

equipment over time. Because depreciation and interest expenses are determined by the amount of past and current capital purchases, we used the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions over time, based on such factors as interest rates and debt financing. Capital is depreciated over time instead of being consumed in the same period it is purchased. The CIPI accurately reflects the annual price changes associated with capital costs, and is a useful simplification of the actual capital accumulation process. By accounting for the vintage nature of capital, we are able to provide an accurate, stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes. These unstable annual price changes do not reflect the actual annual price changes for Medicare capital-related costs. CMS's CIPI reflects the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we used a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides the best time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. While the AHA Panel Survey provided a consistent database back to 1963, it did not provide annual capital purchases. The AHA Panel Survey did provide time series of depreciation and interest expenses that could be used to infer capital purchases over time. Although the AHA Panel Survey was discontinued after September 1997, we were able to use all of the available historical data from this survey since our proposed base year is FY 1997.

In order to estimate capital purchases from AHA data on depreciation and interest expenses, the expected life for each cost category (building and fixed equipment, movable equipment, debt instruments) is needed. The expected life is used in the calculation of vintage weights. We used FY 1997 Medicare cost reports to determine the expected life of building and fixed equipment and movable equipment. The expected life of any piece of equipment can be

determined by dividing the value of the fixed asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. From the FY 1997 cost reports, we determined the expected life of building and fixed equipment to be 23 years, and the expected life of movable equipment to be 11 years. By comparison, the FY 1992-based index showed that the expected life for building and fixed equipment was 22 years, while that for movable equipment was 10 years. Our analysis of data for FYs 1996, 1998, and 1999 indicates very little change in these measures over time.

We used the fixed and movable weights derived from the FY 1997 Medicare cost reports to separate the AHA Panel Survey depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation. By multiplying the annual depreciation amounts by the expected life calculations from the FY 1997 Medicare cost reports, we determined year-end asset costs for building and fixed equipment and movable equipment. We subtracted the previous year asset costs from the current year asset costs and estimated annual purchases of building and fixed equipment and movable equipment back to 1963. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment, movable equipment, and debt instruments. Each of these sets of vintage weights is explained in detail below.

For building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment derived from the AHA Panel Survey. The real annual purchase amount was used to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, the Boeckh institutional construction index. Because building and fixed equipment has an expected life of 23 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 23-year periods.

Vintage weights for each 23-year period are calculated by dividing the

real building and fixed capital purchase amount in any given year by the total amount of purchases in the 23-year period. This calculation is done for each year in the 23-year period, and for each of the twelve 23-year periods from 1963 to 1997. The average of the twelve 23-year periods is used to determine the 1997 average building and fixed equipment vintage weights.

For movable equipment vintage weights, we used the real annual capital purchase amounts for movable equipment derived from the AHA Panel Survey. The real annual purchase amount was used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amount by the movable equipment price proxy, the PPI for machinery and equipment. Because movable equipment has an expected life of 11 years, the vintage weights for movable equipment are deemed to represent the average purchase pattern of movable equipment over 11-year periods.

Vintage weights for each 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-year period. This calculation is done for each year in the 11-year period, and for each of the twenty-four 11-year periods from 1963 to 1997. The average of the twenty-four 11-year periods is used to determine the FY 1997 average movable equipment vintage weights.

For interest vintage weights, we used the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) derived from the AHA Panel Survey. Nominal annual purchase amounts were used to capture the value of the debt instrument. Because debt instruments have an expected life of 23 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 23-year periods.

Vintage weights for each 23-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 23-year period. This calculation is done for each year in the 23-year period and for each of the twelve 23-year periods from 1963 to 1997. The average of the twelve 23-year periods is used to determine the FY 1997 average interest vintage weights. The vintage weights for the FY 1992 CIPI and the proposed FY 1997 CIPI are presented in Table 14.

TABLE 14.—CURRENT AND PROPOSED VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

| Year (from farthest to most recent) | Building and fixed equipment | | Movable equipment | | Interest | |
|-------------------------------------|------------------------------|---------------------------|-------------------|---------------------------|------------------|---------------------------|
| | FY 1992 22 years | Proposed FY 1997 23 years | FY 1992 10 years | Proposed FY 1997 11 years | FY 1992 22 years | Proposed FY 1992 23 years |
| 1 | 0.019 | 0.018 | 0.069 | 0.063 | 0.007 | 0.007 |
| 2 | 0.020 | 0.021 | 0.075 | 0.068 | 0.008 | 0.009 |
| 3 | 0.023 | 0.023 | 0.083 | 0.074 | 0.010 | 0.011 |
| 4 | 0.026 | 0.025 | 0.091 | 0.080 | 0.012 | 0.012 |
| 5 | 0.028 | 0.026 | 0.097 | 0.085 | 0.014 | 0.014 |
| 6 | 0.030 | 0.028 | 0.103 | 0.091 | 0.016 | 0.016 |
| 7 | 0.031 | 0.030 | 0.109 | 0.096 | 0.018 | 0.019 |
| 8 | 0.032 | 0.032 | 0.115 | 0.101 | 0.021 | 0.022 |
| 9 | 0.036 | 0.035 | 0.124 | 0.108 | 0.024 | 0.026 |
| 10 | 0.039 | 0.039 | 0.133 | 0.114 | 0.029 | 0.030 |
| 11 | 0.043 | 0.042 | | 0.119 | 0.035 | 0.035 |
| 12 | 0.047 | 0.044 | | | 0.041 | 0.039 |
| 13 | 0.050 | 0.047 | | | 0.047 | 0.045 |
| 14 | 0.052 | 0.049 | | | 0.052 | 0.049 |
| 15 | 0.055 | 0.051 | | | 0.059 | 0.053 |
| 16 | 0.059 | 0.053 | | | 0.067 | 0.059 |
| 17 | 0.062 | 0.057 | | | 0.074 | 0.065 |
| 18 | 0.065 | 0.060 | | | 0.081 | 0.072 |
| 19 | 0.067 | 0.062 | | | 0.088 | 0.077 |
| 20 | 0.069 | 0.063 | | | 0.093 | 0.081 |
| 21 | 0.072 | 0.065 | | | 0.099 | 0.085 |
| 22 | 0.073 | 0.064 | | | 0.103 | 0.087 |
| 23 | | 0.065 | | | | 0.090 |
| Total | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 | 1.000 |

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate of increase for each expenditure category. Our proposed price proxies for the FY 1997-based CIPI are the same as those for the FY 1992-based CIPI. We still believe these are the most appropriate proxies for hospital capital costs that meet our selection

criteria of relevance, timeliness, availability, and reliability. We ran the proposed FY 1997-based index using the Moody's Aaa bonds average yield and using the Moody's Baa bonds average yield as proxy for the for-profit interest cost category. There was no difference in the two sets of index percent changes either historically or forecasted. The rationale for selecting

the price proxies is explained more fully in the August 30, 1996 final rule (61 FR 46196). The proposed proxies are presented in Table 13.

Global Insights, Inc., DRI-WEFA forecasts a 0.7 percent increase in the proposed rebased FY 1997 CIPI for FY 2003, as shown in Table 15.

TABLE 15.—FY 1992 AND PROPOSED FY 1997-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, 1995–2004

| Federal fiscal year | CIPI, FY 1992-based | Proposed CIPI, FY 1997-based |
|------------------------|---------------------|------------------------------|
| 1995 | 1.2 | 1.5 |
| 1996 | 1.0 | 1.3 |
| 1997 | 0.9 | 1.2 |
| 1998 | 0.7 | 0.9 |
| 1999 | 0.7 | 0.9 |
| 2000 | 0.9 | 1.1 |
| 2001 | 0.7 | 0.9 |
| Average: FYs 1995–2001 | 0.9 | 1.1 |
| Forecast: | | |
| 2002 | 0.6 | 0.8 |
| 2003 | 0.5 | 0.7 |
| 2004 | 0.6 | 0.7 |
| Average: FYs 2002–2004 | 0.6 | 0.7 |

Source: Global Insights, Inc, DRI-WEFA, 1st Qtr. 2002; @USMACRO/MODTREND @CISSIM/TRENDLONG0202.

This 0.7 percent increase is the result of a 1.3 percent increase in projected vintage-weighted depreciation prices (building and fixed equipment, and movable equipment) and a 2.7 percent increase in other capital expense prices, partially offset by a 2.2 percent decrease in vintage-weighted interest rates in FY 2003, as indicated in Table 16.

TABLE 16.—CMS PROPOSED CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND COMPONENTS, FISCAL YEARS 1985–2005

| Fiscal year | Total | Total depreciation | Depreciation, building and fixed equipment | Depreciation, movable equipment | Interest | Other |
|---------------------------------------|-------|--------------------|--|---------------------------------|----------|--------|
| Wgts FY 1997 | 1.000 | 0.7135 | 0.3422 | 0.3713 | 0.2346 | 0.0519 |
| Vintage-Weighted Price Changes | | | | | | |
| 1995 | 1.5 | 2.7 | 4.0 | 1.6 | -1.8 | 2.5 |
| 1996 | 1.3 | 2.5 | 3.8 | 1.4 | -2.3 | 2.6 |
| 1997 | 1.2 | 2.3 | 3.6 | 1.2 | -2.4 | 2.8 |
| 1998 | 0.9 | 2.1 | 3.3 | 0.9 | -3.0 | 3.2 |
| 1999 | 0.9 | 1.9 | 3.2 | 0.7 | -2.8 | 3.2 |
| 2000 | 1.1 | 1.7 | 3.1 | 0.4 | -1.6 | 3.4 |
| 2001 | 0.9 | 1.5 | 2.9 | 0.1 | -2.2 | 4.3 |
| Forecast: | | | | | | |
| 2002 | 0.8 | 1.4 | 2.8 | 0.0 | -2.2 | 4.0 |
| 2003 | 0.7 | 1.3 | 2.7 | -0.1 | -2.2 | 2.7 |
| 2004 | 0.7 | 1.3 | 2.5 | -0.1 | -2.1 | 2.8 |
| 2005 | 0.7 | 1.3 | 2.5 | -0.1 | -2.0 | 2.8 |

Rebasing the CIPI from FY 1992 to FY 1997 increased the percent change in the FY 2003 forecast by 0.2 percentage points, from 0.5 to 0.7 as shown in Table 15. The difference is caused mostly by changes in cost category weights, particularly the smaller weight for interest and larger weight for depreciation. Because the interest component has a negative price change associated with it for FY 2003, the smaller share it accounts for in the FY 1997-based index means it has less of an impact than in the FY 1992-based index. The changes in the expected life and vintage weights have only a minor impact on the overall percent change in the index.

V. Other Decisions and Proposed Changes to the Prospective Payment System for Inpatient Operating Costs and Graduate Medical Education Costs

A. Transfer Payment Policy

1. Expanding the Postacute Care Transfer Policy to Additional DRGs (§ 412.4)

Existing regulations at § 412.4(a) define discharges under the acute care hospital inpatient prospective payment system 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.

Under section 1886(d)(5)(J) of the Act, which was added by section 4407 of Public Law 105–33, 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 requires 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 skilled nursing facility (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 final rule (63 FR 40975 through 40976), we specified the appropriate time period during which we would consider postacute home health services to constitute a transfer situation as within 3 days after the date of discharge. Also, in the July 31, 1998 final rule, we did not include in the definition of postacute transfer cases

patients transferred to a swing-bed for skilled nursing care (63 FR 40977).

The Conference Agreement that accompanied Public Law 105–33 noted that “(t)he Conferees are concerned that Medicare may in some cases be overpaying hospitals for patients who are transferred to a postacute care setting after a very short acute care hospital stay. The conferees believe that Medicare’s payment system should continue to provide hospitals with strong incentives to treat patients in the most effective and efficient manner, while at the same time, adjust PPS [prospective payment system] payments in a manner that accounts for reduced hospital lengths of stay because of a discharge to another setting.” (H.R. Report No. 105–217, 105th Cong., 1st Sess., 740 (1997).)

In the July 31, 1998 final rule (63 FR 40975), we implemented section 1886(d)(5)(J) of the Act, which 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 the following DRGs

to be subject to the special 10 DRG transfer rule:

- DRG 14 (Specific Cerebrovascular Disorders Except Transient Ischemic Attack);
- DRG 113 (Amputation for Circulatory System Disorders Except Upper Limb and Toe);
- DRG 209 (Major Joint Limb Reattachment Procedures of Lower Extremity);
- DRG 210 (Hip and Femur Procedures Except Major Joint Procedures Age >17 with CC);
- DRG 211 (Hip and Femur Procedures Except Major Joint Procedures Age >17 without CC);
- DRG 236 (Fractures of Hip and Pelvis);
- DRG 263 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis with CC);
- DRG 264 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis without CC);
- DRG 429 (Organic Disturbances and Mental Retardation); and
- DRG 483 (Tracheostomy Except for Face, Mouth and Neck Diagnoses).

Similar to our existing policy for transfers between two acute care hospitals, the transferring hospital in a postacute transfer for 7 of the 10 DRGs receives twice the per diem rate the first day and the per diem rate for each following day of the stay prior to the transfer, up to the full DRG payment. However, 3 of the 10 DRGs exhibit a disproportionate share of costs very early in the hospital stay in postacute transfer situations. For these 3 DRGs, hospitals receive 50 percent of the full DRG payment 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. This is consistent with section 1886(d)(5)(J)(i) of the Act, which recognizes that in some cases “a substantial portion of the costs of care are incurred in the early days of the inpatient stay.”

The statute provides that, after FY 2000, the Secretary is authorized to expand this policy to additional DRGs. In July 1999, the previous Administration committed to not expanding the number of DRGs included in the policy until FY 2003. Therefore, CMS did not propose any change to the postacute care settings or the 10 DRGs in FY 2001 or FY 2002.

Under contract with CMS (Contract No. 500-95-0006), Health Economics Research, Inc. (HER) conducted an analysis of the impact on hospitals and hospital payments of the postacute care transfer provision. We included in the August 1, 2000 final rule (65 FR 47079) a summary of that analysis. Among

other issues, the analysis sought to evaluate the reasonableness of expanding the transfer payment policy beyond the current 10 selected DRGs.

The analysis supported the initial 10 DRGs selected as being consistent with the nature of the Congressional mandate. According to HER, “[t]he top 10 DRGs chosen initially by HCFA exhibit very large PAC [postacute care] levels and PAC discharge rates (except for DRG 264, Skin Graft and/or Debridement for Skin Ulcer or Cellulitis without CC, which was paired with DRG 263). All 10 appear to be excellent choices based on the other criteria as well. Most have fairly high short-stay PAC rates (except possibly for Strokes, DRG 14, and Mental Retardation, DRG 429).”

The HER report discussed the issues related to potentially expanding the postacute care transfer policy to all DRGs. In favor of this expansion, HER pointed to the following benefits:

- A simple, uniform, formula-driven policy;
- The same policy rationale exists for all DRGs;
- DRGs with little utilization of short-stay postacute care would not be harmed by the policy;
- Less confusion in discharge destination coding; and
- Hospitals that happen to be disproportionately treating the current 10 DRGs may be harmed more than hospitals with an aggressive, short-stay, postacute care transfer policy for other DRGs.

The complete HER report may be obtained at: <http://www.cms.gov/medicare/ippsmain.htm>.

Consistent with HER’s findings, we believe expanding the postacute care transfer policy to all DRGs may be the most equitable approach at this time, since a policy that is limited to certain DRGs may result in disparate payment treatment across hospitals, depending on the types of cases treated. We are considering implementing this expansion of the postacute transfer policy in the final rule. For example, a hospital specializing in some of the types of cases included in the current 10 DRG transfer policy would receive reduced payments for those cases transferred for postacute care after a brief acute inpatient stay, while a hospital specializing in cases not included in the current 10 DRGs may be just as aggressive in transferring its patients for postacute care, but it would receive full payment for those cases.

Another aspect of the issue is that some hospitals have fewer postacute care options available for their patients. In its June 2001 Report to Congress:

Medicare in Rural America, MedPAC wrote: “[a] shortage of ambulatory and post-acute care resources may prevent rural hospitals from discharging patients as early in the episode of care as urban hospitals would” (page 68). MedPAC went on to note that the decline in length of stay for urban hospitals since 1989 was greater for urban hospitals than for rural hospitals (34 percent compared with 25 percent through 1999), presumably due to earlier discharges to postacute care settings. Although MedPAC contemplated returning money saved by expanding the policy to the base payment rate, thereby increasing payments for nontransfer cases, currently section 1886(d)(5)(I)(ii) of the Act provides that any expansion to the postacute transfer policy would not be budget neutral. (Budget neutrality refers to adjusting the base payment rates to ensure total aggregate payments are the same after implementing a policy change as they were prior to the change.) Nevertheless, over the long run, reducing the Medicare Trust Fund expenditures for patients who are transferred to a postacute care setting after a very short acute care hospital stay will improve the program’s overall financial stability. Our analysis indicates that expanding the postacute care transfer policy to all DRGs would reduce program payments for these cases by approximately \$1.9 billion for FY 2002.

If we were to expand the transfer policy to all DRGs, we would expand the list of those DRGs where a disproportionate share of the costs of the entire stay occurs early in the stay. We conducted analysis to identify those DRGs that would be eligible for the special transfer payment methodology specified in § 412.4(f)(2). As stated above, currently, three DRGs (DRGs 209, 210, and 211) are paid under a special transfer payment calculation whereby they receive 50 percent of the full DRG payment amount on the first day of the stay for cases transferred to a postacute care provider.

We identified cases that were transferred to home health care, SNFs, or long-term care, matching records by beneficiary identification numbers and discharge and admission dates. We standardized charges to account for differences in area wage levels, indirect medical education costs, and disproportionate share payments, and we reduced charges to costs using the available cost-to-charge ratios.

We then grouped the costs by DRG and length of stay. The average costs for transfer cases with a length of stay of 1 day were compared to the costs of transfer cases whose length of stay

approximated the geometric mean length of stay for that particular DRG. The average costs for the transfer cases with a length of stay of 1 day were also compared to costs for all cases with a length of stay approximating the geometric mean length of stay across the DRG. Based on this analysis, we identified the following DRGs that, if the postacute care transfer policy were to be expanded, would qualify for the special postacute care transfer payment policy of 50 percent of the full DRG payment for the first day of the stay:

- DRG 7 (Peripheral and Cranial Nerve and Other Nervous System Procedures with CC);
- DRG 159 (Hernia Procedures Except Inguinal and Femoral Age >17 with CC);
- DRG 218 (Lower Extremity and Humerus Procedure Except Hip, Foot, Femur Age >17 with CC);
- DRG 226 (Soft Tissue Procedures with CC);
- DRG 263 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis with CC);
- DRG 264 (Skin Graft and/or Debridement for Skin Ulcer or Cellulitis without CC);
- DRG 306 (Prostatectomy with CC);
- DRG 308 (Minor Bladder Procedures with CC);
- DRG 315 (Other Kidney and Urinary Tract O.R. Procedures);
- DRG 493 (Laparoscopic Cholecystectomy without C.D.E. with CC); and
- DRG 497 (Spinal Fusion Except Cervical with CC).

This list contains DRGs not currently paid under the special formula (DRGs 209, 210, and 211 will continue to receive the special payment). All of the DRGs in the list meet the following criteria: The average costs of transfer cases on the first day equals the average costs of cases staying the geometric mean length of stay; the geometric mean length of stay is 4 days or greater; and there were at least 50 transfer cases occurring on the first day of the stay.

We also note that DRGs 263 and 264 (which are included in the current list of 10 DRGs subject to the postacute care transfer policy) would qualify for special payment, even though both DRGs have not previously received payment under the special payment provision. However, DRG 264 does qualify under the criteria described above for identifying cases for the potential expanded postacute care transfer policy. Because DRGs 263 and 264 are paired DRGs (that is, the only difference in the cases assigned to DRG 263 as opposed to DRG 264 is that the patient has a complicating or comorbid

condition), we would include both DRGs under this expanded policy. If we were to include only DRG 264, there would be an incentive not to include a code identifying a complicating or comorbid condition, so that a transfer case would be assigned to DRG 264 instead of DRG 263 due to the higher per diem payment for DRG 264.

