappropriate to share the details of the audit procedures with providers and allow them the opportunity for comment. The Medicare audit program has always been confidential, to be shared only with the fiscal intermediaries, and will continue to be so. However, as with the audits conducted as part of any cost report settlement process, the fiscal intermediaries will request documentation needed to audit the FTE resident count and will provide hospitals with the opportunity to review and to respond to the proposed audit adjustments, prior to the finalization of the audit adjustments.

(4) Expansions Under Newly Approved Programs

Under section 1886(h)(7)(ii)(III) of the Act, as added by section 422(a)(3) of Pub. L. 108-173, a hospital may request that its reference resident level be adjusted to include residents in certain newly approved programs. Specifically, if a hospital's new program was accredited by the appropriate accrediting body (that is, the Accreditation

Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA)) before January 1, 2002, but was not in operation during the hospital's reference period, the hospital may submit a timely request that we adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital(s). In the May 18, 2004 proposed rule (69 FR 28296), for a hospital that requests an adjustment due to a newly approved program, we proposed to determine a hospital's reference period as we otherwise would. If a hospital received accreditation for a new medical residency training program before January 1, 2002, but the program was not in operation (that is, the hospital did not begin training residents in that program) during its reference period (which will be either the most recent cost reporting period ending on or before September 30, 2002, or the cost reporting period that includes July 1, 2003), the hospital may submit a timely request by June 4, 2004 (later revised to June 14, 2004), as explained in the OTN, that its resident level for its reference period be adjusted to reflect the number of accredited slots for which that new medical residency training program was approved. We note that section 1886(h)(7)(A)(ii)(III) of the Act does not require that CMS include the number of residents for which the new program is accredited in the hospital's reference cost reporting period for purposes of determining direct GME and IME payment in that reference cost reporting period. Rather, CMS is only required to include the number of residents for which a new program was accredited in the resident level for purposes of determining if, and by how much, a hospital's FTE resident cap should be reduced under section 1886(h)(7)(A) of the Act.

For example, assume a hospital that has a fiscal year end of June 30 received accreditation in October 2001 to train 10 residents in a new surgery program. The hospital does not have an expansion of an existing program not reflected on its most recent settled cost report, so its reference period is the most recent cost reporting period ending on or before September 30, 2002. The hospital first begins to train residents in the new surgery program on July 1, 2002. The new surgery residents are not reflected on the hospital's June 30, 2002 cost report, which is the hospital's most recent cost reporting period ending on or before September 30, 2002. Thus, the hospital may submit a timely request that we increase its resident level for the cost report ending June 30, 2002, by 10 FTE residents to reflect the residents approved for the new surgery program for purposes of determining if the hospital's reference resident level is below its otherwise applicable resident cap. However, we note that if the hospital's fiscal year end in this example was September 30, a program accredited in October 2001 and begun on July 1, 2002, would be in operation during the hospital's cost reporting period ending on September 30, 2002, and the hospital could not receive an increase to its resident level for its cost reporting period ending September 30, 2002, to include the total number of accredited resident positions in the new surgery program. If the new program was accredited for a range of residents (for example, a hospital receives accreditation to train 6 to 8 residents in a new internal medicine program), we proposed that the hospital may request that its resident level for its most recent cost reporting period ending on or before September 30, 2002 be adjusted to reflect the maximum number of accredited positions (which, in this example, would be 8 internal medicine residents). We also proposed that

at the time the hospital makes the timely request to have its resident level adjusted to include the number of accredited resident positions, the new program need not be training the full complement of residents for which the program was accredited. (Proposed redesignated §413.79(c)(3)(A)(3)(ii)). In addition, if more than one hospital was approved as a training site for the residents in the newly accredited program (that is, more than one hospital sponsors the program or there are other participating institutions that serve as training sites for the residents in the program), we proposed that the adjustment to a requesting hospital's reference resident level would reflect the appropriate portions of the FTE residents in the new program that would be training at that hospital.

Similarly, if, in addition to having accreditation for a new program, a hospital has an expansion of an existing program that is not reflected on the most recent settled cost report, that hospital may submit a timely request that its resident level for the cost reporting period that includes July 1, 2003, be adjusted to include the number of resident positions for which a new program was accredited. We proposed that a hospital whose reference period is the one that includes July 1, 2003, may only request that its reference resident level be adjusted to include the accredited number of residents for a new program if, in accordance with section 1886(h)(7)(A)(ii)(III) of the Act, the new program was approved by the appropriate accrediting body before January 1, 2002, but was not in operation during the cost reporting period that includes July 1, 2003. This proposal was based on our interpretation of the statutory language, which states that "the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include the number of residents that were approved . . . for a medical residency program . . . but

which was not in operation during the cost reporting period used under subclause (I) or (II) . . ." (emphasis added). Because the statute provides for an adjustment to the reference resident level "specified under subclause I or II," as mentioned above, for hospitals that request an adjustment under section 1886(h)(7)(A)(ii)(III) of the Act, we proposed to identify the applicable reference period as we otherwise would under section 1886(h)(7)(A)(ii)(I) and (II) of the Act. That is, we proposed to use the hospital's most recent cost reporting period ending on or before September 30, 2002, as the reference cost reporting period, unless the hospital submits a timely request to use the cost reporting period that includes July 1, 2003, due to an expansion of an existing program that is not reflected on the cost recent settled cost report. We also noted that, as mentioned above, subclause (III) requires that the program be accredited before January 1, 2002, but not be in operation during the hospital's reference cost reporting period, or in this case, the period that includes July 1, 2003. This means that, in order for the hospital to receive an adjustment to its reference resident level under section 1886(h)(7)(A)(ii)(III) of the Act for the cost reporting period that includes July 1, 2003, the new program also cannot be in operation in the cost reporting period that includes July 1, 2003. Thus, while we believe it is possible for a hospital to qualify for this adjustment because the hospital started a new program that is not reflected on its most recent cost reporting period ending on or before September 30, 2002, we believe that few, if any, hospitals will qualify for this adjustment for a new program that was not in operation in the cost report that includes July 1, 2003, because it is unlikely that a

program would receive its accreditation prior to January 1, 2002, and still not be in operation by July 1, 2003.

Comment: Several commenters believed that the proposed "new program" exception as outlined in the proposed rule and the recently issued One-Time Notification (Change Request 3247, Transmittal 87, issued on May 26, 2004) is too restrictive. Under the proposal, a hospital's resident count can only be increased if no residents from the newly approved program were training during the relevant cost reporting period. One commenter gave an example that if a new residency program "was accredited on January 1, 2001 and began training residents on July 1, 2001, and the hospital's relevant cost reporting year for implementing section 422 was July 1, 2001 to June 30, 2002, that year would likely reflect only residents being trained in the first program year [of the new program.] If the hospital's FTE resident count is below its resident FTE cap for that year . . . it is at risk of having its cap reduced even though it has committed to training the residents in that program and was intending to use its 'cap space' for that program." The commenter asserted that such a result is contrary to the intent of Congress and that the proposed rule should be modified in its final version to allow new residency programs to grow to their full complement.