Rather than expand the postacute care transfer policy to all DRGs, another option that we are considering for the final rule is expanding the postacute care transfer policy only to additional DRGs that have high rates of transfers, similar to the initial implementation of only 10 DRGs. For example, an incremental expansion would be to add another 10 DRGs to the policy. Using the same criteria to identify DRGs with high postacute care transfer rates, we identified additional DRGs to include in the postacute care transfer policy. We note that three of the DRGs we identified are paired DRGs (that is, they contain a CC/no-CC split). For the same reason given above for treating paired DRGs consistently, we would include the pairs for the 10 DRGs identified. We estimate the impact of this approach would be to reduce payments to hospitals by approximately \$916 million for FY 2002. Under this approach, discharges from the following 13 DRGs (in addition to the 10 DRGs already subject to the postacute care transfer policy) could be considered to be subject to an alternative postacute care transfer policy:

- DRG 12 (Degenerative Nervous System Disorders);
- DRG 79 (Respiratory Infections and Inflammations Age >17 with CC);
- DRG 80 (Respiratory Infections and Inflammations Age >17 without CC);
- DRG 107 (Coronary Bypass with Cardiac Catheterization);
- DRG 109 (Coronary Bypass with PTCA or Cardiac Catheterization);
- DRG 148 (Major Small and Large Bowel Procedures with CC);
- DRG 149 (Major Small and Large Bowel Procedures without CC);
- DRG 239 (Pathological Fractures and Musculoskeletal System and Connective Tissue Malignancy);
- DRG 243 (Medical Back Problems);
- DRG 320 (Kidney and Urinary Tract Diagnoses Age >17 with CC);
- DRG 321 (Kidney and Urinary Tract Diagnoses Age >17 without CC);
- DRG 415 (O.R. Procedure for Infections and Parasitic Diseases); and
- DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis).

Expanding the postacute care transfer policy in this limited manner, however, would retain many of the potential inequities of the current system. Although we are concerned about the potential for a large impact of implementing any expansion of the postacute care transfer payment policy, we believe that the current policy may create payment inequities across patients and across hospitals. By expanding the postacute transfer policy, we would expect to reduce or eliminate these possible inequities. Therefore, we are soliciting comments on the two options we have identified and discussed in this proposed rule. In the final rule, we could adopt one of the approaches discussed above, or some other approach based on comments received on this proposal for addressing this issue. If commenters submit comments on alternate approaches, we are asking them to also provide useful data relating to alternative DRGs to which the expansion should or should not apply and detailed supporting explanations.

If we adopt either of the proposals discussed above or a variation based on comments submitted, we would follow procedures similar to those that are currently followed for treating cases identified as transfers in the DRG recalibration process. That is, as described in the discussion of DRG recalibration in section II.C. of this proposed rule, additional transfer cases would be counted as a fraction of a case based on the ratio of a hospital's transfer payment under the per diem payment methodology to the full DRG payment for nontransfer cases.

2. Technical Correction

When we revised our regulations on payments for discharges and transfers under § 412.4 in the July 31, 1998 final rule (63 FR 41003), we inadvertently did not exclude discharges from one hospital area or unit to another inpatient area or unit of the hospital that is paid under the acute care hospital inpatient prospective payment system (§ 412.4(b)(2)) from the types of cases paid under the general rule for transfer cases. We are proposing to correct the regulation text to reflect our policy (as reflected in prior preamble language) that transfers from one area or unit within a hospital to another are not paid as transfers (except as described under the special 10 DRG rule at § 412.4(c)). We are proposing to correct this error by revising § 412.4(f)(1) to provide that only the circumstances described in paragraph (b)(1) and (c) of § 412.4 are paid as transfers under the general transfer rule. This proposed correction

would reflect the fact that transfers under § 412.4(b)(2) are to be paid as discharges and not transfers.

B. Sole Community Hospitals (SCHs)
(§§ 412.77 and 412.92)

1. Phase-In of FY 1996 Hospital-Specific Rates

Under the acute care hospital inpatient prospective payment system, special payment protections are provided to a sole community hospital (SCH). Section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that, by reason of factors such as isolated location, weather conditions, travel conditions, absence of other like hospitals (as determined by the Secretary), or historical designation by the Secretary as an essential access community hospital, is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations that set forth the criteria that a hospital must meet to be classified as an SCH are located in § 412.92.

To be classified as an SCH, a hospital either must have been designated as an SCH prior to the beginning of the hospital inpatient prospective payment system on October 1, 1983, or must be located more than 35 miles from other like hospitals, or the hospital must be located in a rural area and meet one of the following requirements:

- It is located between 25 and 35 miles from other like hospitals, and it—
- Serves at least 75 percent of all inpatients, or at least 75 percent of Medicare beneficiary inpatients, within a 35-mile radius or, if larger, within its service area; or
- Has fewer than 50 beds and would qualify on the basis of serving at least 75 percent of its area's inpatients except that some patients seek specialized care unavailable at the hospital.
- It is located between 15 and 35 miles from other like hospitals, and because of local topography or extreme weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- The travel time between the hospital and the nearest like hospital is at least 45 minutes because of distance, posted speed limits, and predictable weather conditions.

Effective with hospital cost reporting periods beginning on or after April 1, 1990, section 1886(d)(5)(D)(i) of the Act, as amended by section 6003(e) of Public Law 101-239, provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment to the hospital for the cost reporting period:

- The Federal rate applicable to the hospital;
- The updated hospital-specific rate based on FY 1982 costs per discharge; or
- The updated hospital-specific rate based on FY 1987 costs per discharge.

Section 405 of Public Law 106-113 added section 1886(b)(3)(I) to the Act, and section 213 of Public Law 106-554 made further amendments to that section of the Act extending to all SCHs the ability to rebase their hospital-specific rates using their FY 1996 operating costs, effective for cost reporting periods beginning on or after October 1, 2000. The provisions of section 1886(b)(3)(I) of the Act were addressed in the June 13, 2001 interim final rule with comment period (66 FR 32177) and were finalized in the August 1, 2001 final rule (66 FR 39872).

In the June 13, 2001 interim final rule, we correctly described the provisions of section 1886(b)(3)(I) of the Act, as amended, and their implementation. However, in the August 1, 2001 final rule, in summarizing the numerous legislative provisions that had affected payments to SCHs, we incorrectly described the application of the statutory provisions in the background section of the preamble on SCHs (66 FR 39872). (We wish to point out that the Addendum to the August 1, 2001 final rule accurately describes the calculation of the hospital-specific rate (66 FR 39944).) Specifically, the payment options that we described in the August 1, 2001 preamble language on SCHs were incorrect in that we did not include the Federal rate in the blends. Therefore, we are providing below a correct description of the provisions of section 1886(b)(3)(I) of the Act and clarifying their application in determining which of the payment options will yield the highest rate of payment for SCHs.

For purposes of payment to SCHs for which the FY 1996 hospital-specific rate yields the greatest aggregate payment, the Federal rate is included in the blend, as set forth below:

- For discharges during FY 2001, 75 percent of the greater of the Federal amount or the updated FY 1982 or FY 1987 hospital-specific rates (identified in the statute as the subsection (d)(5)(D)(i) amount), plus 25 percent of the updated FY 1996 hospital-specific rate (identified in the statute as the “rebased target amount”).
- For discharges during FY 2002, 50 percent of the greater of the Federal amount or the updated FY 1982 or FY 1987 hospital-specific rates, plus 50 percent of the updated FY 1996 hospital-specific rate.

- For discharges during FY 2003, 25 percent of the greater of the Federal amount or the updated FY 1982 or FY 1987 hospital-specific rates, plus 75 percent of the updated FY 1996 hospital-specific rate.

For discharges during FY 2004 and subsequent fiscal years, the hospital-specific rate would be determined based on 100 percent of the updated FY 1996 hospital-specific rate.

For each cost reporting period, the fiscal intermediary determines which of the payment options will yield the highest rate of payment. Payments are automatically made at the highest rate using the best data available at the time the fiscal intermediary makes the determination. However, it may not be possible for the fiscal intermediary to determine in advance precisely which of the rates will yield the highest payment by year's end. In many instances, it is not possible to forecast the outlier payments, the amount of the disproportionate share hospital (DSH) adjustment, or the indirect medical education (IME) adjustment, all of which are applicable only to payments based on the Federal rate. The fiscal intermediary makes a final adjustment at the close of the cost reporting period to determine precisely which of the payment rates would yield the highest payment to the hospital.

If a hospital disagrees with the fiscal intermediary's determination regarding the final amount of program payment to which it is entitled, it has the right to appeal the fiscal intermediary's decision in accordance with the procedures set forth in Subpart R of Part 405, which concern provider payment determinations and appeals.

The regulation text of § 412.77 and § 412.92(d) that was revised to incorporate the provisions of section 1886(b)(3)(I) of the Act, as amended, and published in the June 13, 2001 interim final rule with comment period (66 FR 32192 through 32193) and finalized in the August 1, 2001 final rule (66 FR 39932), is accurate.

2. SCH Like Hospitals

Section 1886(d)(5)(D)(iii) of the Act provides that, to qualify as a SCH, a hospital must be not more than 35 road miles from another hospital. There are several other conditions under which a hospital may qualify as a SCH, including if it is the “* * * sole source of inpatient hospital services reasonably available to individuals in a geographic area * * *” because of factors such as the “* * * absence of other like hospitals * * *” We have defined a “like hospital” in regulations as a hospital furnishing short-term, acute

care (§ 412.92(c)(2)). Like hospitals refers to hospitals paid under the acute care hospital inpatient prospective payment system.

We have become aware that, in some cases, new specialty hospitals that offer a very limited range of services have opened within the service area of a SCH and may be threatening the special status of the SCH. For example, a hospital that offers only a select type of surgery on an inpatient basis would qualify under our existing rules as an SCH "like hospital" if it met the hospital conditions of participation and was otherwise eligible for payment under the acute care hospital inpatient prospective payment system. Under our existing regulations, a SCH could lose its special status due to the opening of such a specialty hospital, even though there is little, if any, overlap in the types of services offered by the SCH and the specialty hospital.

We believe that limiting eligibility for SCH status to hospitals without SCH like hospitals in their service area is a way to identify those hospitals that truly are the sole source of short-term acute-care inpatient services in the community. A limited-service, specialty hospital, by definition, would not offer an alternate source of care in the community for most inpatient services and therefore, we believe, should not be considered a "like" hospital with the effect of negating SCH status of a hospital that is the sole source of short-term acute care inpatient services in the community. Therefore, we are proposing to amend the definition of SCH like hospitals under § 412.92(c)(2), effective with cost reporting periods beginning on or after October 1, 2002, to exclude any hospital that provides no more than a very small percent of the services furnished by the limited-service facility that overlap with the services provided by the SCH. We believe the percentage of overlapping services should be sufficiently small so that we can ensure that only hospitals that truly are the sole source of short-term acute-care in their community qualify for SCH status. Therefore, we are proposing that this percentage be set at 3 percent. However, we are soliciting public comments on alternate appropriate levels of service overlap, as well as on the overall proposed change to the definition of like hospitals.

C. Outlier Payments: Technical Change (§ 412.80)

Sections 1886(d)(5)(A) and (d)(5)(K) of the Act provide for payments, in addition to the basic prospective payments, for "outlier" cases; that is, cases involving extraordinarily high

costs. Cases qualify for outlier payments by demonstrating costs that exceed a fixed loss cost outlier threshold equal to the prospective payment rate for the DRG plus any IME (§ 412.105) and DSH (§ 412.106) payments for the case and, for discharges on or after October 1, 2001, additional payments for new technologies or services.

Implementing regulations for outlier payments are located in subpart F of part 412. Paragraph (a) of § 412.80 specifies the basic rules for making the additional outlier payments, broken down into three applicable effective periods. We have become aware that in paragraph (a)(2), which relates to outlier payments for discharges occurring on or after October 1, 1997, and before October 1, 2001, we did not include language to specify that the additional costs of outlier cases must exceed the standard DRG payment and any additional payment the hospital would receive for IME and for DSH, plus a fixed loss dollar threshold. Therefore, we are proposing to make a technical change by revising § 412.80(a)(2), applicable for discharges occurring during the period between October 1, 1997 and October 1, 2001, to include the appropriate language regarding additional payments for IME and payments for DSH. (We note that when we amended § 412.80 to incorporate the provisions on the additional payments for new technology under paragraph (a)(3) (66 FR 46924, September 7, 2001), effective October 1, 2001, we did include this language.)

D. 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 prospective payment system 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 amount rather than the rural standardized amount. Although the other urban and rural standardized amounts were the same for discharges beginning with that date, rural referral centers continue to receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 1886(d)(8)(E) of the Act, as amended, creates a mechanism, separate and apart from the MGCRB, permitting an urban hospital to apply to the Secretary to be treated as being located in the rural area of the State in which the hospital is located. The statute directs the Secretary to treat a qualifying hospital as being located in the rural

area for purposes of provisions under section 1886(d) of the Act. One of the criteria under section 1886(d)(8)(E) of the Act is that the hospital would qualify as an SCH or a rural referral center if it were located in a rural area. An SCH would be eligible to be paid on the basis of the higher of its hospital-specific rate or the Federal rate. On the other hand, a primary benefit under section 1886(d) of the Act for an urban hospital to become a rural referral center would be waiver of the proximity requirements that are otherwise applicable under the MGCRB process, as set forth in § 412.230(a)(3)(i).

Although hospitals that are reclassified as rural under section 1886(d)(8)(E) of the Act are not permitted to reclassify through the MGCRB, effective October 1, 2000, hospitals located in what is now an urban area if they were ever a rural referral center, were reinstated to rural referral center status. These hospitals may then take advantage of the waiver from the proximity requirements for reclassification.

In addition, as discussed in 62 FR 45999 and 63 FR 26317, under section 4202 of Public Law 105-33, a hospital that was classified as a rural referral center for FY 1991 is to be classified as a rural referral center for FY 1998 and later years so long as that hospital continued to be located in a rural area and did not voluntarily terminate its rural referral center status. Otherwise, a hospital seeking rural referral center status must satisfy 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. 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 (specifying 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). 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.)

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 mean case-mix index value includes all urban hospitals

nationwide, and the proposed regional values are the median values of urban hospitals within each census region, excluding those with approved teaching programs (that is, those hospitals receiving indirect medical education payments as provided in § 412.105). These values are based on discharges occurring during FY 2001 (October 1, 2000 through September 30, 2001) and include bills posted to CMS's records through December 2001.

We are proposing that, 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, 2002, must have a case-mix index value for FY 2001 that is at least—

- 1.3229; or
- The median case-mix index value 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 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) | 1.2089 |
| 2. Middle Atlantic (PA, NJ, NY) | 1.2235 |
| 3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 1.2985 |
| 4. East North Central (IL, IN, MI, OH, WI) | 1.2377 |
| 5. East South Central (AL, KY, MS, TN) | 1.2459 |
| 6. West North Central (IA, KS, MN, MO, NE, ND, SD) | 1.1616 |
| 7. West South Central (AR, LA, OK, TX) | 1.2641 |
| 8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY) | 1.3255 |
| 9. Pacific (AK, CA, HI, OR, WA) | 1.2779 |

The preceding numbers will be revised in the final rule to the extent required to reflect the updated FY 2001 MedPAR file, which will contain data from additional bills received through March 31, 2002.

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 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. We are proposing 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). That is the latest year for which we have complete discharge data available.

Therefore, we are proposing 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, 2002, 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; or
- The median number of discharges for urban hospitals in the census region in which the hospital is located, as indicated in the following table:

| Region | Number of discharges |
|--|----------------------|
| 1. New England (CT, ME, MA, NH, RI, VT) | 6,905 |
| 2. Middle Atlantic (PA, NJ, NY) | 8,648 |
| 3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) | 8,914 |
| 4. East North Central (IL, IN, MI, OH, WI) | 8,040 |
| 5. East South Central (AL, KY, MS, TN) | 6,748 |
| 6. West North Central (IA, KS, MN, MO, NE, ND, SD) | 5,696 |
| 7. West South Central (AR, LA, OK, TX) | 6,220 |
| 8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY) | 9,167 |
| 9. Pacific (AK, CA, HI, OR, WA) | 7,053 |

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. These

numbers will be revised in the final rule based on the latest FY 2001 cost report data.

We reiterate that an osteopathic hospital, if it is to qualify for rural referral center status for cost reporting

periods beginning on or after October 1, 2002, must have at least 3,000 discharges for its cost reporting period that began during FY 2001.

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

1. Background

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 for a Medicare discharge to reflect the higher indirect operating costs of teaching hospitals relative to nonteaching hospitals. The existing regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105. The additional payment is based on the 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 multiplier, which is represented as c , in the following equation: $c \times [(1 + r)^{.405} - 1]$. 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 1886(d)(5)(B)(ii)(VII) of the Act provides that, for discharges occurring during FY 2003 and thereafter, the "c" variable, or formula multiplier, is 1.35. The formula multiplier of 1.35 represents a 5.5-percent increase in IME payment for every 10-percent increase in the resident-to-bed ratio.

2. Temporary Adjustments to the FTE Cap To Reflect Residents Affected by Residency Program Closure: Resident-to-Bed Ratio for Displaced Residents (§§ 412.105(a) and (f)(1)(ix))

In the August 1, 2001 hospital inpatient prospective payment system final rule (66 FR 39899), we expanded the policy at existing § 413.86(g)(8) (proposed to be redesignated as § 413.86(g)(9) in this proposed rule), which allows a temporary adjustment to a hospital's FTE cap when a hospital trains additional residents because of another hospital's closure, to also allow a temporary adjustment when a hospital trains residents displaced by the closure of another hospital's residency program (but the hospital itself remains open). We revised regulations at existing § 413.86(g)(8) to state that, if a hospital that closes its residency training program agrees to temporarily reduce its FTE cap, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the former hospital's residency training program. We defined "closure of a hospital residency training program" as when the hospital ceases to offer training for

residents in a particular approved medical residency training program. The methodology for adjusting the caps for the "receiving" hospital and the "hospital that closed its program" as they apply to the IME adjustment and direct GME payments is set forth in the regulations at existing §§ 412.105(f)(1)(ix) and 413.86(g)(8)(iii), respectively.

In the August 1, 2001 rule, we noted a commenter who requested that CMS further revise the regulations to grant temporary relief to hospitals in calculating the IME adjustment with regard to application of the resident-to-bed ratio cap (66 FR 39900). The commenter believed that while the cap on the number of residents has been temporarily adjusted, if the receiving hospital is not allowed to also adjust its resident-to-bed ratio in the prior year, the lower resident-to-bed ratio from the prior year would act to reduce the IME payments to the receiving hospital. The commenter suggested that, similar to the exception for residents in hospitals that begin new programs under § 412.105(a)(1), an adjustment should be made to the prior year's FTE residents equal to the increase in the current year's FTEs that is attributable to the transferred residents. In response to the commenter, we stated that we had decided not to allow the exclusion of these displaced residents in applying the resident-to-bed ratio cap. We explained that, while we believed that the receiving hospital may be held to a lower cap in the first year of training the displaced residents, the receiving hospital would benefit from the higher cap in the subsequent years as the displaced residents complete their training and leave that hospital. However, we indicated that we would consider suggestions for possible future changes to this policy.

We have revisited this policy and now realize that our rationale for not allowing the adjustment for displaced residents to the resident-to-bed ratio cap may have been faulty. We initially believed that, in the year following the last year in which displaced residents trained at the receiving hospital, the receiving hospital would benefit from the higher resident-to-bed ratio cap. However, we have determined that, while it is correct that the hospital will have a higher resident-to-bed ratio cap because of the higher number of displaced residents in the prior year, the receiving hospital's FTE count decreases as the displaced residents finish their training. Therefore, the receiving hospital would not need a higher resident-to-bed ratio cap to accommodate the remaining FTEs.

Consequently, the higher resident-to-bed ratio cap in fact would not benefit the receiving hospital. Thus, we are now proposing to allow the exclusion of residents displaced by either the closure of another hospital's program or another hospital's closure in applying the resident-to-bed ratio cap. Specifically, assuming a hospital is eligible to receive a temporary adjustment to its FTE cap as described in existing § 413.86(g)(8), we are proposing that, solely for purposes of applying the resident-to-bed ratio cap in the *first* year in which the receiving hospital is training the displaced residents, the receiving hospital may adjust the numerator of the prior year's resident-to-bed ratio by the number of FTE residents that has caused the receiving hospital to exceed its FTE cap. (We note that this adjustment to the resident-to-bed ratio cap does not apply to changes in bed size). In the years subsequent to the first year in which the receiving hospital takes in the displaced residents, we believe an adjustment to the numerator of the prior year's resident-to-bed ratio is unnecessary because the receiving hospital's actual FTE count in those years would either stay the same or, as the displaced residents complete their training or leave that hospital, decrease each year. If all other variables remain constant, an increase in the current year's resident-to-bed ratio will establish a higher cap for the following year. In the second and subsequent years of training the displaced residents, the receiving hospital's resident-to-bed ratio for the current year would not be higher than the prior year's ratio and thus would not be limited by the resident-to-bed ratio cap.

In the cost reporting period following the departure of the last displaced residents, when the temporary FTE cap adjustment is no longer applicable, we are proposing that, solely for purposes of applying the resident-to-bed ratio cap, the resident-to-bed ratio be calculated *as if* the displaced residents had not trained at the receiving hospital in the prior year. In other words, in the year that the hospital is no longer training displaced residents, the attendant FTEs should be removed from the numerator of the resident-to-bed ratio from the prior year (that is, the resident-to-bed ratio cap). We believe that because we are proposing to allow the adjustment to the resident-to-bed ratio cap in the first year in which the receiving hospital trains displaced residents, it is equitable to remove those FTEs when calculating the resident-to-bed ratio cap after all the displaced

residents have completed their training at the receiving hospital.

The following is an example of how the receiving hospital's IME resident-to-bed ratio cap would be adjusted for displaced residents coming from either a closed hospital or a closed program:

Example: Hospital A has a family practice program with 3 residents. On June 30, 2002, Hospital A closes. Hospital B, which also has a family practice program, agrees to continue the training of Hospital A's residents beginning July 1, 2002. Its fiscal year end is June 30. As of July 1, 2002, the 3 residents displaced by the closure of Hospital A include 1 PGY1 resident, 1 PGY2 resident, and 1 PGY3 resident. In addition, Hospital B has 5 of its own residents, an IME FTE resident cap of 5, and 100 beds. Subject to the criteria under existing § 413.86(g)(8), Hospital B's FTE cap is temporarily increased to 8 FTEs. According to the proposed policy stated above, Hospital B's resident-to-bed ratio and resident-to-bed ratio cap would be determined as follows:

July 1, 2002 through June 30, 2003

- Resident-to-bed ratio: 5 FTEs + 3 displaced FTEs / 100 beds = .08 (line 3.18 of Worksheet E, Part A of the Medicare cost report, Form CMS 2552-96).

(**Note:** For purposes of applying the rolling average calculation at § 412.105(f)(1)(v) to this example, it is assumed that Hospital B had 5 FTE residents in both the prior and the penultimate cost reporting periods. Therefore, 5 FTEs are used in the numerator of the resident-to-bed ratio. Under § 412.105(f)(1)(v), displaced residents are added to the receiving hospital's rolling average FTE count in each year that the displaced residents are training at the receiving hospital.)

- Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2002) + 3 displaced FTEs (from fiscal year end June 30, 2003) / 100 beds = .08 (line 3.19 of Worksheet E, Part A of Form CMS 2552-96).

- The lower of the resident-to-bed ratio from the current year (.08) or the resident-to-bed ratio cap from the prior year (.08) is used to calculate the IME adjustment. Therefore, Hospital B would use a resident-to-bed ratio of .08 (line 3.20 of Worksheet E, Part A of Form CMS 2552-96).

July 1, 2003 through June 30, 2004

The PGY3 displaced resident has completed his or her family practice training on June 30, 2003 and has left Hospital B. Hospital B continues to train a displaced (now) PGY2 resident, and a displaced (now) PGY3 resident.

- Resident-to-bed ratio: 5 FTEs + 2 displaced FTEs / 100 beds = .07 (line

3.18 of Worksheet E, Part A of Form CMS 2552-96).

- Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2003) + 3 displaced FTEs (from fiscal year end June 30, 2003) / 100 beds = .08 (line 3.19 of Worksheet E, Part A of Form CMS 2552-96).

- The lower of the resident-to-bed ratio from the current year (.07) or the resident-to-bed ratio cap from the prior year (.08) is used to calculate the IME adjustment. Hospital B would use a resident-to-bed ratio of .07 (line 3.20 of Worksheet E, Part A of Form CMS 2552-96).

July 1, 2004 through June 30, 2005

Another of the remaining displaced residents has completed his or her family practice training on June 30, 2004 and has left Hospital B. Hospital B continues to train one displaced (now) PGY3 resident.

- Resident-to-bed ratio: 5 FTEs + 1 displaced FTE / 100 beds = .06 (line 3.18 of Worksheet E, Part A of Form CMS 2552-96).

- Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2004) + 2 displaced FTEs (from fiscal year end June 30, 2004) / 100 beds = .07 (line 3.19 of Worksheet E, Part A of Form CMS 2552-96).

- The lower of the resident-to-bed ratio from the current year (.06) or the resident-to-bed ratio cap from the prior year (.07) is used to calculate the IME adjustment. Hospital B would use a resident-to-bed ratio of .06 (line 3.20 of Worksheet E, Part A of Form CMS 2552-96).

July 1, 2005 through June 30, 2006

The last displaced resident has completed his or her family practice training on June 30, 2005 and has left Hospital B. Hospital B no longer trains any displaced residents, and, therefore, the last displaced resident is removed from the numerator of the resident-to-bed ratio cap.

- Resident-to-bed ratio: 5 FTEs + 0 displaced FTEs / 100 beds = .05

- Resident-to-bed ratio cap: 5 FTEs (from fiscal year end June 30, 2005) + 0 displaced FTEs (subtract 1 displaced FTE from FYE June 30, 2005) / 100 beds = .05

- The lower of the resident-to-bed ratio from the current year (.05) or the resident-to-bed ratio cap from the prior year (.05) is used to calculate the IME adjustment. Hospital B would use a resident-to-bed ratio of .05.

We are proposing that this exception to the resident-to-bed ratio cap for residents coming from a closed hospital or a closed program would be effective for cost reporting periods beginning on

or after October 1, 2002. We are proposing to revise § 412.105(a)(1) accordingly.

3. Counting Beds for the IME and DSH Adjustments (§ 412.105(b) and § 412.106(a)(1)(i))

As discussed under section V.E.2. of this proposed rule, the regulations for determining the number of beds to be used in calculating the resident-to-bed ratio for the IME adjustment are located at § 412.105(b). These regulations also are used to determine the number of beds for other purposes, including calculating the DSH adjustment at § 412.106(a)(1)(i). Section 412.105(b) specifies that the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period. The number of available bed days does not include beds or bassinets in the healthy newborn nursery, custodial care beds, or beds in excluded distinct part hospital units.

Section 2405.3G of Part I of the Medicare Provider Reimbursement Manual (PRM) further defines "available" beds. Specifically, section 2405.3G states that an available bed is a bed that is permanently maintained and is available for use to lodge inpatients. However, there has been some uncertainty concerning the application of this definition of "available." For example, a question arises as to whether beds in rooms or entire units that are unoccupied for extended periods of time should continue to be counted on the basis that, if there would ever be a need, they could be put into use.

Counting the number of beds in a hospital is intended to measure the size of a hospital's routine acute care inpatient operations. While hospitals necessarily maintain some excess capacity, we believe there is a point where excess capacity may distort the bed count. Therefore, we are proposing to revise our policy concerning the determination of a hospital's bed size to exclude beds that represent an excessive level of unused capacity. We believe this proposed refinement of our bed counting policy would better capture the size of a hospital's inpatient operations as described above.

We analyzed Medicare hospital data and found that, among hospitals that have between 100 and 130 beds, hospitals receiving DSH payments have lower occupancy rates than similar hospitals not receiving DSH payments. Because DSH payments are higher for urban hospitals with more than 100

beds, there may be an incentive for these hospitals to maintain excess capacity in order to qualify for those higher payments. Among 189 urban hospitals in this bed-size range that did not receive DSH payments during FY 1999, the average occupancy rate was 55 percent. However, among 294 urban hospitals in this bed-size range that did receive DSH payments during FY 1999, the average occupancy rate was 47 percent. Twenty-five percent of this group of hospitals (those receiving DSH payments) had occupancy rates below 35 percent. Among the hospitals not receiving DSH payments, 25 percent had occupancy rates below 43 percent. We believe this is indicative of a tendency among some small urban hospitals to maintain excess capacity in order to qualify for higher DSH payments. Therefore, we are proposing that if a hospital's reported bed count results in an occupancy rate (average daily census of patients divided by 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 (proposed § 412.105(b)(3)).

For example, if a hospital reports 105 beds for a cost reporting period, but has an average daily census of 26 patients for that same cost reporting period, its occupancy rate equals 24.8 percent (that is, 26/105). Because its occupancy rate is below the proposed minimum threshold of 35 percent, its maximum available bed count would be 74, which is the number of beds that would result in an occupancy rate of 35 percent, given an average daily census of 26 patients (that is, 26/.35).

We would otherwise continue to determine a hospital's bed size using existing regulations and program manual instructions, including the application of the available bed policy.

Following are the steps a hospital would undertake in determining its number of beds in a cost reporting period under our proposed policy:

Step 1: Determine the number of available beds using the existing regulations at § 412.105(b) and PRM instructions.

Step 2: Determine the average daily census by dividing the total number of inpatient acute care days in the hospital by the number of days in the cost reporting period.

Step 3: Divide the average daily census determined in step 2 by 35 percent.

Step 4: Use the lower of the number of beds as determined under step 1, or

the result of step 3 for purposes of the IME and DSH calculations.

We believe that this proposed policy more accurately indicates the size of a hospital's operations. We are proposing to specify under proposed § 412.105(b)(3) that if a hospital's reported bed count results in an occupancy rate below 35 percent, the applicable bed count for that hospital would be the number of beds that would result in an occupancy rate of 35 percent. We are proposing to make this proposed policy effective for discharges occurring on or after October 1, 2002.

F. Medicare-Dependent, Small Rural Hospitals: Ongoing Review of Eligibility Criteria (§ 412.108(b))

Section 6003(f) of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239) added section 1886(d)(5)(G) to the Act and created the category of Medicare-dependent, small rural hospitals (MDHs). MDHs are eligible for a special payment adjustment under the acute care hospital inpatient prospective payment system. Initially, in order to be classified as an MDH, a hospital must have met all of the following criteria:

- The hospital is located in a rural area (as defined in § 412.63(b));
- The hospital has 100 or fewer beds (as defined at § 412.105(b)) during the cost reporting period;
- The hospital is not classified as an SCH (as defined at § 412.92); and
- The hospital has no less than 60 percent of its inpatient days or discharges attributable to inpatients receiving Medicare Part A benefits during its cost reporting period beginning in FY 1987.

MDHs were eligible for a special payment adjustment under the acute care hospital inpatient prospective payment system, effective for cost reporting periods beginning on or after April 1, 1990, and ending on or before March 31, 1993. Hospitals classified as MDHs were paid using the same methodology applicable to SCHs, that is, based on whichever of the following rates yielded the greatest aggregate payment for the cost reporting period:

- The national Federal rate applicable to the hospital.
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.

Section 13501(e)(1) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66) extended the MDH provision through FY 1994 and provided that, after the hospital's first three 12-month cost reporting periods beginning on or after April 1, 1990, the

additional payment to an MDH whose applicable hospital-specific rate exceeded the Federal rate was limited to 50 percent of the amount by which the hospital-specific rate exceeded the Federal rate. The MDH provision expired effective with cost reporting periods beginning on or after October 1, 1994.

Section 4204(a)(3) of Public Law 105-33 reinstated the MDH special payment for discharges occurring on or after October 1, 1997 and before October 1, 2001, but did not revise the qualifying criteria for these hospitals or the payment methodology.

Section 404(a) of Public Law 106-113 extended the MDH provision to discharges occurring before October 1, 2006.

As specified in the June 13, 2001 interim final rule with comment period (66 FR 32172) and finalized in the August 1, 2001 final rule (66 FR 39883), section 212 of Public Law 106-554 provided that, effective with cost reporting periods beginning on or after April 1, 2001, a hospital has the option to base MDH eligibility on two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, rather than on the cost reporting period that began during FY 1987 (section 1886(d)(5)(G)(iv)(IV) of the Act). According to section 1886(d)(5)(G)(iv)(IV) of the Act, the criteria for at least 60 percent Medicare utilization will be met if, in at least "2 of the 3 most recently audited cost reporting periods for which the Secretary has a settled cost report", at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals receiving Medicare Part A benefits.

We would like to point out that cost reports undergo different levels of review. For example, some cost reports are settled with a desk review; others, through a full field audit. We believe the intention of the law is to provide hospitals the ability to qualify for MDH status based on their most recent settled cost reporting periods, each of which undergoes a level of audit in its settlement.

Hospitals that qualify under section 1886(d)(5)(G)(iv)(IV) of the Act are subject to the other provisions already in place for MDHs. That is, all MDHs are paid using the payment methodology as defined in § 412.108(c) and may be eligible for the volume decrease provision as defined in § 412.108(d).

Under existing classification procedures at § 412.108(b), a hospital must submit a written request to its fiscal intermediary to be considered for

MDH status based on at least two of its three most recently audited cost reporting periods for which the Secretary has a settled cost report (as specified in § 412.108(a)(1)(iii)(c)). The fiscal intermediary will make its determination and notify the hospital within 90 days from the date it receives the hospital's request and all of the required documentation. The intermediary's determination is subject to review under 42 CFR Part 405, Subpart R. MDH status is effective 30 days after the date of written notification of approval.

We are proposing to clarify and to codify in the regulations (proposed § 412.108(b)(4)) that an approved classification as an MDH remains in effect unless there is a change in the circumstances under which the classification was approved. That is, in order to maintain its eligibility for MDH status, a hospital must continue to be a small (100 or fewer beds), rural hospital, with no less than 60 percent Medicare inpatient days or discharges during either its cost reporting period beginning in FY 1987 or during at least two of its three most recently settled cost reporting periods.

We also are proposing to clarify and to codify in the regulations (proposed § 412.108(b)(5)) that the fiscal intermediary will evaluate on an ongoing basis whether or not a hospital continues to qualify for MDH status. This proposed clarification would include evaluating whether or not a hospital that qualified for MDH status under section 1886(d)(5)(G)(iv)(IV) of the Act continues to qualify for MDH status based on at least two of its three most recently settled cost reporting periods.

In addition, we are proposing, (proposed § 412.108(b)(6)) that if a hospital loses its MDH status, that change in status would become effective 30 days after the fiscal intermediary provides written notification to the hospital that it no longer meets the MDH criteria. If the hospital would like to be considered for MDH status after another cost reporting period has been audited and settled, we are proposing to require that the hospital must reapply by submitting a written request to its fiscal intermediary (proposed § 412.108(b)(7)). An MDH that continues to meet the criteria would not have to reapply.

G. Eligibility Criteria for Reasonable Cost Payments to Rural Hospitals for Nonphysician Anesthetists
(§ 412.113(c))

Currently, a rural hospital can qualify and be paid on a reasonable cost basis

for qualified nonphysician anesthetists (certified registered nurse anesthetists (CRNAs) and anesthesiologist assistants) services for a calendar year beyond 1990 and subsequent years as long as it can establish before January 1 of that year that it did not provide more than 500 surgical procedures requiring anesthesia services, both inpatient and outpatient.

In the September 1, 1983 interim final rule with comment period that implemented the acute care hospital inpatient prospective payment system, we established the general policy to include, under that prospective payment system, inpatient hospital services furnished incident to a physician's service, with a time-limited exception for the inpatient hospital services of anesthetists (48 FR 39794). The purpose of this exception, which originally was for cost reporting periods beginning before October 1, 1986, was that the practice of physician-employer and anesthetist-employee was so widespread that we believed "it would be disruptive of medical practice and adverse to the quality of patient care to require all such contracts to be renegotiated in the limited time available before the implementation of the prospective payment system."

Section 2312 of Public Law 98-369 provided for reimbursement to hospitals on a reasonable cost basis as a pass-through for the costs that hospitals incur in connection with 27 the services of CRNAs.³ Section 2312(c) provided that the amendment was effective for cost reporting periods beginning on or after October 1, 1984, and before October 1, 1987.

Section 9320 of Public Law 99-509 (which established a fee schedule for the services of nurse anesthetists) amended section 2312(c) of Public Law 98-369 by extending the pass-through provision for cost reporting periods beginning before January 1, 1989. Section 608 of Public Law 100-485 limited the pass-through provision effective during 1989, 1990, and 1991, to hospitals meeting the following criteria:

- As of January 1, 1988, the hospital employed or contracted with a certified nonphysician anesthetist;
- In 1987, the hospital had a volume of surgical procedures (including inpatient and outpatient procedures) requiring anesthesia services that did not exceed 250 (or such higher number

as the Secretary determines to be appropriate); and

- Each certified nonphysician anesthetist employed by, or under contract with, the hospital has agreed not to bill under Part B of Medicare for professional services furnished by the anesthetist at the hospital.

Subsequently, section 6132 of Public Law 101-239 amended section 608 of Public Law 100-458 by raising the established 250-procedure threshold to 500 procedures (effective for anesthesia services furnished on or after January 1, 1990), and extended the cost pass-through indefinitely. However, section 6132 of Public Law 101-239 left intact the requirement that the hospital must have not exceeded a maximum number of surgical procedures (effectively raised to 500), both inpatient and outpatient, requiring anesthesia services during 1987. Also, the statutory authority for the Secretary to adopt such other appropriate maximum threshold volume of procedures as determined appropriate was not affected by section 6132.

In light of the age of this provision, we undertook to reexamine the appropriateness of the current 500-procedure threshold. Nonphysician anesthetists who are not employed by or have a contractual relationship with a hospital paid under this provision may receive payments under a fee schedule. Payments under the fee schedule are generally somewhat lower than those made on a reasonable cost basis. Therefore, hospitals that exceed 500 procedures may have difficulty retaining access to nonphysician anesthetists' services because cost reimbursement is unavailable. According to data from the American Association of Nurse Anesthetists (AANA), the average total annual compensation for a CRNA in 2001 was approximately \$155,000. The AANA estimates that, based on payments under the Medicare fee schedule, a CRNA would have to provide at least 800 anesthesia procedures to reach this average level of compensation.

The statute provides the Secretary with the authority to determine the appropriateness of the volume threshold, in part, so that changes necessary to meet the needs of rural hospitals can be made. As we have found that hospitals that exceed the 500 surgical procedures may have difficulty in retaining access to nonphysician anesthetists' services, we believe that the appropriate maximum threshold for surgical procedures should be raised in order for the payment exception to apply to those hospitals most in need of this payment treatment. Based upon the data available to us concerning the best

³ We noted in the August 31, 1984 final rule that section 2312 and the Conference Report used the term "CRNA" throughout. However, we believed it was Congressional intent to apply this pass-through payment amount to the services of all qualified hospital-employed nonphysician anesthetists (49 FR 34748).

estimates of average total compensation to a CRNA, we believe that the maximum volume threshold for surgical procedures requiring anesthesia services should be raised to 800. Therefore, to ensure continued access to nonphysician anesthetists' services in rural hospitals, we are proposing to revise §§ 412.113(c)(2)(ii) and (c)(2)(iii) to raise the 500-procedure threshold to 800 procedures.

H. Medicare Geographic Classification Review Board (MGCRB) Reclassification Process (§§ 412.230, 412.232, and 412.273)

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 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.

1. Withdrawals, Terminations, and Cancellations

Under § 412.273(a) of our regulations, a hospital, or group of hospitals, may withdraw its application for reclassification at any time before the MGCRB issues its decision or, if after the MGCRB issues its decision, within 45 days of publication of our annual notice of proposed rulemaking concerning changes to the acute care hospital inpatient prospective payment system for the upcoming fiscal year (for example, this proposed rule for FY 2003). In the August 1, 2001 final rule, we specified that, for purposes of implementing section 304 of Public Law 106-554, the withdrawal procedures and the applicable timeframes in the existing regulations would apply to hospitals that receive 3-year reclassification for wage index purposes (66 FR 39886). Once effective, a withdrawal means that the hospital would not be reclassified for purposes of the wage index for FY 2003 (and would not receive continued reclassification for FYs 2004 and 2005), unless the hospital subsequently cancels its withdrawal.

Consistent with section 1886(d)(10)(D)(v) of the Act, a hospital

may terminate its approved 3-year reclassification during the second or third years (§ 412.273(b)). This is a separate action from a reclassification withdrawal that occurs in accordance with the timeframes described above. Currently, in order to terminate an approved 3-year reclassification, we require the hospital to notify the MGCRB in writing within 45 days of the publication date of the annual proposed rule for changes to the hospital inpatient prospective payment system (§ 412.273(b)(1)(i)). A termination, unless subsequently cancelled, is effective for the full fiscal years remaining in the 3-year period.

We also provided that a hospital may apply for reclassification to a different area for the year corresponding to the second or third year of the reclassification (that is, an area different from the one to which it was originally reclassified) and, if successful, the reclassification would be for 3 years. Since the publication of the final rule, we received an inquiry regarding a situation where a hospital with an existing 3-year wage index reclassification successfully reclassifies to a different area, then withdraws from that second reclassification within the allowable timeframe for withdrawals. This scenario raises several issues not specifically addressed in the August 1, 2001 final rule, which we are proposing to clarify in this proposed rule.

For example, the question arises, at what point does a hospital's termination of a 3-year reclassification become effective when a hospital applies for reclassification to another area? As noted above, the August 1, 2001 final rule specified that a hospital must file a written request with the MGCRB within 45 days of publication of the annual proposed rule to terminate the reclassification. However, the rules do not specify at what point a previous 3-year reclassification is terminated when a hospital applies for reclassification to another area in subsequent years. One might conclude that an application for a wage index reclassification to another area constitutes a written notification of a hospital's intent to terminate an existing 3-year reclassification. Under this scenario, however, if the application to the second area were denied, it would then be necessary for the hospital to formally cancel the termination of its reclassification to the first area within 45 days of publication of the proposed rule to avoid a lapse in reclassification status the following year. Therefore, we are proposing to clarify, in § 412.273(b)(2)(iii), that, in a situation where a hospital with an existing 3-year wage index

reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1. In such a case, it will not be necessary for the hospital to submit a separate written notice of its intent to terminate its existing 3-year reclassification. Of course, a hospital also may still terminate an existing 3-year reclassification through written notice to the MGCRB, regardless of whether it successfully reclassifies to a different area.