Response: Under section 1886(h)(7)(ii)(III) of the Act, as added by section 422(a)(3) of Pub. L. 108-173, a hospital may request that its reference resident level be adjusted to include residents in certain newly approved programs. Specifically, if a hospital's new program was accredited by the appropriate accrediting body (that is, the ACGME or the AOA) or approved by the American Board of Medical Specialties

(ABMS) before January 1, 2002, but was not in operation during the hospital's reference period, the hospital may submit a timely request that we adjust the reference resident level to include the number of residents for which a new program was accredited at a hospital(s). While we sympathize with the commenters' points, we have interpreted "not in operation" to mean that the hospital was not training residents in that program during its reference cost reporting period. As such, a residency program that was accredited before January 1, 2002, and was training any residents during the hospital's reference cost reporting period would not be eligible to make a timely request that its resident level for its reference period be adjusted to reflect the number of accredited slots for which that new medical residency training program was approved.

We are, however, sympathetic to the commenters' point that hospitals with new residency programs that were in operation during the reference period may not be able to grow to their full complement of residents if their FTE resident cap is reduced if their reference FTE resident count is below their reference FTE resident cap. However, such a hospital may apply for additional FTE resident slots under section 1886(h)(7)(B) of the Act in an attempt to adjust its cap to allow for payment for the additional slots in the new program. In this final rule, as discussed under section IV.O.2.m. of this preamble, we are adding an evaluation criterion to address the situation where a hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) of the Act and the hospital had started a new residency program (accredited before January 1, 2002) that was in operation during the reference period but had not yet reached a full complement and the hospital has requested additional slots to allow the new program to train residents in FTE positions

that were not included in the reference resident period. For the purposes of this criterion, we are defining a new program as a program that has been in operation (training residents) for three or fewer years in the reference period. In addition, the hospital must not qualify for adjustment to its reference FTE resident count under section 1886(h)(7)(ii)(III) of the Act and the hospital's FTE resident cap must have been reduced under section 1886(h)(7)(A)(i) of the Act.

Comment: One commenter described a situation where a hospital took over permanent sponsorship and training of residents in a program from another hospital that was experiencing financial difficulties. The hospital became the sponsor of and received accreditation for 16 residents in the program by November 2002, while continuing to train the remnant of residents that transferred from the other hospital. The hospital began training its own residents in the program on July 1, 2003, and planned to grow the program to its full complement of 16 residents by July 1, 2005. The commenter requested that, due to the circumstances surrounding the program which experienced a temporary drop in enrollment due to another hospital's financial difficulties, the hospital be permitted to adjust its reference resident level on its cost report that includes July 1, 2003 to reflect the full 16 accredited slots, rather than the 10 actual FTEs that were training in that cost reporting period.

Response: As with many situations brought to our attention by commenters, we are sympathetic to this commenter's concerns, but we note that the language at section 1886(h)(7)(ii)(III) of the Act precludes us from granting the commenter's request. Specifically, under section 1886(h)(7)(ii)(III) of the Act, a hospital may request that its

reference resident level be adjusted to include residents in certain newly approved programs if the new program was accredited by the appropriate accrediting body before January 1, 2002, was not in operation during the hospital's reference period, and the hospital submits a timely request that we adjust the reference resident level to include the number of residents for which a new program was accredited at the hospital. Therefore, the commenter's hospital would not qualify to have the resident level on its cost report that includes July 1, 2003 adjusted to reflect residents in its new program for two reasons: first, its program received accreditation after January 1, 2002, not before January 1, 2002 as the statute specifies; second, the program was in operation during the hospital's reference cost reporting period (that is, the cost report that includes July 1, 2003). In order for the hospital to receive an adjustment to its reference resident level under section 1886(h)(7)(A)(ii)(III) of the Act for the cost reporting period that includes July 1, 2003, the new program also cannot be in operation in the cost reporting period that includes July 1, 2003.

(5) Affiliations

Section 1886(h)(7)(A)(iii) of the Act, as added by section 422(a)(3) of Pub. L. 108-173, directs the Secretary to consider whether a hospital is a member of a Medicare GME affiliated group (as defined under §413.86(b)) as of July 1, 2003, in determining whether a hospital's FTE resident cap should be reduced. As described above, some hospitals that have reduced their resident levels below their FTE resident caps may have affiliated with other hospitals that would otherwise exceed their FTE resident caps. Thus, while some hospitals were below their FTE resident caps prior to

entering into a Medicare GME affiliation agreement, upon affiliating, their FTE resident caps were temporarily reduced because some or all of their excess FTE slots were temporarily added to the FTE caps of other hospitals as part of the affiliation agreement. Under the Medicare GME affiliation agreement, these otherwise "excess" FTE slots have been transferred for use by other hospitals, and, therefore, CMS would take into account the revised caps under the affiliation agreement for both the hospital that would otherwise be below its FTE resident cap and the revised caps of the other hospital(s) that are part of an affiliated group. In determining whether hospitals' FTE resident caps should be reduced under section 1886(h)(7)(A)(i) of the Act, section 1886(h)(7)(A)(iii) of the Act directs CMS to consider hospitals "which are members of the same affiliated group . . . as of July 1, 2003." In the May 18, 2004 proposed rule (69 FR 28297), we proposed that hospitals that are affiliated "as of July 1, 2003" means hospitals that have in effect a Medicare GME affiliation agreement, as defined in existing §413.86(b), for the program year July 1, 2003 through June 30, 2004, and have submitted a Medicare GME affiliation agreement by July 1, 2003 to their fiscal intermediaries with a copy to CMS. These hospitals may have already been affiliated prior to July 1, 2003, or may have affiliated for the first time on July 1, 2003. In either case, in determining possible reductions to a hospital's FTE resident cap, we proposed to use a hospital's cap as revised by the July 1, 2003 Medicare GME affiliation agreement. We believe this interpretation is consistent with the intent of section 1886(h)(7)(A)(iii) of the Act, as added by section 422(a)(3) of Pub. L. 108-173, in that a hospital's FTE resident cap should not be reduced if some or all of its excess resident slots have been transferred for use by hospitals with

which it is affiliated (that is, the hospital is training at least as many FTE residents as are in its "affiliated" FTE resident cap).

Although hospitals in an affiliated group base the FTE cap adjustments on an aggregate FTE resident cap, we proposed that we would determine whether a hospital's FTE resident cap should be reduced on a hospital-specific basis. Section 1886(h)(7)(A)(iii) of the Act states that "the provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group . . ." (emphasis added). Clause (i) of section 1886(h)(7)(A) of the Act, as described above, requires the reduction of hospitals' FTE resident caps under certain circumstances, based on the otherwise applicable FTE resident cap and the resident level in the applicable reference period, as described above (which would be either a hospital's most recent cost reporting period ending on or before September 30, 2002, or the cost reporting period that includes July 1, 2003). We proposed to interpret this reference to clause (i) to mean that the Secretary is to use a hospital's July 1, 2003 "affiliated" FTE resident cap as the otherwise applicable FTE resident cap when determining a possible reduction to the FTE resident cap. In other words, if a hospital is affiliated as of July 1, 2003, we proposed to superimpose the "affiliated" FTE resident cap onto the hospital's reference cost reporting period.