The scenario of a hospital with an existing 3-year reclassification seeking reclassification to a second area raises another issue. If the hospital's request is approved by the MGCRB, but the hospital withdraws from that successful reclassification and "falls back" to its original 3-year reclassification, does the hospital retain the right to cancel that withdrawal the next year? In this way, a hospital could accumulate multiple reclassifications from which it could choose in any given year through canceling prior withdrawals or terminations to one area and withdrawing or terminating reclassifications to other areas.

We do not believe section 304 of Public Law 106-554 was intended to be used in such a manner. Therefore, we are proposing to clarify existing policy that a previous 3-year reclassification may not be reinstated after a subsequent 3-year reclassification to another area takes effect. This would mean that a hospital that is reclassified to an area for purposes of the wage index may have only one active 3-year reclassification at a time. Once a 3-year reclassification to a second area becomes effective, a previously terminated 3-year reclassification may not be reinstated by terminating or withdrawing the reclassification to the second area and then canceling the termination or withdrawal of the reclassification to the first area.

As we stated in the August 1, 2001 final rule, we believe the 3-year wage index reclassification policy was intended to provide consistency and predictability in hospital reclassifications and the wage index data. Allowing hospitals multiple reclassification options to choose from would create a situation where many hospitals move in unpredictable ways between the proposed and final rules based on their calculation of which of several areas would yield the highest wage index. This would reduce the predictability of the system, hampering the ability of the majority of hospitals to

adequately project their future revenues. Therefore, we are proposing to amend § 412.273(b)(2)(ii) to provide that, once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, even within 3 years from the date of such withdrawal or termination. We are also proposing a technical correction to § 412.273(b)(2)(i) to correct the terminology regarding canceling (rather than terminating) a withdrawal.

Finally, the August 1, 2001 final rule did not specifically describe the process to cancel a withdrawal or termination. Therefore, we are proposing to add a new § 412.273(d) (existing paragraph (d) would be redesignated as paragraph (e)) to describe the process whereby a hospital may cancel a previous withdrawal or termination of a 3-year wage index reclassification. Specifically, a hospital may cancel a previous withdrawal or termination by submitting written notice of its intent to the MGCRB no later than the deadline for submitting reclassification applications for reclassifications effective at the start of the following fiscal year (§ 412.256(a)(2)).

2. Effect of Change of Ownership on Hospital Reclassifications

Sections 412.230(e)(2)(ii) and 412.232(d)(2)(ii) provide that, for reclassifications effective beginning FY 2003, a hospital must provide a 3-year average of its average hourly wages using wage survey data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

As discussed in the August 1, 2001 final rule, we received a comment suggesting that, for purposes of calculating the 3-year average hourly wages, we permit a hospital that has changed ownership the option of excluding prior years' wage data submitted by a previous owner in order for the new hospital to qualify for reclassification. Although we responded to the comment (66 FR 39890), we have now determined that there is a need to further clarify our policy regarding change of ownership and hospitals that do not accept assignment of the previous owner's provider agreement.

In our response to the comment, we stated that, where a hospital has simply changed ownership and the new owners have acquired the financial assets and liabilities of the previous owners, all of the applicable wage data associated with that hospital are included in the calculation of its 3-year average hourly wage. Where this is not the case and there is no obligation on the part of the

new hospital to claim the financial assets or assume the liabilities of a predecessor hospital, the wage data associated with the previous hospital's provider number would not be used in calculating the new hospital's 3-year average hourly wage.

Section 489.18(c) provides that, when there is a change of ownership, the existing provider agreement will automatically be assigned to the new owner. Our regulations at § 412.230(e)(2) do not specifically address the situation of new hospitals seeking to reclassify for wage index purposes, in light of the requirement that reclassification is based on a 3-year average hourly wage. Therefore, we are proposing to revise § 412.230(e)(2), by adding a new paragraph (e)(2)(iii), to clarify our existing policy to specify that, in situations where a hospital does not accept assignment of the existing hospital's provider agreement under § 489.18, the hospital would be treated as a new hospital with a new provider number. In that case, the wage data associated with the previous hospital's provider number would not be used in calculating the new hospital's 3-year average hourly wage. As we stated in the August 1, 2001 final rule, we believe this policy clarification is consistent with how we treat hospitals whose ownership has changed for other Medicare payment purposes. We are proposing to revise § 412.230 to clarify, under proposed new paragraph (e)(2)(iii), that once a new hospital has accumulated at least 1 year of wage data using survey data from the CMS hospital wage survey used to determine the wage index, it is eligible to apply for reclassification on the basis of those data.

I. Payment for Direct Costs of Graduate Medical Education (§ 413.86)

1. Background

Under section 1886(h) of the Act, Medicare pays hospitals for the direct costs of graduate medical education (GME). The payments are based in part on the number of residents trained by the hospital. Section 1886(h) of the Act caps the number of residents that hospitals may count for direct GME.

Section 1886(h)(2) of the Act, as amended by section 9202 of the Consolidated Omnibus Reconciliation Act (COBRA) of 1985 (Public Law 99-272), and implemented in regulations at § 413.86(e), establishes a methodology for determining payments to hospitals for the costs of approved GME programs. Section 1886(h)(2) of the Act, as amended 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 complex (or 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's 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 with both primary care and obstetrics and gynecology residents and 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.

Section 1886(h)(2) of the Act was further amended by section 311 of Public Law 106-113 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. Generally, section 1886(h)(2)(D) of the Act establishes a "floor" and a "ceiling" based on a locality-adjusted, updated, weighted average PRA. Each hospital's PRA is compared to the floor and ceiling to determine whether its PRA should be revised. For cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, the floor PRA is 70 percent of the locality-adjusted, updated, weighted average PRA. For cost reporting periods beginning on or after October 1, 2001, and before October 1, 2002, section 511 of Public Law 106-554 amended the floor PRA to equal 85 percent of the locality-adjusted, updated, weighted average PRA. PRAs that are below the applicable floor PRA for a particular cost reporting period would be adjusted to equal the floor PRA. PRAs that exceed the ceiling, that is, 140 percent of the locality-adjusted, updated, weighted average PRA, would, depending on the fiscal year, either be frozen and not increased for inflation, or

increased by a reduced inflation factor. Existing regulations at § 413.86(e)(4) specify the methodology for calculating each hospital's weighted average PRA and the steps for determining whether a hospital's PRA will be revised.

2. Determining the Weighted Average PRAs for Newly Participating Hospitals (§ 413.86(e)(5))

As stated earlier, under section 1886(h) of the Act and implementing regulations, in most cases Medicare pays hospitals for the direct costs of GME on the basis of per resident costs in a 1984 base year. However, under existing § 413.86(e)(5), if a hospital did not have residents in an approved residency training program, or did not participate in Medicare during the base period, the hospital's base period for its PRA is its first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period. If there are at least three existing teaching hospitals with PRAs in the same geographic wage area (MSA), as that term is used in 42 CFR Part 412, the fiscal intermediary will calculate a PRA based on the lower of the new teaching hospital's actual cost per resident in its base period or a weighted average of all the PRAs of existing teaching hospitals in the same MSA. There must be at least three existing teaching hospitals with PRAs in the MSA for this calculation. If there are less than three existing teaching hospitals with PRAs within the new teaching hospital's MSA, effective for cost reporting periods beginning on or after October 1, 1997, the fiscal intermediary uses the updated regional weighted average PRA (determined for each of the nine census regions established by the Bureau of Census for statistical and reporting purposes) for the new teaching hospital's MSA (see 62 FR 46004, August 29, 1997). A new teaching hospital is assigned a PRA equal to the lower of its actual allowable direct GME costs per resident or the weighted average PRA as calculated by the fiscal intermediary. Using a methodology based on a weighted average ensures that a new teaching hospital receives a PRA that is representative of the costs of training residents within its specific geographic wage area.

Under existing policy, to calculate the weighted average PRA of teaching hospitals within a particular MSA, the fiscal intermediary begins by determining the base year PRA and the base year FTE count of each respective teaching hospital within that MSA. The weighted average PRA is (a) the sum of the products of each existing teaching

hospital's base year PRA in the MSA and its base year FTEs, (b) divided by the sum of the base year FTEs from each of those hospitals. While a methodology using base year PRAs and FTEs was appropriate and workable in the years closely following the implementation of hospital-specific PRAs, it has become administratively burdensome for both CMS and the fiscal intermediaries to recreate base year information in calculating a weighted average. The methodology is particularly problematic in instances where there are large numbers of teaching hospitals in an MSA.

In addition, as discussed in section V.I.1. of this proposed rule, hospitals that were training nonprimary care residents during FYs 1994 and 1995 have a distinct nonprimary care PRA, because there was no update in the inflation factor for these years (§ 413.86(e)(3)(ii)). Thus, most teaching hospitals currently have two PRAs: one for primary care and obstetrics and gynecology; and one for all other residents. (Hospitals that first train residents after FY 1995 only have a single PRA, regardless of whether they train primary care or other residents.) However, since the current methodology for calculating weighted average PRAs is based on data from FY 1984, which was prior to the years during which the PRAs were not adjusted for inflation to reflect nonprimary care residents, the methodology does not account for *all* PRAs (both primary care and obstetrics and gynecology and nonprimary care) within an MSA.

Accordingly, we are proposing to simplify and revise the weighted average PRA methodology under § 413.86(e)(5)(i)(B) to reflect the average of all PRAs in an MSA, both primary care and obstetrics and gynecology, and nonprimary care. We would continue to calculate a weighted average PRA. However, rather than using 1984 base year data, we are proposing to use PRAs (both primary care and obstetrics and gynecology and nonprimary care) and FTE data from the most recently settled cost reports of teaching hospitals in an MSA. We are proposing that the intermediary would calculate the weighted average PRA using the following steps:

Step 1: Identify *all* teaching hospitals (including those serviced by another intermediary(ies)) in the same MSA as the new teaching hospital.

Step 2: Identify the respective primary care and obstetrics and gynecology FTE counts, the nonprimary care FTE counts, or the total FTE count (for hospitals with a single PRA) of each teaching hospital in step 1 from the

most recently settled cost reports. (Use the FTE counts from line 3.07 and line 3.08 of the Medicare cost report, CMS-2552-96, Worksheet E-3, Part IV.)

Step 3: Identify the PRAs (either a hospital's primary care and obstetrics and gynecology PRA and nonprimary care PRA, or a hospital's single PRA) from the most recently settled cost reports of the hospitals in step 1, and update the PRAs using the CPI-U inflation factor to coincide with the fiscal year end of the new teaching hospital's base year cost reporting period. For example, if the base year fiscal year end of a new teaching hospital is December 31, 2003, and the most recently settled cost reports of the teaching hospitals within the MSA are from the fiscal year ending June 30, 2000, September 30, 2000, or December 31, 2000, the PRAs from these cost reports would be updated for inflation to December 31, 2003.

Step 4: Calculate the weighted average PRA using the PRAs and FTE counts from steps 2 and 3. For each hospital in the calculation:

(a) Multiply the primary care PRA by the primary care and obstetrics and gynecology FTEs.

(b) Multiply the nonprimary care PRA by the nonprimary care FTEs.

(c) For hospitals with a single PRA, multiply the single PRA by the hospital's total number of FTEs.

(d) Add the products from steps (a), (b), and (c) for all hospitals.

(e) Add the FTEs from step 3 for all hospitals.

(f) Divide the sum from step (d) by the sum from step (e). The result is the weighted average PRA for hospitals within an MSA.

The following is an example of how to calculate a weighted average PRA under the proposed methodology:

Example

Assume that new Hospital A has a June 30 fiscal year end and begins training residents for the first time on July 1, 2003. Thus, new Hospital A's base year for purposes of establishing a PRA is the fiscal year ending June 30, 2004. New Hospital A is located in MSA 1234, in which three other teaching hospitals exist, Hospital B, Hospital C, and Hospital D. These three hospitals also have a fiscal year end of June 30 and their most recently settled cost reports are for the fiscal year ending June 30, 2000. For fiscal year ending June 30, 2000, Hospital B has 200 primary care and obstetrics and gynecology FTEs, 150 nonprimary care FTEs, and 150 nonprimary care FTEs. Hospital C has 50 primary care and obstetrics and gynecology FTEs and 60

nonprimary care FTEs. Hospital D has 25 FTEs. After updating the PRAs for inflation by the CPI-U to June 30, 2004, Hospital B has a primary care and obstetrics and gynecology PRA of \$120,000 and a nonprimary care PRA of \$115,000, Hospital C has a primary care and obstetrics and gynecology PRA of \$100,000 and a nonprimary care PRA of \$97,000, and Hospital D has a single PRA of \$90,000.

(a) Primary care:

Hospital B: $\$120,000 \times 200$ FTEs =
\$24,000,000

Hospital C: $\$100,000 \times 50$ FTEs =
\$5,000,000

(b) Nonprimary care:

Hospital B: $\$115,000 \times 150$ FTEs =
\$17,250,000

Hospital C: $\$97,000 \times 60$ FTEs =
\$5,820,000

(c) Single PRA:

Hospital D: $\$90,000 \times 25$ FTEs =
\$2,250,000

(d) $\$24,000,000 + 5,000,000 +$
 $\$17,250,000 + \$5,820,000 +$
 $\$2,250,000 = \$54,320,000.$

(e) $200 + 50 + 150 + 60 + 25 = 485$ total
FTEs.

(f) $\$54,320,000 / 485$ FTEs = \$112,000,
the weighted average PRA for
MSA1234 for fiscal year ending
June 30, 2004.

New Hospital A's PRA would be the lower of \$112,000 or its actual base year GME costs per resident.

We are proposing that this new weighted average calculation would be effective for hospitals with direct GME base years that begin on or after October 1, 2002.

In addition, we are taking the opportunity to clarify the language under existing § 413.86(e)(5)(i)(B), which relates to calculating the weighted average under existing policy. Specifically, existing § 413.86(e)(5)(i)(B) states: "The weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under part 412 of this chapter, for cost reporting periods beginning in the same fiscal years [emphasis added]." We believe this language could be misinterpreted to imply that only those PRAs of hospitals in the same geographic wage area (MSA) that have the same fiscal year end as the new teaching hospital should be used in the weighted average calculation. However, the PRAs of all hospitals within the MSA of the new teaching hospital should be used, not just the PRAs of hospitals with the same fiscal year end as the new teaching hospital. The proposed revision appears under a proposed new § 413.86(e)(5)(i)(c).

3. Aggregate FTE Limit for Affiliated Groups (§§ 413.86 (b) and (g)(7))

Section 1886(h)(4)(H)(ii) of the Act permits, but does not require, the Secretary to prescribe rules that allow institutions that are member of the same affiliated group (as defined by the Secretary) to elect to apply the FTE resident limit on an aggregate basis. This provision allows the Secretary to permit hospitals flexibility in structuring rotations within a combined cap when they share residents' time. In accordance with the broad authority conferred by the statute, we created criteria for defining "affiliated group" and "affiliation agreements" in both the August 29, 1997 final rule (62 FR 45965) and the May 12, 1998 final rule (63 FR 26317). Because we have received many inquiries from the hospital industry on this policy, we are proposing to clarify in regulations the requirements for participating in an affiliated group. These requirements are explicitly derived from the policy explained in the August 29, 1997 and May 12, 1998 final rules.

Specifically, we are proposing to add under § 413.86(b) a new definition of "Affiliation agreement." This new proposed definition would state that an affiliation agreement is a written, signed, and dated agreement by responsible representatives of each respective hospital in an affiliated group (as defined in § 413.86(b)), that specifies—

- The term of the agreement, which, at a minimum must be one year, beginning on July 1 of a year.
- Each participating hospital's direct and indirect FTE cap.
- The annual adjustment to each hospital's FTE caps, for both direct GME and IME. This adjustment must reflect the fact that any positive adjustment to one hospital's direct and indirect FTE caps must be offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount.
- The names of the participating hospitals and their Medicare provider numbers.

In addition, we are proposing to add a new § 413.86(g)(5)(iv) and a new § 413.86(g)(7) to clarify the requirements for a hospital to receive a temporary adjustment to its FTE cap through an affiliation agreement. (Existing § 413.86(g)(5)(iv) through (vi) are proposed to be redesignated as § 413.86(g)(5)(v) through (vii), respectively; and existing §§ 413.86(g)(7) through (g)(12) are proposed to be redesignated as §§ 413.86(g)(8) through (g)(13),

respectively, to accommodate these additions.) Specifically, we are proposing that a hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules, to reflect residents added or subtracted because the hospital is participating in an affiliated group (as that term is defined under § 413.86(b)). Under this proposed provision—

- Each hospital in the affiliated group must submit the affiliation agreement (as that term is proposed to be defined under § 413.86(b)), to the CMS fiscal intermediary servicing the hospital and send a copy to CMS's Central Office no later than July 1 of the residency program year during which the affiliation agreement will be in effect.

- There must be a rotation of a resident(s) among the hospitals participating in the affiliated group during the term of the affiliation agreement, such that more than one of the hospitals counts the proportionate amount of the time spent by the resident(s) in their FTE resident counts. (However, no resident may be counted in the aggregate as more than one FTE.) This requirement is intended to ensure that the participating hospitals maintain a "cross-training" relationship during the term of the affiliation agreement.

- The net effect of the adjustments (positive or negative) on the affiliated hospitals' aggregate FTE cap for each affiliation agreement must not exceed zero.

- If the affiliation agreement terminates for any reason, the FTE cap for each hospital in the affiliated group will revert to the individual hospital's pre-affiliation FTE cap.

Except for the proposed new § 413.86(g)(7)(iv) regarding the treatment of FTE caps after termination of the affiliation agreement, each provision of proposed new § 413.86(g)(7) is explicitly derived from policy stated in the May 12, 1998 final rule (63 FR 26336). We are proposing to incorporate in regulations policy that was previously established under the formal rulemaking process.

We are proposing a change in policy concerning what happens to each participating affiliated hospital's FTE cap when an affiliation agreement terminates (proposed new § 413.86(g)(7)(iv)). In the preamble of the May 12, 1998 final rule (63 FR 26339), we stated: "Each agreement must also specify the adjustment to each respective hospital cap in the event the agreement terminates, dissolves, or, if the agreement is for a specified time period, for residency training years and cost reporting periods subsequent to the

period of the agreement for purposes of applying the FTE cap on an aggregate basis. In the absence of an agreement on the FTE caps for each respective institution following the end of the agreement, each hospital's FTE cap will be the indirect and direct medical education FTE count from each hospital's cost reporting period ending in 1996 and the cap will not be applied on an aggregate basis." Our purpose for allowing hospitals to redistribute their FTE caps (within the limits of the aggregate FTE caps) upon the termination of an affiliation was to enable hospitals by agreement to more closely reflect the realities of the residency rotational arrangement. However, in practice, very few hospitals have altered their FTE caps following termination of affiliation agreements. Rather, the vast majority of hospitals opted to revert to their respective 1996 FTE caps upon the termination of an affiliation. In addition, we have found that our existing policy is susceptible to the following abusive practice that does not comport with our original purpose for allowing redistribution of FTE caps among hospitals following termination of an affiliation agreement. We have learned of a number of instances in which one hospital (Hospital A) affiliated with another hospital (Hospital B) in anticipation of Hospital B's closure at some point during the residency program year. In these instances, the affiliation agreement was made solely for the purpose of obtaining a permanent adjustment to Hospital A's FTE cap through the terms of the termination clause. We do not believe these permanent FTE cap adjustments that result from hospital closures (or any other circumstances) were intended when Congress passed the provision on affiliation agreements. As stated above, we believe affiliations were meant to provide flexibility for hospitals in the rotations of residents where, in the normal course of an affiliation between two or more hospitals, the actual number of residents training at each hospital may vary somewhat from year to year. Affiliations were *not* intended to be used as a vehicle for circumventing the statutory FTE cap on the number of residents. In addition, we have separately addressed issues that arise when residents are displaced because of a pending hospital closure. We have in place a policy at existing § 413.86(g)(8) (proposed to be redesignated as § 413.86(g)(9) in this proposed rule) that permits *temporary* FTE cap adjustments for hospitals that take on the training of residents

displaced by the closure of another hospital.

Therefore, we are proposing that, effective October 1, 2002, for hospitals with affiliation agreements that terminate (for any reason) on or after that date, the direct and indirect FTE caps for each hospital in the affiliated group will revert back to each individual hospital's original FTE cap prior to the affiliation (proposed new § 413.86(g)(7)(iv)). This policy would not preclude the participating hospitals from entering into additional affiliation agreements for later residency years.

Since this proposed policy would be effective for agreements that terminate on or after October 1, 2002, hospitals that have already received a permanent FTE cap adjustment from their fiscal intermediaries through the existing termination clause policy would retain those cap adjustments.

We also are proposing to make a conforming clarification at § 412.105(f)(1)(vi) for purposes of IME payments.

4. Rotating Residents to Other Hospitals

At existing § 413.86(f), we state, in part, that a hospital may count residents training in all areas of the hospital complex; no individual may be counted as more than one FTE; and, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as a partial FTE based on the proportion of *time worked at the hospital* to the total time worked (emphasis added). A similar policy exists at §§ 412.105(f)(1)(ii) and (iii) for purposes of counting resident FTEs for IME payment. Although these policies concerning the counting of the number of FTE residents for IME and direct GME payment purposes have been in effect since October 1985, we continue to receive questions about whether residents can be counted by a hospital for the time during which the resident is rotated to other hospitals.

We would like to clarify that it is longstanding Medicare policy, based on language in both the regulations and the statute, to prohibit one hospital from claiming the FTEs training at another hospital for IME and direct GME payment. This policy applies even when the hospital that proposes to count the FTE resident(s) actually incurs the costs of training the residents(s) (such as salary and other training costs) at another hospital.

First, section 1886(h)(4)(B) of the Act states that the rules governing the direct GME count of the number of FTE residents "shall take into account individuals who serve as residents for only a portion of a period with a

hospital or simultaneously with more than one hospital." In the September 4, 1990 **Federal Register** (55 FR 36064), we stated that " * * * regardless of which teaching hospital employs a resident who rotates among hospitals, each hospital would count the resident in proportion to the amount of time spent at its facility." Therefore, another hospital *cannot* count the time spent by residents training at another hospital. Only the hospital where the residents are actually training can count those FTEs for that portion of time. For example, if, during a cost reporting year, a resident spends 3 months training at Hospital A and 9 months training at Hospital B, Hospital A can only claim .25 FTE and Hospital B can only claim .75 FTE. Over the course of the entire cost reporting year, the resident would add up to 1.0 FTE.

We have been made aware of some instances where an urban hospital may incur all the training costs of residents while those residents train at a rural hospital, because the rural hospital may not have the resources or infrastructure to claim those costs and FTEs on a Medicare cost report. However, even in this scenario, the urban hospital is precluded from claiming any FTEs for the proportion of time spent in training at that rural hospital, or at any other hospital.

We note, however, that, consistent with the statutory provisions of section 1886(d)(5)(B)(iv) of the Act for IME payment and section 1886(h)(4)(E) of the Act for direct GME payment, a hospital may count the time residents spend training in a *nonhospital* setting if the hospital complies with the regulatory criteria at § 413.86(f)(4).

J. Responsibilities of Medicare-Participating Hospitals in Emergency Cases (EMTALA)

1. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on Medicare-participating hospitals that offer emergency services. These obligations concern individuals who come to a hospital emergency department and request examination or treatment for medical conditions, and apply to all of these patients, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867 of the Act sets forth requirements for medical screening examinations for medical conditions, as well as necessary stabilizing treatment or appropriate transfer. In addition, section 1867 of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire

about the individual's payment method or insurance status. Section 1867 of the Act also provides for the imposition of civil monetary penalties on hospitals and physicians responsible for the following: (a) Negligently failing to appropriately screen a patient seeking emergency medical care; (b) negligently failing to provide stabilizing treatment to an individual with an emergency medical condition; or (c) negligently transferring a patient in an inappropriate manner. (Section 1867(e)(4) of the Act defines "transfer" to include both transfers to other health care facilities and cases in which the patient is released from the care of the hospital without being moved to another health care facility.)

These provisions, taken together, are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA). As a result, many people initially referred to EMTALA as "COBRA" or the "COBRA antidumping" statute. Congress enacted these antidumping provisions in the Social Security Act because of its concern with an "increasing number of reports" that hospital emergency rooms were refusing to accept or treat patients with emergency conditions if the patients did not have insurance:

"* * * The Committee is most concerned that medically unstable patients are not being treated appropriately. There have been reports of situations where treatment was simply not provided. In numerous other situations, patients in an unstable condition have been transferred improperly, sometimes without the consent of the receiving hospital.

"There is some belief that this situation has worsened since the prospective payment system for hospitals became effective. The Committee wants to provide a strong assurance that pressures for greater hospital efficiency are not to be construed as license to ignore traditional community responsibilities and loosen historic standards.

"[Under the statute] [a]ll participating hospitals with emergency departments would be required to provide an appropriate medical screening examination for any individual who requests it (or has a request made on his behalf) to determine whether an emergency medical condition exists or if the patient is in active labor." (H.R. Rept. No. 99-241, Part 1, 99th Cong., 1st Sess. (1985), p. 27.)

The regulations implementing section 1867 of the Act are found at 42 CFR 489.24, Special responsibilities of Medicare hospitals in emergency cases. Section 489.24 provides for the following:

- Paragraph (a) requires that when an individual presents to a hospital's emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition, the hospital must provide for an appropriate medical screening examination to determine whether or not an emergency medical condition exists.

- Paragraph (b) provides the definitions of terms, including "comes to the emergency department," "emergency medical condition," "stabilized," and "to stabilize."

- Paragraph (c) addresses procedures a hospital must follow when it determines that an emergency medical condition exists. If the hospital determines that an emergency medical condition exists, the hospital must provide for further medical examination and treatment as required to stabilize the patient. If the hospital does not have the capabilities to stabilize the patient, an appropriate transfer to another facility is permitted. A transfer is appropriate when the medical benefits of the transfer outweigh the medical risks of the transfer and other requirements, specified in the regulation at paragraph (d), are met. Also, the hospital may transfer an unstable patient who makes an informed written request. Paragraph (c) further states that a hospital may not delay an appropriate medical screening examination, or further examination or treatment, to inquire about the individual's payment method or insurance status.

In addition, § 489.24 addresses: (a) Restriction of a transfer until the individual is stabilized; (b) the responsibilities of the receiving hospital; (c) termination of the provider agreement for failure to comply with EMTALA requirements; and (d) matters concerning consultation with Peer Review Organizations (paragraphs (d) through (h), respectively).

Some EMTALA-related requirements are implemented under regulations at §§ 489.20(l), (m), (q), and (r)(1), (r)(2), and (r)(3). Those regulations deal with a hospital's obligations to report the receipt of patients that it has reason to believe may have been transferred inappropriately; to post signs in the emergency department describing a patient's rights to emergency treatment under section 1867 of the Act; and to maintain patient records, physician on-call lists, and emergency room logs. We

are including this brief description for informational purposes but, because we are not proposing to change the regulations in § 489.20, they will not be discussed further in this document.

In promulgating these cited regulatory sections and in enforcing the provisions of EMTALA, we are aware of the necessary balance between the hospital's and a physician's legal duty to provide examination and treatment under the statute and the practical realities of the manner in which hospitals and medical staffs are organized and operated on a day-to-day basis, as well as proper mobilization of resources within hospitals in order to comply with these legal duties. Reports of overcrowding in hospital emergency departments are common in many parts of the country. Within the requirements of EMTALA, individuals should be treated at the appropriate site of care.

Hospitals and physicians have now had over 15 years of experience in organizing themselves to comply with the provisions of EMTALA. Throughout this section of this proposed rule relating to EMTALA, we solicit comments from hospitals, physicians, patients, and beneficiary groups on the proposed changes to the EMTALA policies.

2. Special Advisory Bulletin on EMTALA Obligations

On November 10, 1999, CMS (previously, HCFA) and the Office of the Inspector General (OIG) published jointly in the **Federal Register** a Special Advisory Bulletin addressing the requirements of the patient antidumping statute and the obligations of hospitals to medically screen all patients seeking emergency services and provide stabilizing medical treatment as necessary to all patients, including enrollees of managed care plans, whose conditions warrant it (64 FR 61353). The Special Advisory Bulletin addressed issues of dual staffing of hospital emergency rooms by managed care and nonmanaged care physicians, prior authorization requirements of some managed care plans, use of advance beneficiary notices (ABNs) or other financial responsibility forms, handling of individuals' inquiries about financial liability for emergency services, and voluntary withdrawal of a treatment request. Although it does not amend the Code of Federal Regulations, the Special Advisory Bulletin informs individuals of HHS policy regarding application of the patient antidumping statute and offers advice on the best practices to follow to avoid violation of the requirements imposed under that statute.

As discussed further in section V.J.4. of this preamble, we are now proposing to codify certain policies on prior authorization that are currently stated only in the Special Advisory Bulletin. We believe these changes in the regulations are needed to ensure uniform and consistent application of policy and to avoid any misunderstanding of EMTALA requirements by patients, physicians, or hospital employees.

3. EMTALA Provisions in This Proposed Rule

Recently, a number of questions have been raised about the applicability of § 489.24 to specific situations. These questions arise in the context of managed care plans' requirements for prior authorization, case experiences involving elective procedures, and situations when patients have been admitted as inpatients but are not stabilized, or later experience a deterioration in their medical condition. Some hospitals are uncertain whether various conditions of participation found in 42 CFR part 482 apply to these situations or whether the EMTALA requirements included in the provider agreement regulations at § 489.24 apply, or both. Some representatives of the provider community have asked us to reexamine CMS policy on the applicability of EMTALA to provider-based departments. Finally, there have also been questions concerning the applicability of EMTALA to physicians who are "on call" and to hospitals that own ambulances when those ambulances operate under communitywide emergency medical services (EMS) protocols. To help promote consistent application of the regulations concerning the special responsibilities of Medicare hospitals in emergency cases, we are proposing changes to § 489.24 to clarify its application to these situations and at the same time address concerns about EMTALA raised by the Secretary's Advisory Committee on Regulatory Reform. These changes are discussed more fully below and include the following:

- We are proposing to change the requirements relating to emergency patients presenting at those off-campus outpatient clinics that do not routinely provide emergency services. We believe these changes would enhance the quality and promptness of emergency care by permitting individuals to be referred to appropriately equipped emergency facilities close to such clinics.
- We are proposing to clarify when EMTALA applies to both inpatients and

outpatients. We believe these clarifications would enhance overall patient access to emergency services by helping to relieve administrative burdens on frequently overcrowded emergency departments.

- We are proposing to clarify the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff "on-call" lists. We expect these clarifications would help improve access to physician services for all hospital patients by permitting hospitals local flexibility to determine how best to maximize their available physician resources. We are currently aware of reports of physicians, particularly specialty physicians, severing their relationships with hospitals, especially when those physicians belong to more than one hospital medical staff. Physician attrition from these medical staffs could result in hospitals having no specialty physician service coverage for their patients. Our proposed clarification of the on-call list requirement would permit hospitals to continue to attract physicians to serve on their medical staffs and thereby continue to provide services to emergency room patients.

- We are proposing to clarify the responsibilities of hospital-owned ambulances so that these ambulances can be more fully integrated with citywide and local community EMS procedures for responding to medical emergencies and thus use these resources more efficiently for the benefit of these communities.

We solicit comments on all of these proposed changes.

4. Prior Authorization

Some managed care plans may seek to pay hospitals for services only if the hospitals obtain approval from the plan for the services before providing the services. Requirements for this approval are frequently referred to as "prior authorization" requirements. However, EMTALA (specifically, section 1867(h) of the Act and our regulation at § 489.24(c)(3)) explicitly prohibit hospitals from delaying screening or stabilization services in order to inquire about the individual's method of payment or insurance status. Thus, prior authorization requirements are a matter of concern because hospitals could, in seeking prior authorization from an insurer, present a barrier to or delay in the provision of services required by EMTALA.

After review of these considerations, we believe that our existing policy will best implement the intent of the statute by prohibiting a participating hospital from seeking authorization from the

individual's insurance company for screening services or services required to stabilize an emergency medical condition until after the hospital has provided the appropriate medical screening examination required by EMTALA to the patient and has initiated any further medical examination and treatment that may be required to stabilize the patient's emergency medical condition.

We are soliciting comments as to whether the regulations should be further revised to state that the hospital may seek other information (apart from information about payment) from the insurer about the individual, and may seek authorization for all services concurrently with providing any stabilizing treatment, as long as doing so does not delay required screening and stabilization services.

In addition, we are proposing to specify that an emergency physician is not precluded from contacting the patient's physician at any time to seek advice regarding the patient's medical history and needs that may be relevant to the medical screening and treatment of the patient, as long as this consultation does not inappropriately delay required screening or stabilization services.

As explained earlier, this policy was stated in a Special Advisory Bulletin published jointly by CMS (then HCFA) and the OIG. However, we are now proposing to clarify existing language at § 489.24(c)(3) (proposed to be redesignated as paragraph (d)(4)) in this proposed rule to include this policy in the regulations.

5. Hospital Responsibility for Communication With Medicare+Choice Organizations Concerning Post-Stabilization Care Services

Section 422.113 of our existing regulations establishes rules concerning the responsibility of Medicare+Choice organizations for emergency and post-stabilization care services provided to Medicare+Choice enrollees (65 FR 40170, June 29, 2000). Under § 422.113(c)(2), a Medicare+Choice organization is financially responsible for post-stabilization care under certain circumstances, including situations in which the organization cannot be contacted or does not respond timely to a hospital's request for preapproval of this care.

It has come to our attention that, in some instances, hospitals may have failed to contact Medicare+Choice organizations on a timely basis to seek authorization for post-stabilization services. In such a case, the Medicare+Choice organization does not

have the opportunity provided for under the regulations to decide whether to approve the provision of post-stabilization services at the hospital where the emergency services were provided, or to require that the enrollee instead be transferred to another hospital for such services. Therefore, we are proposing to add a new paragraph (d)(6) under § 489.24 to specify that a hospital must promptly contact the Medicare+Choice organization after a Medicare+Choice enrollee who is treated for an emergency medical condition is stabilized.

6. Clarification of "Comes to the Emergency Department"

Section 1867(a) of the Act and our regulations at § 489.24(a) provide, in part, that if any individual comes to the emergency department of a hospital and a request is made on that individual's behalf for examination or treatment of a medical condition, the hospital must provide an appropriate medical screening examination within the capability of the hospital's emergency department. If the hospital determines that such an individual has an emergency medical condition, the hospital is further obligated to provide either necessary stabilizing treatment or an appropriate transfer. Occasionally, questions have arisen as to whether these EMTALA requirements apply to situations in which a patient comes to a hospital, but does not present to the hospital's emergency department. We are proposing to clarify under what circumstances a hospital is obligated under EMTALA to screen, stabilize, or transfer an individual who comes to a hospital, presenting either at its dedicated emergency department, as proposed to be defined below, or elsewhere on hospital property, seeking examination or treatment.

Sometimes individuals come to hospitals seeking examination or treatment for medical conditions that could be emergency medical conditions, but present for examination or treatment at areas of the hospital other than the emergency department. For example, a woman in labor may go directly to the labor and delivery department of a hospital or a psychiatric outpatient experiencing a psychiatric crisis may present at the psychiatry department. In the June 22, 1994 final rule (59 FR 32098), we defined "comes to the emergency department" at § 489.24(b) to clarify that a hospital's EMTALA obligations are triggered whenever an individual presents on hospital property in this manner in an attempt to gain access to the hospital for emergency care and requests examination or

treatment for an emergency medical condition. At the time we adopted this interpretation of "comes to the emergency department," we explained: "We believe that section 1867 of the Act also applies to all individuals who attempt to gain access to the hospital for emergency care. An individual may not be denied services simply because the person failed to actually enter the facility's designated emergency department." (59 FR 32098)

We repeated this standard for situations in which a hospital becomes bound to meet EMTALA's screening and stabilization or transfer requirements with respect to individuals who present on hospital property in an attempt to gain access to the hospital for emergency care, but outside of a hospital's emergency department, in interpretative guidelines published in the State Operations Manual:

"If an individual arrives at a hospital and is not technically in the emergency department, but is on the premises (including the parking lot, sidewalk and driveway) of the hospital and requests emergency care, he or she is entitled to a medical screening examination." (State Operations Manual Appendix V—Responsibilities of Medicare Participating Hospitals in Emergency Cases, V-16)

Thus, an individual can "come to the emergency department," creating an EMTALA obligation on the part of the hospital, in one of two ways: The individual can present at a hospital's dedicated emergency department (as proposed to be defined below) and request examination or treatment for a medical condition; or the individual can present elsewhere on hospital property in an attempt to gain access to the hospital for emergency care (that is, at a location that is on hospital property but is not part of a dedicated emergency department), and request examination or treatment for what may be an emergency medical condition.

Because of the need to clarify the applicability of EMTALA to a particular individual depending on where he or she presents on hospital property in order to obtain emergency care, we are proposing to define "dedicated emergency department." "Dedicated emergency department" would mean a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions, as defined in § 489.24(b), and is either located: (1) On the main hospital campus; or (2) off the main hospital campus and is treated by Medicare under § 413.65(b) as a department of the

hospital. The EMTALA statute was intended to apply to individuals presenting to a hospital for emergency care services. Accordingly, we believe it is irrelevant whether the dedicated emergency department is located on or off the hospital main campus, as long as the individual is presenting to "a hospital" for those services. Therefore, we are proposing in our definition of "dedicated emergency department" that such a department may be located on the main hospital campus, or it may be a department of the hospital located off the main campus. (We note that this proposed definition would encompass not only what is generally thought of as a hospital's "emergency room," but would also include other departments of hospitals, such as labor and delivery departments and psychiatric units of hospitals, that provide emergency or labor and delivery services, or both, or other departments that are held out to the public as an appropriate place to come for medical services on an urgent, nonappointment basis.)

We are soliciting public comment on whether this proposed definition should more explicitly define what is a "dedicated emergency department." Specifically, we are seeking comment on whether a "significant portion of the time" should be defined more objectively; for example, in terms of some minimum number or minimum percentage of patients (20, 30, 40 percent or more of all patients seen) presenting for emergency care at a particular area of the hospital in order for it to qualify as a "dedicated emergency department." As an alternative, we could also consider a qualifying criteria that is based on determining whether the facility is used "regularly" for the evaluation or treatment of emergency medical conditions. Similarly, we are seeking comments on how we could define "regularly" more objectively in our consideration of this alternative. We further seek comments from hospitals, physicians, and others on how hospitals currently organize themselves to react to situations in which individuals come to a hospital requesting a screening examination or medical treatment, or both.

This proposed rule would clarify for hospitals that they must provide at least a medical screening examination to all individuals who present to an area of a hospital meeting the definition of dedicated emergency department and request examination or treatment for a medical condition, or have such a request made on their behalf. As we explain in section V.J.7. of this preamble, individuals who present to an

area of a hospital other than a dedicated emergency department on hospital property must receive a medical screening examination under EMTALA, only when the individual requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf, as provided in the proposed changes to § 489.24(b) in this proposed rule.

7. Applicability of EMTALA: Individual Comes to the Dedicated Emergency Department for Nonemergency Services

We sometimes receive questions as to whether EMTALA's requirements apply to situations in which an individual comes to a hospital's dedicated emergency department, but no request is made on the individual's behalf for emergency medical evaluation or treatment. In view of the specific language of section 1867 of the Act and the discussion in section V.J.6. of this proposed rule, which proposes to define a hospital's dedicated emergency department as a specially equipped and staffed area of the hospital that is used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions located on the main hospital campus or at an off-campus department of the hospital, we believe that a hospital must be seen as having an EMTALA obligation with respect to any individual who comes to the dedicated emergency department, if a request is made on the individual's behalf for examination or treatment for a medical condition, whether or not the treatment requested is explicitly for an emergency condition. A request on behalf of the individual would be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs examination or treatment for a medical condition. This does not mean, of course, that all EMTALA screenings must be equally extensive. The statute plainly states that the objective of the appropriate medical screening examination is to determine whether or not an emergency medical condition exists. Therefore, hospitals are not obligated to provide screening services beyond those needed to determine that there is no emergency.

In general, a medical screening examination is the process required to reach, with reasonable clinical confidence, a determination about whether a medical emergency does or does not exist. We expect that in most cases in which a request is made for medical care that clearly is unlikely to involve an emergency condition, an

individual's statement that he or she is not seeking emergency care, together with brief questioning by qualified medical personnel, would be sufficient to establish that there is no emergency condition and that the hospital's EMTALA obligation would thereby be satisfied.

To clarify our policy in this area, we are proposing to redesignate paragraphs (c) through (h) of § 489.24 as paragraphs (d) through (i) (we are proposing to remove existing paragraph (i), as explained in section V.J.10. of this preamble) and to add a new paragraph (c) to state that if an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an "emergency medical condition" as defined in paragraph (b). (See example 1 below.)

Example 1: A woman walks up to the front desk of a hospital's emergency room, a dedicated emergency department, and tells the hospital employee attending the front desk that she had a wound sutured several days earlier and was directed by her doctor to have the sutures removed that day. The front desk attendant registers the woman according to the hospital's normal registration procedure and directs the woman to the waiting area. An emergency nurse, who has been designated by the hospital as a "qualified medical person" (as provided for in existing § 489.24(a)), calls the woman into the examination area of the emergency room. The nurse asks the woman if she has experienced any discomfort or noticed any problems in the area sutured. The woman explains that she is feeling fine, and the wound is not causing her any discomfort, but that her doctor had directed her a week ago to have the sutures removed that day. The nurse physically inspects the sutures and determines that the wound is healing appropriately. The nurse explains to the woman that she does not have an emergency medical condition and may direct the woman to an outpatient clinic where nonemergency personnel will provide the services the woman has requested.