Specifically, as we stated under section IV.O.2.f.(1) of this preamble, consistent with section 1886(h)(7)(A)(ii)(I) of the Act, to determine possible reductions to a hospital's FTE resident cap, we proposed that we would use a hospital's most recent cost reporting period ending on or before September 30, 2002. If a hospital is part of a

Medicare affiliated group for the program year beginning July 1, 2003, we are proposing to compare the hospital's July 1, 2003 "affiliated" FTE resident cap to its resident level on the most recent cost report ending on or before September 30, 2002. If the hospital's resident level from its most recent cost report ending on or before September 30, 2002, is below its July 1, 2003 "affiliated" FTE resident cap, we are proposing to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment under the July 1, 2003 affiliation agreement, by 75 percent of the difference between the hospital's resident level and the July 1, 2003 "affiliated" FTE resident cap.

Alternatively, as stated above under section IV.O.2.f.(2) of this preamble, consistent with section 1886(h)(7)(A)(ii)(II) of the Act, a hospital may submit a timely request to CMS that its cost report that includes July 1, 2003, be used as the reference period to determine possible FTE resident cap reductions because of an expansion of an existing program that is not reflected on the hospital's most recent settled cost report. If a hospital is affiliated for the program year beginning July 1, 2003, and we grant the hospital's timely request to use the cost reporting period that includes July 1, 2003, because its expansion of an existing program(s) is not reflected on the most recent settled cost report, we proposed to compare the hospital's July 1, 2003 "affiliated" FTE resident cap to its resident level on the cost report that includes July 1, 2003. If the hospital's resident level from its cost report that includes July 1, 2003 is below its July 1, 2003 "affiliated" FTE resident cap, we proposed to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment

under the July 1, 2003 affiliation agreement, by 75 percent of the difference between the hospital's resident level and the July 1, 2003 "affiliated" FTE resident cap.

For example, Hospital A's most recent cost report ending on or before September 30, 2002 is FYE December 31, 2001. Hospital A has a direct GME FTE resident cap (unadjusted for an affiliation) of 100, and an IME FTE resident cap (unadjusted for an affiliation) of 90. Hospital A did not have an expansion of an existing program that was not reflected on its most recent settled cost report, and therefore, its FYE December 31, 2001 cost report is being used as the reference period for purposes of determining a possible reduction to its FTE resident caps. Hospital A's unweighted direct GME count of allopathic and osteopathic FTE residents on its December 31, 2001 cost report is 60. Hospital A's IME count of allopathic and osteopathic FTE residents on its December 31, 2001 cost report is 55.

Hospital B, with a FYE of September 30, expanded an existing program, and that expansion is not reflected on its most recent settled cost report. Hospital B has submitted, and we have granted, a timely request that its cost report that includes July 1, 2003 (that is, its FYE September 30, 2003 cost report) be used for purposes of determining a possible reduction to its FTE resident caps. Hospital B has a direct GME FTE resident cap (unadjusted for an affiliation) of 100, and an IME FTE resident cap (unadjusted for an affiliation) of 95. Hospital B's direct GME unweighted count of allopathic and osteopathic FTE residents on its September 30, 2003 cost report is 120, and its IME count of allopathic and osteopathic FTE residents for the same period is 110.

On July 1, 2003, Hospital A and Hospital B entered into a Medicare GME affiliation agreement. Under the affiliation agreement, the hospitals' FTE resident caps are revised as follows:

Affiliation Year July 1, 2003 through June 30, 2004				
	Direct GME FTE Resident Cap	**Direct GME Affiliated Cap**	**IME FTE Resident Cap**	**IME Affiliated Cap**
Hospital A	100	60	90	55
Hospital B	100	140	95	130

To apply section 1886(h)(7)(A)(i) of the Act, Hospital A's affiliated FTE resident caps as of July 1, 2003, are compared to its direct GME and IME allopathic and osteopathic FTE resident counts from its FYE December 31, 2001 cost report, and Hospital B's affiliated FTE resident caps as of July l, 2003, are compared to its direct GME and IME allopathic and osteopathic FTE resident counts from its FYE September 30, 2003 cost report, as follows:

	Affiliated Direct GME Cap	**Unweighted Allopathic and Osteopathic FTE Count**	**Unweighted count below affiliated cap?**	**If yes, reduce <u>actual</u> FTE resident cap by 75 percent of difference between affiliated cap and unweighted count**
Hospital A	60	60 (from FYE 12/31/01)	No	--
Hospital B	140	120 (from FYE 9/30/03)	Yes	100-[.75(140-120)] = **85**

	Affiliated IME Cap	**Allopathic and Osteopathic FTE Count**	**Count below affiliated cap?**	**If yes, reduce <u>actual</u> FTE resident cap by 75 percent of difference between affiliated cap and count**
Hospital A	55	55 (from FYE 12/31/01)	No	--
Hospital B	130	110 (from FYE 9/30/03)	Yes	95-[.75(130-110)] = **80**

Effective for portions of cost reporting periods beginning on or after July 1, 2005, Hospital A's FTE resident caps for direct GME and IME will remain at 100 and 90, respectively, while Hospital B's FTE resident caps for direct GME and IME will be reduced to 85 and 80, respectively.

We also noted that there are hospitals that may have been members of a Medicare GME affiliated group in program years that coincide with or overlap the reference cost reporting periods, but these hospitals were not affiliated as of July 1, 2003. As such, they are not subject to the May 18, 2004 proposed policy described above applicable to section 1886(h)(7)(A)(iii) of the Act, as added by section 422(a)(3). For these hospitals, we proposed to compare the resident level in the applicable reference period to the FTE resident cap as adjusted by the affiliation agreement applicable to that reference period. If a hospital's resident level is below its otherwise applicable FTE resident cap for that reference period cost report, we proposed to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment under the affiliation agreement for that period, by 75 percent of the difference between the hospital's resident level and the otherwise applicable FTE resident cap. (Proposed redesignated §413.79(c)(3)(iv)(B)). For example, assume a hospital with a June 30 fiscal

year end affiliated for one program year from July 1, 2001, through June 30, 2002. On its June 30, 2002 cost report (that is, its most recent cost report ending on or before September 30, 2002), its FTE resident cap is 20, its cap as revised by the affiliation agreement is 25, and its resident level is 21 FTEs. Because this hospital's resident level of 21 is below its otherwise applicable FTE resident cap of 25, the hospital's FTE resident cap of 20 will be reduced as follows: 20 – [(.75(25 – 21)] = 17. We proposed to apply the same methodology described above in the event that the reference period is a hospital's cost report that includes July 1, 2003 (that is, for a hospital that had an expansion of a program that is not reflected on its most recent settled cost report and that made a timely request to use the period that includes July l, 2003), if that hospital is not affiliated as of July 1, 2003, but its cost report that includes July 1, 2003 overlaps with a program year for which the hospital was affiliated. In other words, section 1886(h)(7)(A)(i) of the Act will be applied by comparing a hospital's reference resident level to the otherwise applicable FTE resident cap, as adjusted for any affiliation agreement for the reference period.

Comment: Some commenters acknowledged the challenges that CMS faced in implementing section 422, particularly section 1886(h)(7)(A)(iii) of the Act related to hospitals that are members of a Medicare GME affiliated group "as of July 1, 2003," and commended CMS for its work on proposals related to this provision. However, those commenters, along with many others, expressed concern about the proposed policy related to hospitals that were affiliated as of July 1, 2003, and asked that our final policy

concerning possible FTE resident cap reductions for these hospitals be amended substantially.

Generally, the comments concerning Medicare GME affiliation agreements fell into the following four categories:

(1) Hospitals that are affiliated for the academic year beginning July 1, 2003 should have their applicable FTE resident cap for the period including July 1, 2003 compared to their applicable resident level for the period including July 1, 2003. The commenters expressed great concern regarding the proposed methodology whereby a hospital's "affiliated" FTE resident cap for the period July 1, 2003 to June 30, 2004 would be compared to the hospital resident FTE counts corresponding to a different (in some cases, not even overlapping) period for purposes of section 422. Although the commenters recognized that, in proposing this methodology, CMS was attempting to reconcile and give meaning to seemingly inconsistent provisions within section 422, they strongly believed that teaching hospitals should be provided with, and that CMS has the authority to provide, the "most straightforward" option. They stated that it would not "make sense" to reduce the FTE resident cap of a hospital based on a comparison of its cap in an affiliation agreement that was from a period different than its reference cost reporting period. Therefore, most commenters generally recommended that each hospital's specific July 1, 2003 "affiliated" FTE resident cap should be compared to its FTE resident count for the July 1, 2003 through June 30, 2004 academic year, while one commenter recommended that CMS allow each hospital to elect whether to have its specific July 1, 2003 "affiliated" FTE resident cap compared to its FTE resident count for

the period July 1, 2003 to June 30, 2004, for purposes of determining if and by how much the hospital's FTE resident caps would be reduced.

(2) Hospitals that are affiliated for the academic year beginning July 1, 2003 should be permitted to compare their FTE resident caps from their modified, final submitted Medicare GME affiliation agreements for the academic year beginning July 1, 2003 and ending June 30, 2004 to their applicable resident level for the cost reporting period including July 1, 2003. The commenters noted that the existing regulations allow hospitals to modify their affiliation agreements by June 30 of a particular academic year to reflect the realities of the time spent in various training rotations in the event that the planned number of FTEs trained at each hospital, as specified in the affiliation agreement submitted to the fiscal intermediary by July 1 of that year, differs from the actual training rotations that occurred during the year. The commenters stressed that, for purposes of the "redistribution of unused resident slots", it is also important to allow affiliated hospitals to modify their arrangements to reflect the actual distribution of the member hospitals' FTE residents and their aggregate FTE resident cap; and the use of final, possibly modified affiliated FTE caps could avert unintended adverse consequences.

(3) Hospitals that are affiliated for the academic year beginning July 1, 2003 should be given the opportunity after the final rule is published to amend the affiliation agreement that was in place as of June 30, 2004. The commenters asked that CMS grant hospitals that were affiliated for the academic year beginning July 1, 2003, the option to modify those affiliations after publication of the final rule to account for "unintended

consequences," since the deadline of June 30, 2004 for potential amendments to the July 1, 2003 agreements occurred during the comment period for the FY 2005 IPPS proposed rule, and there was still much uncertainty regarding how the agreements would be accounted for under section 422. The commenters stated that they should be granted this option because, when hospitals elected to join an affiliated group as of July 1, 2003, the hospitals "had no way of knowing that this election would have implications for potential reductions to their hospital-specific resident FTE caps."

(4) Hospitals that are affiliated for the academic year beginning July 1, 2003 and that are at or above the aggregate cap should be treated as a group and should not lose any resident positions under section 422. Several commenters argued that the presence of the language at section 1886(h)(7)(A)(iii) of the Act concerning hospitals that are "members of the same affiliated group . . . as of July 1, 2003" implies that Congress was giving special consideration to hospitals that had elected to join an affiliated group for Medicare purposes, and that the initial FTE resident cap and count comparison under section 1886(h)(7)(A)(i) of the Act should first be conducted at the affiliated group level. The commenters urged CMS to ensure that a determination that finds the aggregate count of the hospitals in the affiliation to be higher than the aggregate cap should "automatically and without question" exempt all hospitals within the group from any reduction in hospital-specific caps. Some commenters suggested that this interpretation is consistent with CMS' current policy on affiliated groups for payment purposes when the group as a whole is under the aggregate cap. Some commenters also added that in the case where the groups aggregate FTE count is below the corresponding affiliated

aggregate FTE cap, CMS should use a hospital-specific comparison to determine which hospitals in the group should have their FTE resident caps reduced. Another commenter recommended that CMS should aggregate the excess FTE resident slots for the entire affiliated group, and any reduction should be prorated among all hospitals in the affiliated group.

Response: We have given a considerable amount of thought to each comment received regarding our proposed policy on hospitals that are part of a Medicare GME affiliation group for the academic year beginning July 1, 2003. In addition, during the comment period for the proposed rule, we listened to many questions and concerns raised as a result of the issuance of the OTN, which included a deadline of June 14, 2004 for all hospitals, whether affiliated or not, to submit a timely request to the fiscal intermediary if a hospital wanted its cost report that includes July 1, 2003 to be used for purposes of determining possible reductions to its FTE resident caps. We acknowledge that the proposal concerning affiliated groups presented certain difficulties, particularly in light of the June 14, 2004 deadline. To mitigate those concerns, we issued a notice on June 15, 2004 on the CMS website [Notice on "Redistribution of Unused Resident Positions, **http://www.cms.hhs.gov/providers/hipps/resident.asp**],**"** which stated, "If, in response to comments, we finalize any policy with respect to application of section 1886(h)(7)(A) of the Act that differs from a policy described in the OTNs and the proposed IPPS rule, we will provide another limited opportunity after publication of the final rule for affected hospitals to make or withdraw a timely request under section 1886(h)(7)(A)(ii) of the Act ."