Application: In this case, the woman presented at the hospital's dedicated emergency department and requested examination or treatment for a medical condition—specifically, she asked that her sutures be removed. Therefore, the hospital is bound under section 1867(a) of the Act to provide her a medical screening examination in order to determine whether or not she has an emergency medical condition. The

actions of the nurse, "a qualified medical person," constitute an appropriate medical screening examination under EMTALA because the nurse has determined, with reasonable clinical confidence, that the woman has no emergency medical condition. This appropriate medical screening examination fully satisfies the hospital's EMTALA obligations as to that woman; because the screening examination revealed no emergency medical condition, the hospital properly referred the woman to an outpatient clinic for nonemergency care.

8. Applicability of EMTALA: Individual Presents at an Area of the Hospital on the Hospital's Main Campus Other Than the Dedicated Emergency Department

Routinely, individuals come to hospitals as outpatients for many nonemergency medical purposes, and if such an individual initially presents at an on-campus area of the hospital other than a dedicated emergency department, we would expect that the individual typically would not be seeking emergency care. Under most of these circumstances, EMTALA would therefore not apply (this concept is further discussed in section V.J.8. of this preamble). A hospital would, however, incur an EMTALA obligation with respect to an individual presenting at that area who requests examination or treatment for what may be an emergency medical condition, or had such a request made on his or her behalf. This policy would not require that an emergency medical condition be found, upon subsequent medical examination, to exist. Rather, EMTALA is triggered in on-campus areas of the hospital other than a dedicated emergency department where, in an attempt to gain access to the hospital for emergency care, an individual comes to a hospital and requests an examination or treatment for a medical condition that may be an emergency.

We are proposing to specify in the regulations that such a request would be considered to exist if the individual requests examination or treatment for what the individual believes to be an emergency medical condition. Where there is no actual request because, for example, the individual is unaccompanied and is physically incapable of making a request, the request from the individual would be considered to exist if a prudent layperson observer would believe, based upon the individual's appearance or behavior, that the individual needs emergency examination or treatment. We believe this proposed policy is appropriate because it would not be

consistent with the intent of section 1867 of the Act to deny its protections to those individuals whose need for emergency services arises upon arrival on hospital on-campus property at the hospital's main campus but have not been presented to the dedicated emergency department.

Under the proposed policies discussed above, a request for examination or treatment by an individual presenting for what may be an emergency medical condition at an on-campus area of the hospital other than the dedicated emergency department would not have to be expressed verbally in all cases, but in some cases should be inferred from what a prudent layperson observer would conclude from an individual's appearance or behavior. While there may be a request (either through the individual or a prudent layperson), thereby triggering an EMTALA obligation on the part of the hospital, this policy does not mean that the hospital must maintain emergency medical screening or treatment capabilities in each department or at each door of the hospital, nor anywhere else on hospital property other than the dedicated emergency department. If an individual presents at an on-campus area of the hospital other than the dedicated emergency department in an attempt to gain access to the hospital for emergency care, EMTALA would mandate that the hospital (as a whole) would provide for screening and stabilizing the individual. For example, upon presentation of an individual requesting emergency care, if the department to which the individual presents cannot readily provide screening and, if needed, stabilization services, the department may arrange for appropriate staff to provide these services. Care required to be provided under EMTALA should be provided in the most appropriate setting, as determined by the hospital.

Example 2: An individual bleeding profusely from a severe scalp laceration enters a hospital through the main entry for hospital visitors, and says to one of the receptionists: "I need help." The receptionist sees that the individual's head is bleeding and, noting his request, arranges to have the individual taken to the dedicated emergency department. Minutes later, the staff from the emergency department arrive and transport the individual to the hospital's emergency department to complete the screening and to give any necessary stabilizing treatment.

Application: The individual presented at an on-campus area of the hospital other than the dedicated emergency department (in this case, the main entry for hospital visitors), with his head bleeding profusely, asking for

help. The receptionist, a prudent layperson observing the individual, believed that the individual was seeking emergency examination or treatment, thereby triggering an EMTALA obligation on the part of the hospital. (We note that EMTALA would have been triggered even if no verbal request had been made, since the individual's appearance indicated the clear possibility of an emergency medical condition.) Since the main entry for hospital visitors did not have emergency examination or treatment capabilities, the receptionist appropriately called the hospital's emergency department to summon emergency department staff to provide emergency care for that individual. Once the emergency department staff arrived and transported the individual to the hospital's emergency department, and provided him with the emergency care needed and stabilized the individual, the hospital had satisfied its EMTALA obligation to that individual.

Again, we solicit comments from hospitals and physicians that give examples of ways in which hospitals presently react to situations such as for the example noted above.

Most individuals who come to hospitals as outpatients come for many nonemergency purposes; under most circumstances, EMTALA would not apply. We are proposing that EMTALA would not apply to such an individual who then experiences what may be an emergency medical condition if the individual is an outpatient (as that term is defined at 42 CFR § 410.2) who has come to the hospital outpatient department for the purpose of keeping a previously scheduled appointment. We would consider such an individual to be an outpatient if he or she has begun an encounter (as that term is defined at § 410.2) with a health professional at the outpatient department. Because such individuals are patients of the hospital already, that is, they have a previously established relationship with the hospital, and have come to the hospital for previously scheduled medical appointments, we believe it is inappropriate that they be considered to have "come to the hospital" for purposes of EMTALA. However, we note that such an outpatient under this proposal who experiences what may be an emergency medical condition after the start of an encounter with a health professional would have all protections afforded to patients of a hospital under the Medicare hospital conditions of participation (as discussed in section V.J.13. of this proposed rule). Hospitals that fail to provide treatment to these

patients could face termination of their Medicare provider agreements for a violation of the conditions of participation. In addition, as patients of a health care provider, these individuals are accorded protections under State statutes or common law as well as under general rules of ethics governing the medical professions.

Example 3: A patient who had been discharged from inpatient status following knee replacement surgery comes to the hospital outpatient department for a physical therapy session which had been scheduled 2 weeks earlier. While undergoing therapy, the patient complains of chest pains and lightheadedness. Acting under protocols established by the hospital, staff of the outpatient department contact the hospital's dedicated emergency department, which dispatches appropriate personnel to the department. The patient is taken to the hospital's dedicated emergency department for examination. Upon arrival in the dedicated emergency department, she is given a medical screening examination, which reveals that she has an emergency medical condition related to coronary artery disease. She is stabilized in the dedicated emergency department and is released to the care of her daughter.

Application: In this case, the individual is an outpatient. While she is in a physical therapy session in an outpatient department of the hospital, she experiences what may be an emergency medical condition—chest pains and lightheadedness. This outpatient is under the care of the hospital; she is in a previously scheduled physical therapy appointment and clearly has a previously established relationship with the hospital. In addition, the encounter with hospital staff has begun since her condition arose while she was undergoing therapy. Therefore, although the individual may be experiencing what may be an emergency medical condition, the hospital is not obligated under EMTALA. However, the hospital appropriately provided treatment for this patient, as required under the Medicare conditions of participation (specifically, 42 CFR § 482.55, which requires the hospital to fulfill its condition of participation responsibility for emergency care by contacting the hospital's dedicated emergency department and providing care to the individual through staff of that department). We solicit comments from hospitals and physicians as to what current practices are when an outpatient with a previously scheduled appointment experiences an emergency medical condition.

We are proposing to retitle the definition of "property" at § 489.24(b) to "hospital property" and relocate it as a

separate definition. In addition, we are proposing to clarify which areas and facilities are not considered hospital property.

9. Scope of EMTALA Applicability to Hospital Inpatients

While most issues regarding EMTALA arise in connection with ambulatory patients, questions have occasionally been raised about whether EMTALA applies to inpatients. In late 1998, the United States Supreme Court considered a case (*Roberts v. Galen of Virginia*) that involved, in part, the question of whether EMTALA applies to inpatients in a hospital. In the context of that case, the United States Solicitor General advised the Supreme Court that the Department of Health and Human Services (DHHS) would develop a regulation clarifying its position on that issue. After reviewing the issue in the light of the EMTALA statute, we are proposing that EMTALA would apply to inpatients only under limited circumstances, as described in the following paragraphs.

As noted earlier, once a hospital has incurred an EMTALA obligation with respect to an individual, that obligation continues while the individual remains at the hospital, so that any transfer to another medical facility or discharge of the individual must be in compliance with the rules restricting transfer until the individual is stabilized under existing § 489.24(d). In many cases, medical judgment will dictate that a patient be admitted to the hospital for further treatment on an inpatient basis because the patient's emergency medical condition has not yet been stabilized.

In these cases, the hospital continues to be obligated under section 1867, irrespective of the inpatient admission. Admitting an individual whose emergency medical condition has not been stabilized does not relieve the hospital of further responsibility to the individual under this section. An individual's emergency medical condition will be considered to have been stabilized only when the criteria in § 489.24(b) are met; that is, the individual's condition must be such that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during a transfer of the individual from the facility or, if the patient is a pregnant woman who is having contractions, that the woman has delivered the child and the placenta.

Consistent with the above policy, we emphasize that an admission to inpatient status cannot be used to evade EMTALA responsibilities. Indeed,

permitting inpatient admission to end EMTALA obligations would provide an obvious means of circumventing these requirements that would seemingly contradict the point of the statute to protect emergency patient health and safety. This point should be particularly evident in the case of a woman in labor, a central focus of the statute. Such women are frequently admitted, and the statute clearly contemplated protecting them until completion of the delivery (that is, stabilization). In addition, if an inpatient who had been admitted from the dedicated emergency department with an unstabilized emergency medical condition was never stabilized as an inpatient and is transferred, we would still apply EMTALA in reviewing the transfer. In this context, stability for transfer reflects a complex medical judgment that can be made only based on review of all relevant information in each particular case, including all conditions that could cause the patient to be medically unstable. A patient who goes in and out of apparent stability with sufficient rapidity or frequency would not be considered "stabilized" within the meaning of § 489.24; transient stability of such a patient does not relieve the hospital of its EMTALA obligation. Such a patient would continue to be covered by EMTALA until the patient's overall medical stability with respect to all conditions is achieved.

Except for the limited circumstances described above, we are proposing to clarify that EMTALA does not apply to hospital inpatients. We believe EMTALA does not apply to hospital inpatients because we interpret section 1867 of the Act by reading the statutory language as a whole, with the requirements of paragraphs (b), "Necessary Stabilizing Treatment for Emergency Medical Conditions and Labor," and (c), "Restricting Transfer Until Individual is Stabilized," applying only to those individuals who satisfy the threshold requirement of coming to the hospital and requesting emergency care (as interpreted in this proposed regulation). This interpretation is based upon the statutory language and the legislative history. First, the Congress defined "emergency medical condition" at section 1867(e)(1) of the Act by referring solely to "acute symptoms," which are self-identified, and did not mention other potentially relevant indications, in particular, signs or objective data. "Signs" are observable findings that are identified or confirmed by a clinician based on examination and use of objective data (for example, physiologic measurements, x-ray

results). When a patient's condition deteriorates in the inpatient setting, awareness of a situation potentially requiring emergency care is based on any symptoms, signs, and objective data, reflecting a situation that is not captured by the targeted definition at section 1867(e)(1) of the Act. If the Congress had intended EMTALA to apply to transfers at any time during an inpatient stay, it would not have used a definition of emergency medical condition that focuses exclusively on symptoms and that uniquely defines the individual's status at the time of his or her initial presentation to the hospital, not his or her status as an inpatient. Furthermore, the definition of "appropriate transfer" in paragraph (c)(2) of section 1867 of the Act includes a variety of terms (observation, signs, symptoms, preliminary diagnosis) associated with patient information that is gathered at the initial stage of clinical intervention, when the course of treatment is just beginning. Thus, it would appear to be clear that the authors of this legislation understood the precise meanings of these clinical terms and utilized them accordingly. Further indication that Congress intended this result is the language in section 1867(b)(1)(A) of the Act (stabilization), which requires that the hospital provide "for such further medical examination" as necessary to stabilize. Congress' use of the word "further" acknowledges that there was some initial treatment that occurred in the emergency department.

In addition, the legislative history of EMTALA is replete with references to the problem of individuals denied emergency medical care at hospital emergency rooms, whereas there is no explicit reference to similar problems faced by hospital inpatients. (See, for example, 131 Cong. Rec. 28,587 and 28,588 (1985)). When the Congress considered the need for EMTALA legislation, it noted that Medicare-participating hospitals were bound to meet hospital conditions of participation, but that no specific requirements then existed for appropriate treatment of emergency patients. (See H.R. Rept. No. 241 (I)(1985), reprinted in 1986 U.S.C.C.A.N. 579, 605.) Arguably, the Congress also considered other protections available to hospital inpatients (for example, private causes of action).

This interpretation that EMTALA was not intended to apply to transfers at any time during an inpatient's stay is further supported by the language of the appropriate transfer provisions of section 1867(c) of the Act. While that paragraph does refer to individuals at a

“hospital,” rather than individuals at an “emergency department,” the same paragraph also makes reference to actions to be taken by “a physician * * * physically present in the emergency department.” This explicit mention of a hospital emergency department, even in a paragraph that generally cites an individual at a “hospital,” supports the view that EMTALA was not intended to apply to admitted inpatients who may become unstable subsequent to admission, but only to patients who initially come to the hospital’s emergency department with an emergency medical condition, and only until the condition has been stabilized. Finally, we note that once a hospital admits an individual as a patient, that hospital has a variety of other legal, licensing, and professional obligations with respect to the continued proper care and treatment of such patients.

a. Admitted Emergency Patients. A related issue concerns whether a hospital may satisfy its EMTALA obligations to an admitted emergency inpatient only by effectuating an actual stable discharge or appropriate transfer. We are proposing to clarify that even when an admitted emergency patient is not actually transferred, a determination may be made as to whether or not the patient has been stabilized such that he or she could be transferred at a certain point without likely material deterioration of the patient’s condition, as defined in section 1867(e)(3)(B) of the Act. Under our proposed policy, if the admitted emergency patient could have been transferred as “stable” under the statute and the period of stability is documented by relevant clinical data in the patient’s medical record, the hospital has satisfied its EMTALA obligation by meeting the statutory requirement of providing stabilizing treatment to the point of stability for transfer, and the hospital’s obligation under EMTALA ends, even though the patient may remain in inpatient status at the hospital. If, after stabilization, the individual who was admitted as an inpatient again has an apparent decline of his or her medical condition, either as a result of the injury or illness that created the emergency for which he or she initially came to the dedicated emergency department or as a result of another injury or illness, the hospital must comply with the conditions of participation under 42 CFR Part 482, but has no further responsibility under EMTALA with respect to the individual.

We also note that, just because a hospital may stabilize a patient for purposes of ending its EMTALA obligation to that patient, this does not

relieve the hospital of any further health and safety obligations as to that patient under the Medicare program. While they remain patients in that hospital, these patients are still protected by a number of Medicare health and safety standards (conditions of participation), as explained further below. In addition, as explained above, nothing under EMTALA in any way changes a hospital’s other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

Example 4: A patient comes to Hospital C’s emergency department and requests treatment for an emergency medical condition. The patient knows he has severe heart disease and his chest pains have become more frequent. The patient receives an appropriate medical screening examination and is found to have an emergency medical condition, as indicated by a pain pattern and EKG abnormalities consistent with unstable angina. Stabilizing treatment in the emergency department on an outpatient basis, consisting of oxygen, nitrates and heparin, is initiated.

After several hours of outpatient care, the emergency physician determines that the patient is still not stable for purposes of discharge to his home. The emergency physician concludes that the patient can be treated most effectively by being admitted to Hospital C where he is currently being treated as an outpatient. The patient is admitted as an inpatient for further treatment. The attending physician knows that patients with indications for coronary angioplasty are usually transferred to Hospital D in another city because Hospital D has specialized capabilities that are unavailable at admitting Hospital C. A trip to Hospital D typically requires 2 hours travel by ground ambulance. The physician determines that the patient is stable for purposes of this type of transfer; that is, such a transfer is not likely to result in a material deterioration of the patient’s condition, and documents relevant clinical data in the patient’s medical record. Even though patients with this degree of coronary arterial disease and acute infarction risk are usually transferred, the patient opposes transfer and wants to remain in the local community. In accordance with the wishes of the patient and his family, the attending physician agrees to treat the patient in Hospital C while informing the patient of the risks involved.

Application: In this situation, the admitted patient is not stable for purposes of discharge to his home but the attending physician determined that the patient is stable for the type of transfer usually undertaken by Hospital C for patients with unstable angina considered for angioplasty. This stabilization, which is documented by relevant clinical data in the patient’s medical record, ends Hospital C’s EMTALA obligation to the patient, and that obligation would not be reinstated

by any subsequent deterioration in the patient’s condition.

We are proposing to redesignate paragraph (c) of § 489.24 as paragraph (d), and include these stabilization requirements under a new proposed § 489.2(d)(2). (Proposed redesignated paragraph (d) would be revised further as explained in section V.K.9.b. of this preamble.)

b. Admitted Elective (Nonemergency) Patients. Most hospital admissions do not consist of emergency cases. In most cases, a patient who comes to the hospital and requests admission does so to obtain elective (nonemergency) diagnosis or treatment for a medical condition. Questions have arisen, however, as to whether a hospital would be bound under EMTALA in the situation in which an admitted nonemergency inpatient experiences a deterioration of his or her medical condition.

Under our interpretation of section 1867 of the Act as described above, we believe EMTALA was intended to provide protection to patients coming to a hospital to seek care for an emergency condition. Therefore, we believe that the EMTALA requirements do not extend to admitted nonemergency inpatients. These patients are protected by a number of the Medicare hospital conditions of participation, as explained further under section V.K.13. of this preamble. These patients are further protected by a hospital’s other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

We are proposing to also include these requirements under the proposed redesignated § 489.24(d)(2).

10. Applicability of EMTALA to Provider-Based Entities

On April 7, 2000, we published a final rule specifying the criteria that must be met for a determination regarding provider-based status (65 FR 18504). The regulations in that the April 2000 final rule were subsequently revised to incorporate changes mandated by section 404 of Public Law 106–554 (66 FR 59856, November 30, 2001). However, those revisions did not substantively affect hospitals’ obligations with respect to off-campus departments.

a. Applicability of EMTALA to Off-Campus Hospital Departments. In the April 7, 2000 final rule (65 FR 18504), we also clarified the applicability of EMTALA to hospital departments not located on the main provider campus. At that time, we revised § 489.24 to include a new paragraph (i) to specify the antidumping obligations of hospitals

with respect to individuals who come to off-campus hospital departments for the examination or treatment of a potential emergency medical condition. As explained in the preamble to the April 7, 2000 final rule, we made this change because we believed it was consistent with the intent of section 1867 of the Act to protect individuals who present on hospital property (including off-campus hospital property) for emergency medical treatment. Since publication of the April 7, 2000 final rule, it has become clear that many hospitals and physicians continue to have significant concerns with our policy on the applicability of EMTALA to these off-campus locations. After further consideration, we are proposing to clarify the scope of EMTALA's applicability in this scenario to those off-campus departments that are treated by Medicare under § 413.65(b) to be departments of the hospital, and that are equipped and staffed areas that are used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions. That is, we are proposing to narrow the applicability of EMTALA to only those off-campus departments that are "dedicated emergency departments" as defined in proposed revised § 489.24(b).

This proposed definition would include such departments whether or not the words "emergency room" or "emergency department" were used by the hospital to identify the departments. The definition would also be interpreted to encompass those off-campus hospital departments that would be perceived by a prudent layperson as appropriate places to go for emergency care. Therefore, we are proposing to revise the definition of "Hospital with an emergency department" at § 489.24(b) to account for these off-campus dedicated emergency departments and to also amend the definition of "Comes to the emergency department" at § 489.24(b) to include this same language. We believe this proposed change would enhance the quality of emergency care by facilitating the prompt delivery of emergency care in those cases, thus permitting individuals to be referred to nearby facilities with the capacity to offer appropriate emergency care.

In general, we expect that off-campus departments that meet the proposed definitions stated above would in practice be functioning as "off-campus emergency departments." Therefore, we believe it is reasonable to expect the hospital to assume, with respect to these off-campus departments, all EMTALA obligations that the hospital must assume with respect to the main

hospital campus emergency department. For instance, the screening and stabilization or transfer requirements described in section V.K.1. of this preamble ("Background") would extend to the off-campus emergency departments, as well as to any such departments on the main hospital campus.