Before stating our final policy, we would first like to explain our reasoning behind the proposal concerning affiliated groups relating to section 1886(h)(7)(A)(iii) of the Act. As is the case with any statutory language, the assumption must be that the Congress included this specific language at section 1886(h)(7)(A)(iii) of the Act to direct or grant the authority for the Secretary to take (or not take) certain action concerning affiliated groups that would not otherwise have been taken (or not taken) in the absence of that language. However, sections 1886(h)(7)(A)(i) and (C)(ii) of the Act already accounted for the application of aggregate caps in instances where hospitals might have been affiliated during their reference cost reporting periods by defining "otherwise applicable resident limit" to include adjustments to FTE caps resulting from a hospital's participation in a Medicare GME affiliated group. As a result, we do not believe there is a "most straightforward" interpretation, as the commenter suggested, to the language at section 1886(h)(7)(A)(iii) of the Act concerning affiliations. We believed (and continue to believe) that this language was meant to "protect" hospitals that were affiliated "as of July 1, 2003" in some way. However, we realized that, whatever proposal we chose, some hospitals would benefit while other hospitals would not. We struggled (and have continued to struggle) to interpret the language in a meaningful manner. We ultimately proposed to interpret section 1886(h)(7)(A)(iii) of the Act to mean that, for hospitals that were affiliated "as of July 1, 2003," we would superimpose the "affiliated" FTE resident caps "as of July 1, 2003´onto the hospitals' reference cost reporting periods. Thus, we proposed that, if a hospital is part of a Medicare GME affiliated group for the program year beginning July 1, 2003, we would compare the hospital's July 1, 2003 "affiliated"

FTE resident cap to its resident level on the most recent cost report ending on or before September 30, 2002. Similarly, for a hospital that submitted a timely request to use the cost reporting period that includes July 1, 2003, as its reference cost report, we would compare the hospital's July 1, 2003 "affiliated" FTE resident cap to its resident level on the cost report that includes July 1, 2003.

Since publication of proposed rule, after reviewing all of the comments, we have revisited the proposal and have considered alternative interpretations of section 1886(h)(7)(A)(iii) of the Act. We believe we are adopting an interpretation of the statute that is both consistent with the statute and addresses the commenters' concerns. First, we are convinced by the commenters' argument that the presence of the language at section 1886(h)(7)(A)(iii) of the Act concerning hospitals that are "*members* of the *same* affiliated group . . . as of July 1, 2003" (emphasis added), means that the Secretary should treat those hospitals, and *only* those hospitals, that are affiliated for the academic year beginning July 1, 2003 as a group for purposes of determining possible FTE resident cap reductions. That is, for hospitals that are affiliated "as of July 1, 2003," the comparison under section 1886(h)(7)(A)(i) of the Act between the FTE resident cap and count should *first* be conducted at the affiliated *group* level, and if the hospitals' aggregate FTE resident counts are *equal to or exceed* the hospitals' aggregate affiliated FTE resident caps for direct GME and IME respectively, then no reductions would be made to any of the individual hospitals' FTE resident caps (that is, the hospitals' FTE resident caps without the temporary adjustment under the July 1, 2003 affiliation agreement), even if, when considered on a hospital-specific basis, one or more of the member hospitals FTE

caps would otherwise have been reduced under section 1886(h)(7)(A)(i) of the Act.. As we will explain further below, we are also interpreting "as of July 1, 2003" to mean that the determination as to whether the aggregate affiliated FTE resident cap exceeds the aggregate FTE resident count is made using the sum of the hospital-specific FTE resident caps and the sum of the hospital-specific FTE resident counts from each affiliated group-member hospital's cost report that includes July 1, 2003. We also believe that if hospitals that are "members of the same affiliated group . . . as of July 1, 2003" are to be treated as a group in instances where the FTE resident counts of the group as a whole equal or exceed the aggregate affiliated FTE resident cap, then it is also appropriate that these hospitals should be treated as a group in instances where the FTE resident counts of the group as a whole are *below* the aggregate affiliated FTE resident cap. Section 1886(h)(7)(A)(iii) of the Act states that "*the provisions of clause (i)* shall be applied to hospitals which are members of the same affiliated group . . ." (emphasis added). Clause (i) of section 1886(h)(7)(A) of the Act, as described above, requires the reduction of hospitals' FTE resident caps under certain circumstances, based on the otherwise applicable FTE resident cap and the resident level in the applicable reference period. In this final rule, we are interpreting the reference in section 1886(h)(7)(A)(iii) of the Act to clause (i) to mean that, where the aggregate FTE resident counts of the affiliated group as a whole are *below* the aggregate affiliated FTE resident cap, the Secretary is to use a hospital's cost reporting period that includes July 1, 2003 as the reference period to determine possible reductions to the FTE resident caps. This would apply even when the hospital did not submit a timely request to use the cost report that includes July 1, 2003

(that is, regardless of whether there was an expansion of an existing program that was not reflected on an affiliated hospital's most recent settled cost report). Using FTE information from each hospital's cost report that includes July 1, 2003, we will determine the extent to which any hospitals in the affiliated group trained a number of FTE residents in excess of their individual "affiliated" FTE resident caps. Any hospital in the affiliated group that trained a number of FTE residents in excess of its individual "affiliated" FTE resident caps, would *not* have its FTE resident caps reduced. However, any hospital in the affiliated group that trained *fewer* FTE residents than its individual "affiliated" FTE resident caps *would* have its FTE resident caps reduced, and the aggregate reduction will be shared pro rata among the hospitals whose FTE counts were below their "affiliated" FTE caps during their cost report that includes July 1, 2003. Accordingly, we envision that the fiscal intermediaries will determine possible FTE resident cap reductions to hospitals that are affiliated for the academic year beginning July 1, 2003 in the following manner:

First, the fiscal intermediaries will identify those hospitals that are affiliated "as of July 1, 2003," which as we proposed, means hospitals that have in effect a Medicare GME affiliation agreement, as defined in existing §413.86(b), for the program year July 1, 2003 through June 30, 2004, and have submitted a Medicare GME affiliation agreement by July 1, 2003 to their fiscal intermediaries with a copy to CMS. Consistent with existing regulations regarding affiliated groups (63 FR 26338 May 12, 1998), since a hospital could have an agreement with one hospital for a particular program and another hospital for a different program, the affiliated group for aggregate cap purposes includes