In conjunction with this proposed change in the extent of EMTALA applicability with respect to off-campus facilities, we are also proposing to delete all of existing § 489.24(i), which, as noted above, was established in the April 7, 2000 final rule. We are proposing to delete this paragraph in its entirety because its primary purpose is to describe a hospital's EMTALA obligations with respect to patients presenting to off-campus departments that do not routinely provide emergency care. Under the proposals outlined above, however, a hospital would have no EMTALA obligation with respect to individuals presenting to such departments. Therefore, it would no longer be necessary to impose the requirements in existing § 489.24(i). Even though off-campus provider-based departments that do not routinely offer services for emergency medical conditions would not be subject to EMTALA, some individuals may occasionally come to them to seek emergency care. Under such circumstances, we believe it would be appropriate for the department to call an emergency medical service (EMS) if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of EMS personnel. Consistent with the hospital's obligation to the community and similar to our requirements under § 482.12(f)(2) that apply to hospitals that do not provide emergency services, we would expect the hospital to have appropriate protocols in place for dealing with individuals who come to off-campus nonemergency facilities to seek emergency care. To clarify a hospital's responsibility in this regard, we are proposing to revise § 482.12(f) by adding a new paragraph (3) to state that if emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff of the hospital has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate. (We note that, in a separate document (62 FR 66758, December 16, 1997), we proposed to relocate the existing § 482.12(f)

requirement to a new section of Part 482. Any change to the existing § 482.12(f) that is adopted as a result of the proposal described above will be taken into account in finalizing the December 19, 1997 proposal.) However, the hospital would not incur an EMTALA obligation with respect to the individual.

In summary, we are proposing in existing § 489.24(b) to revise the definitions of "comes to the emergency department" and "hospital with an emergency department", and to include these off-campus departments in our new definition of "dedicated emergency department." We welcome comments on whether this new term is needed or if the term "emergency department" could be defined more broadly to encompass other departments that provide urgent or emergent care services. We are proposing to delete all of existing § 489.24(i) and to make conforming revisions to § 413.65(g)(1).

b. On-Campus Provider-Based Applicability. At existing § 413.65(g)(1), we state, in part, that if any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus, and a request is made on the individual's behalf for examination or treatment of a medical condition, the entity must comply with the antidumping rules at § 489.24. Since provider-based entities, as defined in § 413.65(b), are not under the certification and provider number of the main provider hospital, this language, read literally, would appear to impose EMTALA obligations on providers other than hospitals, a result that would not be consistent with section 1867, which restricts EMTALA applicability to hospitals. To avoid confusion on this point and to prevent any inadvertent extension of EMTALA requirements outside the hospital setting, we are proposing to clarify that EMTALA applies in this scenario to only those *departments* on the hospital's main campus that are provider-based; EMTALA would not apply to provider-based *entities* (such as RHCs) that are on the hospital campus.

In addition, we are proposing in § 489.24(b) to revise the definition of "Comes to the emergency department" to include an individual who presents on hospital property, in which "hospital property" is in part defined as "the entire main hospital campus as defined at § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures that may be located within 250 yards of the hospital's main building but are not part of the hospital, such as physician offices, RHCs, SNFs, or other entities

that participate separately in Medicare, or restaurants, shops, or other nonmedical facilities." We are specifically seeking comments on this proposed revised definition. Generally, this proposed language would clarify that EMTALA does not apply to provider-based entities, whether or not they are located on a hospital campus. This language is also consistent with our policy as stated in questions and answers published on the CMS website: www.cms.gov (CMS EMTALA guidance, 7/20/01, Q/A # 1) that clarifies that EMTALA does not apply to other areas or structures located on the hospital campus that are not part of the hospital, such as fast food restaurants or independent medical practices.

If this proposed change limiting EMTALA applicability to only those on-campus departments of the hospital becomes finalized, we believe that if an individual comes to an on-campus provider-based entity or other area or structure on the campus not applicable under the new policy and presents for emergency care, it would be appropriate for the entity to call the emergency medical service if it is incapable of treating the patient, and to render whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. However, the hospital on whose campus the entity is located would not incur an EMTALA obligation with respect to the individual.

We welcome comments from providers and other interested parties on the proper or best way to organize hospital resources to react to situations on campus where an individual patient or prospective patient requires immediate medical attention.

We are proposing in § 489.24(b) to revise the definition of "Comes to emergency department" (specifically, under proposed new paragraph (1)) and make conforming changes at § 413.65(g)(1).

11. EMTALA and On-Call Requirements

We have frequently received inquiries concerning the applicability of EMTALA for physicians on call. We believe there are a number of misconceptions in the provider industry concerning the extent to which EMTALA requires physicians to provide on-call coverage. Therefore, we are including a section in this preamble that clarifies what kinds of obligations physicians have to provide on-call coverage under EMTALA.

Section 1866(a)(1)(I)(iii) of the Act states, as a requirement for participation in the Medicare program, that hospitals must keep a list of physicians who are

on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. If a physician on the list is called by a hospital to provide emergency screening or treatment and either fails or refuses to appear within a reasonable period of time, the hospital and that physician may be in violation of EMTALA as provided for under section 1867(d)(1)(C) of the Act.

The CMS State Operations Manual (SOM) further clarifies a hospital's responsibility for the on-call physician. The SOM (Appendix V, page V-15, Tag A404) states:

- Each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients.
- Physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times. The hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

Thus, hospitals are required to maintain a list of physicians on call at any one time and physicians or hospitals, or both, may be responsible under the EMTALA statute to provide emergency care if a physician who is on the on-call list fails to or refuses to appear within a reasonable period of time. However, Medicare does not set requirements on how frequently a hospital's staff of on-call physicians are expected to be available to provide on-call coverage. We are aware that practice demands in treating other patients, conferences, vacations, days off, and other similar factors must be considered in determining the availability of staff. We also are aware that some hospitals, particularly those in rural areas, have stated that they incur relatively high costs of compensating physician groups for providing on-call coverage to their emergency departments, and that doing so can strain their already limited financial resources. CMS allows hospitals flexibility to comply with EMTALA obligations by maintaining a level of on-call coverage that is within their capability.

We understand that some hospitals exempt senior medical staff physicians from being on call. This exemption is typically written into the hospital's medical staff bylaws or the hospital's rules and regulations, and recognizes a physician's active years of service (20 or more years) or age (that is, 60 years of age or older), or a combination of both. We wish to clarify that providing such exemptions to members of hospitals'

medical staff does not necessarily violate EMTALA. On the contrary, we believe that the hospital is responsible for maintaining an on-call list in a manner that best meets the needs of its patients as long as the exemption does not affect patient care adversely. Thus, CMS allows hospitals flexibility in the utilization of their emergency personnel.

We also note that there is no predetermined "ratio" that CMS uses to identify how many days that a hospital must provide medical staff on-call coverage based on the number of physicians on staff for that particular specialty. In particular, CMS has no rule stating that whenever there are at least three physicians in a specialty, the hospital must provide 24 hour/7 day coverage. Generally, in determining EMTALA compliance, CMS will consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patients typically require services of on-call physicians, and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on-call physician is unable to respond.

Example 5: Hospital D has 75 beds and is located in a rural area. The hospital provides on-call coverage of orthopedic services on all weekdays and the first 3 weekends of each month. On the fourth weekend of one month, an individual presents at Hospital D's dedicated emergency department and requests examination for a medical condition. The emergency physician on duty screens the individual and finds that she has an orthopedic emergency medical condition requiring the services of an orthopedist. Hospital D does not have on-call orthopedic physician coverage on this date and, therefore, transfers the individual to an urban hospital 20 miles away for necessary treatment. The transfer is arranged in accordance with procedures that Hospital D has for meeting patient needs when a particular specialty is not available or the physician cannot respond for reasons beyond his or her control.

Analysis: Hospital D incurred an EMTALA obligation when the individual presented at Hospital D's dedicated emergency department and requested examination for a medical condition. At that time, Hospital D did not have on-call coverage to provide necessary stabilizing treatment for what was an orthopedic emergency medical condition, even though an orthopedic physician was on-call at other times. The emergency physician at Hospital D weighed the risks involved to transfer the individual to an urban hospital with capabilities to treat the individual and found that it would be more beneficial to the individual to transfer him or her

to the urban hospital 20 miles away, than to provide screening and stabilizing treatment within Hospital D's capabilities (which, at that time, did not include orthopedic services). Hospital D has satisfied its EMTALA obligation by providing screening services within its capability, followed by an appropriate transfer, under procedures developed in advance. To clarify our policies on EMTALA requirements regarding the availability of on-call physicians, we are proposing to add to § 489.24 a new paragraph (j) to specify that each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients. This paragraph would further specify that physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times, and that the hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

12. EMTALA Applicability to Hospital-Owned Ambulances

We stated in the June 22, 1994 final rule (59 FR 32098) that if an individual is in an ambulance owned and operated by a hospital, the individual is considered to have come to the hospital's emergency department, even if the ambulance is not on hospital property. This policy, currently set forth at § 489.24(b), was necessary because we were concerned that some hospitals that owned and operated ambulances at that time were transporting individuals who had called for an ambulance to other hospitals, thereby evading their EMTALA responsibilities to the individuals.

Concerns have since been raised by the provider industry about applications of this policy to ambulances that are owned by hospitals but are operating under communitywide EMS protocols that may require the hospital-owned and other ambulances to transport individuals to locations other than the hospitals that own the ambulances. For instance, we understand that some community protocols require ambulances to transport individuals to the nearest hospital to the patient geographically, whether or not that hospital owns the ambulance.

To avoid imposing requirements that are inconsistent with local EMS requirements, we are proposing to clarify, at proposed revised § 489.24(b) in the definition of "Comes to the emergency department", an exception to our existing rule requiring EMTALA applicability to hospitals that own and

operate ambulances. Our proposal would account for hospital-owned ambulances operating under communitywide EMS protocols. Under our proposal, the rule on hospital-owned ambulances and EMTALA does not apply if the ambulance is operating under a communitywide EMS protocol that requires it to transport the individual to a hospital other than the hospital that owns the ambulance. In this case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property.

13. Conditions of Participation for Hospitals

We are reminding hospitals and others that while this proposed regulation would make it clear that stabilizing an emergency inpatient relieves the hospital of its EMTALA obligations, it does not relieve the hospital of all further responsibility for the patient who is admitted or indicate that the hospital is thus free to improperly discharge or transfer him or her to another facility. Inpatients who experience acute medical conditions receive protections under the hospital conditions of participation, which are found at 42 CFR part 482. In addition, as noted earlier in this preamble, we believe that outpatients who experience what may be an emergency medical condition after the start of an encounter with a health professional would have all protections afforded to patients of a hospital under the Medicare conditions of participation. There are six conditions of participation that provide these protections: emergency services, governing body, discharge planning, quality assurance, medical staff, and outpatient services. We are not proposing in this proposed rule to make changes to any of the conditions of participation.

If a hospital inpatient develops an acute medical condition and the hospital is one that provides emergency services, the hospital is required to ensure that it meets the emergency needs of the patient in accordance with accepted standards of practice. Similarly, regardless of whether the hospital provides emergency services, if an inpatient develops an acute medical condition, the governing body condition of participation (§ 482.12(f)(2), which applies to all Medicare-participating hospitals) would apply. This condition of participation requires that the hospital governing body must ensure that the medical staff has written policies and procedures for appraisal of

emergencies, initial treatment, and referral when appropriate.

The discharge planning condition of participation (§ 482.43, which applies to all Medicare-participating hospitals) requires hospitals to have a discharge planning process that applies to all patients. This condition of participation ensures that patient needs are identified and that transfers and referrals reflecting adequate discharge planning are made by the hospital. If an inpatient develops an acute medical condition and the hospital either does not offer emergency services or does not have the capability to provide necessary treatment, a transfer to another hospital with the capabilities to treat the emergency medical condition could be warranted. Hospitals are required to meet the discharge planning condition of participation in carrying out such a transfer.

The hospital condition of participation governing medical staff (§ 482.22) requires that the hospital have an organized medical staff that operates under bylaws approved by the governing body and is responsible to the governing body for the quality of medical care provided to patients by the hospital. Should the medical staff not be held accountable to the governing body for problems regarding a lack of provision of care to an inpatient who develops an emergency medical condition, this lack of accountability may be reviewed under the medical staff condition of participation, as well, and may result in a citation of noncompliance at the medical staff condition level for the hospital.

Finally, the quality assurance condition of participation (§ 482.21, which applies to all Medicare-participating hospitals) requires the governing body to ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care. In order to comply with this condition of participation, the hospital must evaluate the care it provides hospital-wide. Complaints regarding a lack of provision of care to an inpatient who develops an emergency medical condition must be addressed under the hospital's quality assurance program and may be reviewed under the quality assurance condition of participation.

A hospital's failure to meet the conditions of participation requirements cited above may result in a finding of noncompliance at the condition level for the hospital and lead to termination of the hospital's Medicare provider agreement.

K. Provider-Based Entities

1. Background

a. The April 7, 2000 Final Rule

Since the beginning of the Medicare program, some providers, which we refer to as “main providers,” have functioned as a single entity while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments for services furnished at the provider-based facility, and may also increase the coinsurance liability of Medicare beneficiaries for those services.

In the April 7, 2000 **Federal Register** (65 FR 18504), we published a final rule specifying the criteria that must be met for a determination regarding provider-based status. The regulations at § 413.65(a)(2) define provider-based status as “the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.” The regulations at existing § 413.65(b)(2) state that before a main provider may bill for services of a facility as if the facility is provider-based, or before it includes costs of those services on its cost report, the facility must meet the criteria listed in the regulations at § 413.65(d). Among these criteria are the requirements that the main provider and the facility must have common licensure (when appropriate), the facility must operate under the ownership and control of the main provider, and the facility must be located in the immediate vicinity of the main provider.

The effective date of these regulations was originally October 10, 2000, but was subsequently delayed and is now in effect for new facilities or organizations for cost reporting periods beginning on or after January 10, 2001, as explained further below. Program instructions on provider-based status issued before that date, found in Section 2446 of the Provider Reimbursement Manual, Part 1 (PRM-1), Section 2004 of the Medicare State Operations Manual (SOM), and CMS Program Memorandum (PM) A-99-24, will apply to any facility for periods before the new regulations become applicable to it. (Some of these instructions will not be applied because they have been superseded by specific legislation on provider-based status, as

described in section V.K.3. of this preamble).

b. Frequently Asked Questions Regarding Provider-Based Issues

Following publication of the April 7, 2000 final rule, we received many requests for clarification of policies on specific issues related to provider-based status. In response, we published a list of “Frequently Asked Questions” and the answers to them on the CMS website at www.hcfa.gov/medlearn/provqa.htm. (This document can also be obtained by contacting any of the CMS (formerly, HCFA) Regional Offices.) These questions and answers did not revise the regulatory criteria, but do provide subregulatory guidance for their implementation.

c. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106-554)

On December 21, 2000, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Public Law 106-554) was enacted. Section 404 of BIPA contains provisions that significantly affect the provider-based regulations at § 413.65. Section 404 includes a grandfathering provision for facilities treated as provider-based on October 1, 2000; alternative criteria for meeting the geographic location requirement; and criteria for temporary treatment as provider-based.

(1) Two-Year “Grandfathering”

Under section 404(a) of BIPA, any facilities or organizations that were “treated” as provider-based in relation to any hospital or CAH on October 1, 2000, will continue to be treated as such until October 1, 2002. For the purpose of this provision, we interpret “treated as provider-based” to include those facilities with formal CMS determinations, as well as those facilities without formal CMS determinations that were being paid as provider-based as of October 1, 2000. As a result, existing provider-based facilities and organizations may retain that status without meeting the criteria in the existing regulations under §§ 413.65(d), (e), (f), and (h) until October 1, 2002. These provisions concern provider-based status requirements, joint ventures, management contracts, and services under arrangement. Thus, the provider-based facilities and organizations affected under section 404(a) of BIPA are not required to submit an application for or obtain a provider-based status determination in order to

continue receiving reimbursement as provider-based during this period.

These provider-based facilities and organizations are not exempt from the EMTALA responsibilities of provider-based facilities and organizations set forth at § 489.24, which we are proposing to revise as discussed above, or from the other obligations of hospital outpatient departments and hospital-based entities in existing § 413.65(g), such as the responsibility of off-campus facilities to provide written notices to Medicare beneficiaries of coinsurance liability. These rules are not preempted by the grandfathering provisions of section 404 of BIPA because they do not set forth criteria that must be met for provider-based status as a department of a hospital, but instead identify responsibilities that flow from that status. These responsibilities become effective for hospitals on the first day of the hospital’s cost reporting period beginning on or after January 10, 2001.

(2) Geographic Location Criteria

Section 404(b) of BIPA provides that those facilities or organizations that are not included in the grandfathering provision at section 404(a) are deemed to comply with the “immediate vicinity” requirements of the existing regulations under § 413.65(d)(7) if they are located not more than 35 miles from the main campus of the hospital or CAH. Therefore, those facilities located within 35 miles of the main provider satisfy the immediate vicinity requirement as an alternative to meeting the “75/75 test” under existing § 413.65(d)(7).

In addition, BIPA provides that certain facilities or organizations are deemed to comply with the requirements for geographic proximity (either the “75/75 test” or the “35-mile test”) if they are owned and operated by a main provider that is a hospital with a disproportionate share adjustment percentage greater than 11.75 percent and is (1) owned or operated by a unit of State or local government, (2) a public or private nonprofit corporation that is formally granted governmental powers by a unit of State or local government, or (3) a private hospital that has a contract with a State or local government that includes the operation of clinics of the hospital to ensure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare or Medicaid.

These geographic location criteria will continue indefinitely. While those facilities or organizations treated as provider-based on October 1, 2000 are covered by the 2-year grandfathering

provision noted above, the geographic location criteria at section 404(b) of BIPA and the existing regulations at § 413.65(d)(7) will apply to facilities or organizations not treated as provider-based as of that date, effective with the hospital's cost reporting period beginning on or after January 10, 2001. On October 1, 2002, the statutory moratorium on application of these criteria to the grandfathered facilities will expire. In this proposed rule, we are proposing a further delay, as discussed below.

(3) Criteria for Temporary Treatment as Provider-Based

Section 404(c) of BIPA also provides that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000, and before October 1, 2002, shall be treated as having provider-based status for any period before a determination is made. Thus, recovery for overpayments will not be made retroactively once a request for a determination during that time period has been made. For hospitals that do not qualify for grandfathering under section 404(a) of BIPA, a request for provider-based status should be submitted to the appropriate CMS Regional Office. Until a uniform application is available, at a minimum, the request should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation for purposes of applying the provider-based status criteria in effect at the time the application is submitted. Once such a request has been submitted on or after October 1, 2000, and before October 1, 2002, CMS will treat the facility or organization as being provider-based from the date it began operating as provider-based until the effective date of a CMS determination that the facility or organization is not provider-based.

Facilities requesting a provider-based status determination on or after October 1, 2002, will not be covered by the provision concerning temporary treatment as provider-based in section 404(c) of BIPA. Thus, as stated in § 413.65(n), the CMS Regional Offices will make provider-based status effective as of the earliest date on which a request for determination has been made and all requirements for provider-based status in effect as of the date of the request are shown to have been met, not on the date of the formal CMS determination. Under existing regulations at § 413.65(j), if a facility or organization does not qualify for provider-based status and CMS learns that the provider has treated the facility

or organization as provider-based without having obtained a provider-based determination under applicable regulations, CMS will review all payments and may seek recovery for overpayments, including overpayments made for the period of time between submission of the request or application for provider-based status and the issuance of a formal CMS determination. (As explained in the previous paragraph, such retroactive recovery of payments would not be made for any period to the extent it is prohibited by section 404(c) of BIPA.)

d. The August 24, 2001 and November 30, 2001 Published Regulations

In August 24, 2001 **Federal Register** (66 FR 44672), we proposed to revise the provider-based regulations to reflect the changes mandated by section 404 of BIPA and to make other technical and clarifying changes in those regulations. In the November 30, 2001 **Federal Register** (66 FR 59856), following consideration of public comments received on the August 24, 2001 proposal, we published a final rule that revised the provider-based regulations. However, the only substantive changes in the provider-based regulations were those required by the BIPA legislation.

2. Proposed Changes

In the preamble to the proposed rule published on August 24, 2001 (66 FR 44709), we stated our intent to reexamine the EMTALA regulations and, in particular, to reconsider the appropriateness of applying EMTALA to off-campus locations. We announced that we planned to review these regulations with a view toward ensuring that these locations are treated in ways that are appropriate to the responsibility for EMTALA compliance of the hospital as a whole. We also pointed out that, at the same time, we want to ensure that those departments that Medicare pays as hospital-based departments are appropriately integrated with the hospital as a whole.

In addition, since the statutory grandfathering provision in the BIPA legislation remains in effect only until October 1, 2002, many hospital representatives have contacted CMS to request more guidance because they are concerned that their facilities are not in compliance with existing regulations and would not be able to continue billing as provider-based once the grandfathering provision expires. These hospital representatives are also concerned that the organizational and contractual changes needed to meet current provider-based requirements could take several months to complete.