the original two hospitals that have an agreement and *every* hospital that has an agreement with *any* of those hospitals. Then, for direct GME and IME respectively, the fiscal intermediaries will identify the "1996" FTE resident cap (adjusted for new programs, if applicable), and the unweighted allopathic and osteopathic FTE resident count from each hospital that is part of that affiliated group, from each hospital's cost report that includes July 1, 2003. (Note that since the 1996 cap and FTE count information from the cost report that includes July 1, 2003 is being used for purposes of section 422, the caps as amended on the July 1, 2003 affiliation agreement are irrelevant. The only purpose for the July 1, 2003 affiliation agreement is to identify those hospitals that are affiliated "as of July 1, 2003"). In many cases, the hospitals in the affiliated group will not all have the same fiscal year end. Therefore, for example, for a hospital with a FYE of June 30, the fiscal intermediary will identify the FTE resident cap (that is, the "1996" cap, as adjusted for new programs, if applicable) and the unweighted allopathic and osteopathic FTE resident count from the hospital's FYE June 30, 2004 cost report. For a hospital with a FYE of December 31, the fiscal intermediary will identify the FTE resident cap (that is, the "1996" cap, as adjusted for new programs, if applicable) and the unweighted allopathic and osteopathic FTE resident count from the hospital's FYE December 31, 2003 cost report. Next, the fiscal intermediary will add those FTE resident caps from those cost reports to determine the aggregate "affiliated" cap. The fiscal intermediary will also add the FTE resident counts for IME and direct GME respectively from those cost reports to determine the aggregate count. If the aggregate FTE resident counts are *equal to or exceed* the aggregate FTE resident caps, then no reductions would

be made under section 1886(h)(7)(A)(i)(I) of the Act to the FTE resident caps of any of those hospitals in the affiliated group. Each hospital's "1996" FTE resident cap would not be reduced effective July 1, 2005, even if on a hospital-specific basis, a hospital had trained fewer residents in its cost report that includes July 1, 2003 than its adjusted "affiliated" cap. As stated above for hospitals affiliated as of July 1, 2003, where the number of residents trained by those affiliated hospitals equals or exceeds their aggregated "1996" FTE resident caps, no reductions under section 1886(h)(7)(A)(i) of the Act would be required. However, where the aggregate FTE resident counts are *below* the aggregate FTE resident caps, a reduction to a hospital's FTE resident cap would be necessary. In these cases, *for each hospital,* the fiscal intermediary will determine the following FTE information from the *cost report that includes July 1, 2003*:

1) The "1996" FTE resident cap (as adjusted by new programs, if applicable)-- For IME from worksheet E, Part A of the Medicare cost report, the sum of lines 3.04 and 3.05. For direct GME from worksheet E-3, Part IV of the Medicare cost report, the sum of lines 3.01 and 3.02.
2) The "affiliated" FTE resident cap—For IME, line 3.07. For direct GME, line 3.04.
3) The total number of allopathic and osteopathic FTE residents—For IME, line 3.08. For direct GME, line 3.05.
4) The difference between the aggregate "affiliated" FTE resident cap and the total FTE resident counts for all of the affiliated hospitals—For IME, Σ line 3.08 minus Σ (lines 3.04 + 3.05). For direct GME, Σ line 3.05 minus Σ (lines 3.01 + 3.02).

5) For IME, for those hospitals whose FTE resident count from line 3.08 is *greater* than the "affiliated" FTE resident cap on line 3.07, indicate "zero." For direct GME, for those hospitals whose FTE resident count from line 3.05 is *greater* than the "affiliated" FTE resident cap on line 3.04, indicate "zero." For IME, for those hospitals whose FTE resident count from line 3.08 is *less* than the "affiliated" FTE resident cap on line 3.07, determine the difference between the hospital's "affiliated" FTE resident cap and the hospital's FTE resident count—line 3.08 minus line 3.07. For direct GME, for those hospitals whose FTE resident count from line 3.05 is *less* than the "affiliated" FTE resident cap on line 3.04, determine the difference between the hospital's "affiliated" FTE resident cap and the hospital's FTE resident count—line 3.05 minus line 3.04.

6) For IME and direct GME separately, to determine the total amount by which the FTE resident counts are below the "affiliated" FTE resident caps, add the amounts determined under step 5 for each hospital that trained fewer residents than its "affiliated" FTE resident caps.

7) For IME and direct GME separately, determine a pro rata cap reduction for each hospital by dividing the hospital-specific amount in step 5 by the total amount for all of those hospitals in step 6, and multiply by the amount in step 4. (that is, (step5/step6) x step 4).

8) For IME and direct GME separately, determine the actual cap reduction for each hospital by multiplying the pro rata cap reduction from step 8 by 0.75.

9) For IME and direct GME separately, determine the reduced FTE resident cap for each hospital by subtracting the actual cap reduction from step 8 from the "1996" FTE resident cap from step 1. This is the hospital's FTE resident cap effective July 1, 2005.

The following is an example of how the reductions to the FTE resident caps will be determined where the FTE resident counts in the aggregate for hospitals that were affiliated as of July 1, 2003 are below the hospitals' FTE resident caps in the aggregate. (For ease of illustration, this example focuses on reductions to the IME caps only, but the methodology is the same for reductions to the direct GME caps):

Hospitals A, B, and C are affiliated for the academic year beginning July 1, 2003. Hospital C is also affiliated with Hospitals D and E for the academic year beginning July 1, 2003. Thus, the affiliated group for GME payment purposes, and for purposes of determining possible FTE cap reductions under 422 consists of Hospitals A, B, C, D, and E. Hospital A's and B's cost report that includes July 1, 2003 is their FYE June 30, 2004. Hospital C's and D's cost report that includes July 1, 2003 is their FYE December 31, 2003, and Hospital E's cost report that includes July 1, 2003 is its FYE September 30, 2003. Using steps 1 through 10 above, the reductions to the FTE resident caps of those hospitals in the affiliated group who trained residents below their "affiliated" FTE resident caps are determined in the table below.

Hospital	1996 FTE Caps (step 1)	"Affiliated" FTE Cap (step 2)	FTE Count (step 3)	Difference between FTE Count and "affiliated" Cap (step 5)	Pro rata reduction (step 7)	Actual Cap Reduction (step 8)	Final FTE Cap (step 9)
A	95	115	125	0	0	0	95
B	80	100	125	0	0	0	80
C	120	10	10	0	0	0	120
D	115	90	75	-15	-8	-6	109
E	30	125	65	-60	-32	-24	6
Totals	**440**	**440**	**400**	**-75**	**-40**	**-30**	**410**
		step 4	**-40**	**step 6**			

Hospitals A, B, and C trained residents either equal to or in excess of their "affiliated" FTE resident caps (as determined under step 5), and therefore, no reduction is made to their "1996" FTE resident cap (step 9). However, Hospital D's FTE resident count of 75 was 15 *less* than its "affiliated" FTE resident cap of 90, and Hospital E's FTE resident count of 65 was 60 *less* than its "affiliated" FTE resident cap of 125 (as determined under step 5). Under this methodology, the fact that Hospitals A and B *exceeded* their respective "affiliated" FTE resident caps *minimizes* the reductions to Hospital D's and E's "1996" FTE resident caps through the calculation of a pro rata reduction under step 7. (Hospital C's "affiliated" FTE resident cap equaled its FTE resident count). Thus, under step 8, the actual cap reduction of 6 FTEs for Hospital D is determined by taking 75 percent of 8 (rather than 75 percent of 15), and the actual cap reduction of 24 FTEs for Hospital E is determined by taking 75 percent of 32 (rather than 75 percent of 60). As a result, under step 9, Hospital D's final FTE resident cap effective on July 1, 2005 is determined to be 109 FTEs, and Hospital E's final FTE resident cap effective on July 1, 2005 is determined to be 6 FTEs. We note that the total final FTE

resident cap effective July 1, 2005 is 410 FTEs (the total under step 9), which, mathematically, is the same as subtracting 400 (the total FTEs trained in the group) from 440 (the aggregate "1996" FTE resident caps), multiplying by 75 percent, and subtracting the result from the original aggregate cap of 440 (that is, [440 – (0.75(440-400))] = 410).

We also note that the reductions to Hospital D's and E's "1996" FTE resident caps were minimized only because Hospitals A and B exceeded their "affiliated" FTE resident caps. If *all* hospitals in the affiliated group had trained residents *below* their "affiliated" FTE resident caps based on their cost reports that include July 1, 2003, then a pro rata reduction would not benefit these hospitals. The "1996" FTE resident caps of all of the hospitals in the affiliated group would be reduced by 75 percent of the difference between each hospital's "affiliated" FTE resident cap and FTE resident count.

We believe this final policy concerning hospitals that are affiliated "as of July 1, 2003" addresses the commenters' concerns in that it protects hospitals from any loss of slots if the aggregate counts equal to or exceed the "affiliated" FTE resident caps, and could limit the loss of slots in instances where the aggregate counts are below the "affiliated" FTE resident caps. We have also addressed the commenters' concerns in that, in instances where the aggregate count is below the "affiliated" FTE resident caps, it accounts for the final, modified affiliation agreements, since it uses the affiliated cap as reported on the cost report, and it also allows for a comparison of contemporaneous caps and counts. However, the commenters also requested that we provide an opportunity for hospitals that were affiliated "as of July 1, 2003" to modify their affiliation agreements after publication of the final rule, if the final policy is significantly different from the

proposed policy. We do not believe it is appropriate to allow hospitals to modify their affiliation agreements after publication of the final rule. The only reason we allow hospitals to modify their agreements by June 30 of an academic year is to make the FTE counts of each hospital in the affiliation reflect the realities of the cross-training that occurred within that academic year. Thus, the decision as to whether or not an affiliation agreement should be modified should be based solely on whether the FTE counts first projected in the affiliation agreement on July 1 of a year differ from the actual FTEs that trained at each hospital during the year. We do not believe it is appropriate to allow a modification of the affiliation agreement by a hospital in order to minimize the applicable reductions under section 1886(h)(7)(A)(i) of the Act.

Comment: One commenter described a situation where a hospital that is located in an other than large urban area is part of an affiliated group as of July 1, 2003 with a rural hospital that has less than 250 beds. The commenter stated that while the rural hospital is exempt from reductions to its FTE resident caps, the urban hospital could be "penalized" because of the slots acquired under the affiliation agreement with the rural hospital, if the urban hospital did not fill all of those slots in its reference cost reporting period. The commenter believed that Congress did not intend to discourage urban hospitals from affiliating with rural hospitals, and asked that CMS carve out any FTEs associated with the rural hospital from the urban hospital's FTE resident cap for purposes of determining the number of unused residency slots at the urban hospital.

Response: With the exception of rural hospitals with less than 250 beds as specified at section 1886(h)(7)(A)(i)(II) of the Act, we cannot exempt other hospitals outright from possible reductions to their FTE resident caps. However, as we stated in response to the previous comment concerning hospitals that were part of an affiliated group as of July 1, 2003, if the hospitals' aggregate FTE resident counts equal or exceed the aggregate "affiliated" FTE resident caps, then no reductions would be made to any of the hospitals' specific "1996" FTE resident caps, even if on an individual basis, a hospital in the group was training fewer residents than its "affiliated" FTE resident cap. But if the aggregate FTE resident counts are below the aggregate "affiliated" FTE resident caps, then (except for rural hospitals with less than 250 beds), a hospital in the affiliated group that trained less FTE residents than its individual "affiliated" FTE resident cap would have its "1996" FTE resident cap reduced. Accordingly, the urban hospital described by the commenter would be subject to possible FTE resident cap reductions only if, for the hospital(s) with which it was affiliated as of July 1, 2003, the aggregate FTE resident counts were below the aggregate "affiliated" FTE resident caps and the urban hospital was also training fewer residents than its "affiliated" cap. However, since the rural hospital's FTE resident caps are protected from reductions under section 1886(h)(7)(A)(i)(II) of the Act, the urban hospital could continue to affiliate with the rural hospital on and after July 1, 2005, and, to the extent that the rural hospital has FTE slots available to "lend" to the urban hospital, the urban hospital could receive a temporary increase to its FTE resident caps via the affiliation agreement with the rural hospital. Therefore, although this urban hospital may lose slots under section

1886(h)(7)(A)(i) of the Act, it may be able to receive additional slots temporarily by affiliating with the rural hospital. In addition, the urban hospital may apply for a permanent increase to its FTE resident cap of up to 25 additional FTEs under section 1886(h)(7)(B) of the Act.

Comment: One commenter noted that under the proposed regulations at FR 69 28297 May 18, 2004 a hospital's reference resident level would be compared to the hospital's reference FTE resident cap as adjusted by Medicare GME affiliation agreements if the affiliation agreement is in effect as of July 1, 2003 or for program years that coincide with or overlap the reference cost reporting period. The commenter asked for clarification regarding a hospital that otherwise has an FTE resident cap of zero, but during its reference period, the hospital received a temporary increase to its FTE resident cap by participating in a Medicare GME affiliated group. The commenter stated that in its reference period, its resident level was below its FTE cap as adjusted by the affiliation agreement and asked if, as a result, CMS would reduce its FTE resident cap below zero.

Response: As we stated in the proposed rule FR 69 28299 May 18, 2004, hospitals that are participating in a Medicare GME affiliation agreement as of July 1, 2003 or for program years that coincide with or overlap the reference cost reporting period are not subject to the proposed policy applicable to section 1886(h)(7)(iii) of the Act, as added by section 422(a)(3). For such hospitals, we will compare the resident level in the applicable reference period to the FTE resident cap as adjusted by the affiliation agreement applicable to that reference period. If a hospital's resident level is below its otherwise applicable FTE resident cap for that reference period

cost report, we are proposing to permanently reduce the hospital's FTE resident cap, that is, the hospital's FTE resident cap without the temporary adjustment under the affiliation agreement for that period, by 75 percent of the difference between the hospital's resident level and the otherwise applicable FTE resident cap. However, a resident FTE cap would not be reduced below zero. That is, if the hospital's cap without adjustment under the affiliation agreement is zero, the hospital would not receive a reduction in their FTE resident cap if their reference resident count is below the reference affiliated resident FTE cap.

g. Criteria for Determining Hospitals That Will Receive Increases in Their FTE Resident Caps

Generally, under section 1886(h)(7) of the Act, as added by section 422(a)(3) of Pub. L. 108-173, CMS is to reduce by 75 percent the "unused" resident slots from hospitals that were below their FTE resident caps in a specific reference period, and "redistribute" the FTE slots for use by other hospitals. Under section 1886(h)(7)(B) of the Act, as added by section 422 of Pub. L. 108-173, the Secretary is authorized to increase the otherwise applicable FTE resident cap for each qualifying hospital that submits a timely application by a number that the Secretary may approve, for portions of cost reporting periods occurring on or after July 1, 2005. In implementing section 1886(h)(7)(B) of the Act, we note the difficulty in deciding which teaching hospitals are more "deserving" than others to receive the redistributed unused resident slots. Therefore, in the May 18, 2004 proposed rule (69 FR 28299), we proposed a decision making process that we believe was an objective process. In addition, we noted that

section 422 does not provide detailed guidance to the Secretary for deciding which hospitals should receive the unused resident slots, but rather gives the Secretary discretion in making the choice of which hospitals should qualify.

Section 1886(h)(7)(B) of the Act, as added by section 422, does establish certain parameters in the statutory language for hospitals to qualify to receive increases in their FTE resident caps. First, section 1886(h)(7)(B)(i) of the Act states that the aggregate number of increases in the otherwise applicable resident limits (caps) may not exceed the estimate of the aggregate reduction in the resident limits determined under section 1886(h)(7)(A) of the Act (as specified in section IV.O.2.e. of this preamble). Section 1886(h)(7)(B)(iv) of the Act states that in no case will any hospital receive an FTE cap increase of more than 25 FTE additional residency slots as a result of the redistribution. (Proposed redesignated §413.79(c)(4)). In addition, section 1886(h)(7)(B)(ii) of the Act specifies that in determining which hospitals will receive the increases in their FTE resident caps, the Secretary is required to take into account the demonstrated likelihood that the hospital would be able to fill the position(s) within the first three cost reporting periods beginning on or after July l, 2005.

In setting up an application process for hospitals to apply for the unused resident slots discussed in section IV.O.2.h. of this preamble, we had proposed to implement this "demonstrated likelihood" requirement as an eligibility criterion that a hospital must meet in order for CMS to further consider the hospital's application for an increase in its FTE resident cap. Thus, we had proposed that, in order to be eligible for consideration for an increase under section 1886(h)(7)(B) of the Act, a hospital must first demonstrate the

likelihood that it will able to fill the slots within the first three cost reporting periods beginning on or after July 1, 2005, by meeting at least one of the following four criteria and by providing documentation that it meets that criterion in its application for an increase in its FTE resident cap:

Demonstrated Likelihood Criterion 1. The applying hospital intends to use the additional FTEs to establish a new residency program(s) on or after July 1, 2005 (that is, a newly approved program that begins training residents on or after July 1, 2005).

The hospital must meet the requirements in provisions (1) and (2) below:

(1) In order to demonstrate that the hospital is, in fact, establishing a new residency program, the hospital must--

- Submit an application for approval of a new residency program to the ACGME or the AOA by December 1, 2004, and include a copy of that application with the application to CMS for an increase in its FTE resident cap; or
- Submit an application for approval of a new residency program to the ACGME or the AOA by December 1, 2004, and, if establishing an allopathic program, include a copy of the hospital's institutional review document or program information form concerning the new program with the application for the unused FTE resident slots; or
- Submit an application for approval of a new residency program to the ACGME or the AOA by December 1, 2004, and include written correspondence from the ACGME or AOA acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

(2) To demonstrate that the hospital will be likely to fill the slots requested, the hospital must comply with one of the following:

● If the hospital has other previously established programs, submit documentation that each of the hospital's existing residency programs had a resident fill rate of at least 95 percent in each of program years 2001 through 2003; or

● If the hospital has other previously established residency programs, submit copies of the cover page of the hospital's employment contracts with the residents who are or will be participating in the new residency program (resident specific information may be redacted); or

● If the hospital is establishing a new residency program in a particular specialty, submit documentation indicating that the specialty has a resident fill rate nationally, across all hospitals, of at least 95 percent.

Demonstrated Likelihood Criterion 2. The applying hospital intends to use the additional FTEs to expand an existing residency training program (that is, to increase the number of FTE resident slots in the program) on or after July 1, 2005, and before July 1, 2008.

The hospital must comply with the requirements in provisions (1) and (2) below:

(1) To demonstrate that the hospital intends to expand an existing program, the hospital must comply with one of the following:

● Document that the appropriate accrediting body (the ACGME or the AOA) has approved the hospital's expansion of the number of FTE residents in the program; or

● Document that the National Residency Match Program or the American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program; or

● If expanding an allopathic program, submit a copy of the hospital's institutional review document or program information form for the expansion of the existing residency training program.

(2) To demonstrate that the hospital will be likely to fill the slots of the expanded residency program, the hospital must comply with one of the following:

● Submit copies of the cover page of the hospital's employment contracts with the residents who are or will be participating in the expanded program (resident specific information may be redacted) and copies of the cover page of the hospital's employment contracts with the residents participating in the program prior to the expansion of the program.

● If the hospital has other previously established residency programs, submit documentation that each of the residency programs had a resident fill rate of at least 95 percent in each of program years 2001 through 2003.

● If the hospital is expanding an existing program in a particular specialty, submit documentation that the specialty has a resident fill rate nationally, across all hospitals, of at least 95 percent.

● If the hospital is expanding a program in order to train residents that need a program because another hospital in the State has closed a similar program, and the

applying hospital received a temporary adjustment to its FTE cap(s) (under the requirements of §413.86(g)(9)), submit documentation of this action.

Demonstrated Likelihood Criterion 3. The hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both.

The hospital must submit, with its application, each of the following:

- Copies of the most recent as-submitted Medicare cost reports documenting on Worksheet E, Part A and Worksheet E3, Part IV the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

- Copies of the 2004 residency match information concerning the number of residents the hospital intends to have in its existing programs.

- Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME.

Demonstrated Likelihood Criterion 4. The hospital is applying for the unused FTE resident slots because the hospital is at risk of losing accreditation of a residency training program if the hospital does not increase the number of FTE residents in the program on or after July l, 2005.

The hospital must submit, with its application for an increase in its FTE resident cap, documentation from the appropriate accrediting body of the hospital's risk of lost accreditation as a result of an insufficient number of residents in the program.

In the May 18, 2004 proposed rule, we proposed that each hospital must meet at least one of the above criteria in order to demonstrate the likelihood that it will be able to fill the additional slots associated with any increase in the hospital's FTE resident cap within the first three cost reporting periods beginning on or after July 1, 2005. In other words, each hospital that wishes to apply for an increase in its FTE resident cap must, as a preliminary matter, meet the eligibility requirement of demonstrating the likelihood that it will fill the additional positions, in order for CMS to further consider the hospital's application for an increase in its FTE resident cap.