Moreover, resolution of some of the issues surrounding the provider-based regulations is needed in order to allow development of a uniform application form to enable the CMS Regional Offices to efficiently process the multitudes of requests for provider-based determinations that we expected as the grandfathering period expires.

To address the provider-based issues raised by the hospital industry and to allow for an orderly and uniform implementation strategy once grandfathering ends, we are proposing the following regulatory changes:

a. Scope of Provider-Based Requirements (§ 413.65(a))

Since publication of the April 2000 final rule, we have received many questions about which specific facilities or organizations are subject to the provider-based requirements. In the "Frequently Asked Questions" posted on the CMS website, we identified a number of facility types for which provider-based determinations would not be made, since such determinations would not affect either Medicare payment or Medicare beneficiary liability or scope of benefits. The regulations at § 413.65(a) were further revised to incorporate the exclusion of these facility types from review under the provider-based criteria. We now are proposing to further revise § 413.65(a)(1)(ii) to state that provider-based determinations will not be made with respect to independent diagnostic testing facilities that furnish only services paid under a fee schedule, such as facilities that furnish only screening mammography services, as defined in section 1861(jj) of the Act, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services. A provider-based determination would not be appropriate for a facility that furnishes only screening mammography because of a change made by section 104 of BIPA. That legislation, which amended section 1848(j)(3) of the Act, mandates that all payment for screening mammography services furnished on or after January 1, 2000, be made under the Medicare Physician Fee Schedule (MPFS). Under the MPFS methodology, Medicare payment for the service, regardless of the setting in which it is furnished, is set at the lesser of the fee schedule amount or the actual charge; and no Part B deductible applies. Regardless of the setting, Part B coinsurance is assessed at 20 percent of the lesser of the fee schedule amount or the actual charge. Because the status of a facility as provider-based or freestanding would

not affect the amount of Medicare or Medicaid payment, the beneficiary's scope of benefits, or the beneficiary's liability for coinsurance or deductible amounts, it is not necessary to make a provider-based determination regarding facilities that furnish only screening mammography. We are also proposing to revise § 413.65(a)(1)(ii) by adding a new paragraph (j) to state that we will not make provider-based determinations with respect to departments of providers (for example, laundry or medical records departments) that do not furnish types of health care services for which separate payment could be claimed under Medicare or Medicaid. (Such services frequently are referred to as "billable" services.) As explained more fully below, we would not make determinations with respect to these departments because their status (that is, whether they are provider-based or not) would have no impact on Medicare or Medicaid payment or on the scope of benefits or beneficiary liability under either program.

Despite the previous clarifications described above, providers, associations, and their representatives have continued to state that they are confused as to which facilities or organizations will be the subject of provider-based determinations.

In this document, we are proposing to further clarify the types of facilities that are subject to the provider-based rules, by making several changes to the definitions of key terms in § 413.65(a)(2). First, we are proposing to revise the definition of "department of a provider" to remove the reference to a physician office as being a department of a provider. While a hospital outpatient department, in fact, may furnish services that are clinically indistinguishable from those of physician offices, physician offices and provider departments are paid through separate methods under Medicare and beneficiaries may be liable for different coinsurance amounts. Thus, it is essential to distinguish between these facility types, and we believe avoiding confusion on this issue requires us to remove the reference to a hospital department as a physician office.

We also are proposing to revise § 413.65(a)(2) to state that a "department of a provider", "provider-based entity", or "remote location of a hospital" comprises both the specific physical facility that serves as the site of services of a type for which separate payment could be claimed under the Medicare or Medicaid programs, and the personnel and equipment needed to deliver the services at that facility. We believe this change would help to clarify that we

would make determinations with respect to entities considered in their role as sources of health care services and not simply as physical locations. We also wish to clarify that we do not intend to make provider-based determinations with respect to various organizational components or units of providers that may be designated as "departments" or "organizations" but do not themselves furnish types of services for which separate payment could be claimed under Medicare or Medicaid. Examples of components for which we would not make provider-based determinations include the medical records, housekeeping, and security departments of a hospital. Such departments do perform functions that are essential to the provision of inpatient and outpatient hospital services, but the departments do not provide health care services for which Medicare or Medicaid benefits are provided under title XVIII or title XIX of the Act, and for which separate payment therefore could be claimed, assuming certification and other applicable requirements were met, to one or both programs. Therefore, neither Medicare or Medicaid program liability nor beneficiary liability or scope of benefits would be affected by the ability or inability of these departments to qualify as "provider-based." (We also would not make a provider-based determination with respect to any facility or organization that furnishes only types of health care services for which separate payment could be claimed under either Medicare or Medicaid, even if the facility or organization met all requirements for provider-based status. For example, if a hospital that is not eligible for DSH payments under Medicare or Medicaid or for IME payments under Medicare were to establish a dedicated facility providing only types of cosmetic surgery or experimental therapies that could not be covered under either Medicare or Medicaid, no determination would be made with respect to that facility.)

By contrast, Medicare or Medicaid payment (or both) to hospital departments that provide diagnostic or therapeutic radiology services to outpatients, or primary care, ophthalmology, or other specialty services to outpatients are affected by provider-based status, as would beneficiary liability for Medicare coinsurance amounts. Therefore, we would make provider-based determinations for these departments.

Similarly, if two acute care hospitals that have approved graduate medical education (GME) programs were to

merge to form a single, multicampus hospital consisting of the main hospital campus and a remote location, it would be appropriate to make a determination as to whether the remote location is provider-based with respect to the main hospital campus. Such a determination would be needed because each hospital with an approved residency training program has its own hospital-specific cap on the number of residents (or FTE cap), its own PRA, and its own Medicare utilization used for purposes of receiving Medicare GME payments. A merger of the two hospitals would aggregate the two hospitals' individual FTE caps into a merged FTE cap under the main hospital's provider number, and would require recalculation of the hospital's PRA and a merging of these entities' respective Medicare utilization, resulting in a level of Medicare GME payment to the merged hospital that exceeds the sum of the payments that would be made to each hospital as separate entities. Thus, a provider-based determination would be appropriate and necessary in such a case, even though payment for services by both facilities would be made under the Medicare acute care hospital inpatient prospective payment system.

In deciding whether to make a provider-based determination with respect to a particular facility, it would not be significant that the facility might have a low rate of Medicare utilization, might be utilized by only Medicare or only Medicaid patients, or might not have admitted any Medicare or Medicaid patients in a particular period. The fact that the facility furnishes types of services that are billable under Medicare or Medicaid, or both, would be sufficient to make a determination appropriate.

We are proposing to retain the rules that a department of a provider or a remote location of a hospital (such as, for example, one campus of a multicampus hospital) may not by itself be qualified to participate in Medicare as a provider under the regulations on provider agreements in § 489.2, and the Medicare conditions of participation do not apply to a department as an independent entity. However, we are proposing to delete the requirement at § 413.65(a)(2) that such a department may not be licensed to provide services in its own right. Some States require separate licensing of facilities that Medicare would treat as a department of a hospital or other provider. In these States, we would not require a common license. We would retain the provision that, for purposes of Part 413, the term "department of a provider" does not

include an RHC or, except as specified in § 413.65(m), an FQHC.

Questions have arisen regarding whether the provider-based criteria in § 413.65 are applicable in determining payment for ambulance services. Medicare is converting payment for ambulance services to a fee schedule, as described in a final rule published on February 27, 2002 (67 FR 9100). The ambulance fee schedule is effective April 1, 2001, and involves a transition period. During this transition period, the status of an ambulance supplier as provider-based could influence the amount of Medicare payment. However, the specific provider-based criteria in § 413.65 were not developed for ambulance suppliers, and we believe that many of these criteria could not reasonably be applied to them. Therefore, we are not proposing to apply the criteria at § 413.65 to ambulance services.

b. Further Delay in Effective Date of Provider-Based Rules

As noted earlier, § 413.65(b) was recently revised to reflect the "grandfathering" provision in section 404(a)(1) of BIPA. Under that provision, if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until October 1, 2002.

It now appears likely that any new provider-based rules that may be adopted as the result of this rulemaking effort will not be published in final before mid-summer of 2002. To allow hospitals and other facilities the time they need to make contractual and organizational changes to comply with the new rules, and to ensure that CMS Regional Offices and contractors are able to provide for an orderly transition to the new provider-based rules, we believe an additional delay in the effective date of the provider-based criteria is needed. Therefore, we are proposing to revise § 413.65(b)(2) to state that if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. We are proposing to further provide that the requirements, limitations, and exclusions specified in § 413.65(d) through (j) (as proposed to be redesignated) will not apply to that hospital or CAH for that facility until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of paragraph

(b)(2), a facility would be considered as having been provider-based on October 1, 2000, if on that date it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital. We are proposing to make the new requirements effective on October 1, 2002, with respect to provider-based status for facilities not qualifying for the grandfathering provision.

c. Revision of Application Requirement

Existing regulations at § 413.65(b)(2) establish an explicit application requirement for all facilities seeking provider-based status, except for grandfathered facilities and those treated as provider-based pending a determination on an application filed on or after October 1, 2000, and before October 1, 2002. Under existing § 413.65(b)(3), a main provider or a facility must contact CMS, and the facility must be determined by CMS to be provider-based, before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report. Many providers and provider representatives have expressed concern that the requirement to file an application will increase paperwork burden for hospitals unnecessarily. In response to these concerns, we are proposing to revise the application requirements as follows:

First, we would delete the existing application requirement under § 413.65(b)(3). We are proposing to revise this section to state that except where payment is required to be made under BIPA, as specified in proposed revised § 413.65(b)(2) and (b)(5), if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that its facility meets the criteria in § 413.65(d) and, if it is a hospital, also attest that its facility will fulfill the obligations of hospital outpatient departments and hospital-based entities, as described in proposed § 413.65(g). The provider also would be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request. We note that, under our proposal, there would no longer be an explicit requirement that a provider-based approval be obtained before a facility is treated as provider-based for billing or cost reporting purposes. However, under the proposed revisions to existing § 413.65(k) (Correction of

errors) as described below, CMS would provide a delay in the effective date for any facility that is found not to meet the provider-based criteria following a previous advance determination, if the reason the provider-based criteria are not met is a material change in the provider-facility relationship that was properly reported to CMS. The removal of provider-based status would be effective as of the first cost reporting period following notification of the redetermination, but not less than 6 months after the date of notification.

We are further proposing that if the facility is not located on the main campus of the potential main provider, the provider that wishes to obtain an advance determination of provider-based status would be required to submit an attestation stating that its facility meets the criteria in proposed revised §§ 413.65(d) and (e) and, if the facility is operated as a joint venture or under a management contract, the requirements in proposed §§ 413.65(f) and (h), as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in proposed revised § 413.65(g). The provider seeking such an advance determination would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations. We believe the use of a self-attestation process would strike an appropriate balance between the legitimate interests of hospitals in reducing paperwork and reporting, and the equally legitimate need of CMS to ensure proper accountability for compliance with the qualification requirements for a status that typically leads to a higher level of Medicare or Medicaid payment.

We note that, under these proposed revisions to the application procedures at § 413.65(b), a hospital would not be explicitly required to submit an application and receive a provider-based determination for a facility before the time at which the hospital may bill for services at that facility as provider-based. However, we are considering, alternatively, retaining the existing regulations at § 413.65(b)(2) which state that, except where payment is required to be made under BIPA as specified in proposed revised §§ 413.65(b)(2) and (b)(5), hospitals are explicitly required to submit provider-based applications, and to withhold billing as provider-based until CMS determines that a facility meets the provider-based rules. We are soliciting comments on the

appropriateness of this or other alternative application procedures.

d. Requirements Applicable to All Facilities or Organizations

Under existing § 413.65, all facilities seeking provider-based status with respect to a hospital or other main provider must meet a common set of requirements. These include requirements relating to common licensure (paragraph (d)(1)), operation under the ownership and control of the main provider (paragraph (d)(2)), administration and supervision (paragraph (d)(3)), integration of clinical services (d)(4), financial integration (paragraph (d)(5)), public awareness (paragraph (d)(6)), and location in the immediate vicinity of the main provider (paragraph (d)(7)). (In addition, as described more fully below, specific rules applicable to all facilities rule out provider-based status for facilities operated as joint ventures by two or more providers (paragraph (e)) and limit the types of management contracts that facilities seeking provider-based status may operate under (paragraph (f)).)

Since publication in final of the existing provider-based rules in April 2000, hospitals and other providers have expressed concern that the requirements outlined above are overly restrictive and do not allow them enough flexibility to enter into appropriate business arrangements with other facilities. We understand these concerns, and agree that Medicare rules should not restrict legitimate business arrangements that do not lead to abusive practices or disadvantage Medicare beneficiaries. At the same time, we believe our existing rules provide a high level of assurance that a facility complying with them is, in fact, an integral and subordinate part of the facility with which it is based, and do not accord provider-based status to facilities that are not integral and subordinate to a main provider, but in fact have only a nominal relationship with that provider.

After considering all comments received on these issues, we believe that further changes in the provider-based rules would be appropriate. In particular, we agree with those who argue that a facility's or organization's location relative to the main campus of the provider is relevant to the integration that is likely to exist between the facility or organization and the main provider. For example, if a facility or organization is located on the main campus of a provider, is operated under the main provider's State license, is medically and financially integrated with that provider, and is held out to

the public and other payers as a part of that provider, we believe the necessary degree of integration of the facility or organization into the main provider can be assumed to exist. We also are concerned that further prescribing the types of management contracts or other business arrangements that may exist between the main provider and the facility or organization would unnecessarily restrict its flexibility to establish cost-effective agreements without significantly enhancing the integration of the facility or organization into the main provider. Therefore, we are proposing to simplify the requirements applicable to facilities or organizations located on the campus of the main provider (as campus is defined in existing regulations at § 413.65(a)(2)). Under our proposal, all facilities seeking provider-based status, including both on-campus and off-campus facilities, would be required to comply with the existing requirements regarding licensure, clinical services integration, financial integration, and public awareness. (These requirements are currently codified at §§ 413.65(d)(1), (d)(4), (d)(5), and (d)(6) and, under this proposed rule, would be redesignated as paragraphs (d)(1) through (d)(4), respectively, of § 413.65.)

With respect to financial integration, existing regulations at § 413.65(d)(5) require that the financial operations of the facility or organization be fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The regulations also require that costs of a provider-based facility or organization be reported in a cost center of the provider, and that the financial status of any provider-based facility or organization be incorporated and readily identified in the main provider's trial balance.

Some hospital representatives have questioned the appropriateness of requiring that the costs of a remote location of a hospital be reported in a single cost center, noting that such costs ordinarily would appear in multiple cost centers of the main provider, with (for example) employee health and welfare costs of the remote location being included in the corresponding cost center of the main provider. In recognition of this concern, we are proposing to revise the requirement to state that the costs of a facility or organization that is a hospital department must be reported in a cost center of the provider, and that costs of a provider-based facility or organization other than a hospital department must be reported in the appropriate cost

center or cost centers of the main provider.

Paragraph (d) of § 413.65 would be retitled "Requirements applicable to all facilities or organizations" and, as indicated by its revised title, would set forth those core requirements that any facility or organization would have to meet to qualify for provider-based status.

We are proposing to delete from this paragraph (d) the requirements in existing paragraphs (d)(2) and (d)(3) relating to operation under the ownership and control of the main provider and administration and supervision because we are proposing to no longer apply these requirements to on-campus facilities or organizations. These requirements would be moved to paragraph (e) as described below to reflect the proposed limitation of their applicability to off-campus departments. The core requirements for all facilities or organizations, including facilities located on the main campus, also would not include the requirement regarding location in the immediate vicinity of the main provider (existing § 413.65(d)(7)). Because any facilities or organizations located on the campus of the main provider automatically meet the requirement regarding location in the immediate vicinity (existing § 413.65(d)(7)), the requirement is only of relevance to off-campus facilities or organizations. For clarity, we are proposing to relocate the requirement to paragraph (e) as described below.

We also are proposing to require, in paragraph (d)(5) of § 413.65, all hospital outpatient departments and hospital-based entities, including those located on campus and those located off the campus of the main provider hospital, to fulfill the obligations currently codified and proposed to be retained at § 413.65(g) in order to qualify for provider-based status. (Fulfillment of these obligations is currently required under § 413.65(g).) As explained further below, we also are proposing other changes to paragraph (g).

e. Additional Requirements Applicable to Off-Campus Facilities or Organizations

We recognize that facilities or organizations located off the main provider campus may also be sufficiently integrated with the main provider to justify provider-based designation. However, the off-campus location of the facilities or organizations may make such integration harder to achieve, and such integration should not simply be presumed to exist. Therefore, to ensure that off-campus facilities or organizations seeking

provider-based status are appropriately integrated, we are proposing to retain for these facilities or organizations certain requirements that we are proposing to remove for on-campus facilities or organizations. These requirements are set forth in proposed new § 413.65(e). The requirements set forth in proposed paragraphs (e)(1), (e)(2), and (e)(3) include the requirements on operation under the ownership and control of the main provider (existing § 413.65(d)(2)), administration and supervision (existing § 413.65(d)(3)), and location (existing § 413.65(d)(7)). We also are proposing to include language in proposed new § 413.65(e) to state more clearly that a facility or organization seeking provider-based status must be located in the same State or, when consistent with the laws of both States, in adjacent States.

f. Joint Ventures

Consistent with our views as expressed earlier in this preamble regarding the assumption that a higher degree of integration can be presumed for on-campus facilities or organizations and in recognition of the need to promote reasonable cooperation among providers and avoid costly duplication of specialty services, we are proposing to revise the regulations on joint ventures (currently set forth under § 413.65(e)) to limit their scope to facilities or organizations not located on the campus of any potential main provider. Specifically, we would redesignate § 413.65(e) as § 413.65(f) and revise it to state that a facility or organization that is not located on the campus of the potential main provider cannot be considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. We also are proposing to make minor changes to the second sentence of the redesignated paragraph (f) to clarify its meaning.

g. Clarification of Obligations of Hospital Outpatient Departments and Hospital-Based Entities

Existing regulations impose specific obligations for hospital outpatient departments and hospital-based entities, but do not specify the sanction that applies if the facility or organization does not fulfill its obligations. To clarify policy on this issue and emphasize the importance of compliance with the requirements in this area, we are proposing to revise existing § 413.65(g) to state that to qualify for provider-based status in relation to a hospital, a facility or organization must comply with these requirements. In regard to

these obligations, we are proposing to make three changes in existing 413.65(g). First, for reasons explained in section V.J. of this preamble, we are proposing to revise paragraph (g)(1) by deleting the second sentence of that paragraph. In paragraph (g)(2), we are proposing to delete the reference to site-of-service reductions and instead refer to more accurately determined physician payment amounts, in order to more accurately describe how payment under the physician fee schedule is determined. In addition, we are proposing to revise the first sentence of paragraph (g)(7) to clarify that the notice requirements in it do not apply where a beneficiary is examined or treated for a medical condition in compliance with the antidumping rules in § 489.24. This clarification is needed because we believe it would be a violation of the antidumping requirements if examination or treatment required under § 489.24 was delayed in order to permit notification of the beneficiary or the beneficiary's authorized representative. We would further revise § 413.65(g)(7) to state that notice is required once the beneficiary has been appropriately screened and the existence of an emergency has been ruled out or the emergency condition has been stabilized.

h. Management Contracts

Under existing regulations, facilities or organizations operated under management contracts may be considered provider-based only if they meet specific requirements in § 413.65(f) (proposed to be redesignated as § 413.65(h)). In particular, staff of the facility or organization, other than management staff, may not be employed by the management company but must be employed either by the provider or by another organization, other than the main provider, which also employs the staff of the main provider. Under existing regulations, these requirements apply equally to on-campus and off-campus facilities or organizations.

Consistent with our intent to simplify provider-based requirements for on-campus facilities or organizations, we are proposing to restrict the applicability of proposed redesignated paragraph (h) to off-campus facilities or organizations. In addition, we are proposing two additional changes that we believe are needed to respond to questions that are raised frequently about the regulation. First, we would specify that a facility or organization operated under a management contract may be considered provider-based only if the main provider (or an organization that also employs the staff of the main

provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at 42 CFR Part 414. We would not specify who may employ other support staff, such as maintenance or security personnel, and who are not directly involved in providing patient care, nor would we require licensed professional caregivers such as physicians, physician assistants, or certified registered nurse anesthetists to become provider employees. We also are proposing to revise the regulations to clarify at § 413.65(h)(2) that so-called "leased" employees (that is personnel who are actually employed by the management company but provide services for the provider under a staff leasing arrangement) are not considered to be employees of the provider for purposes of this provision.

i. Inappropriate Treatment of a Facility or Organization as Provider-Based

Below we describe the steps that we would take if we discover that a facility is billing as provider-based without having requested a determination, or if the facility received a provider-based determination but the main provider did not inform CMS of a subsequent material change that affected the provider-based status of its facility.

(1) Inappropriate Billing

The existing regulations at § 413.65(i) state that if we discover that a provider is billing inappropriately, we will recover the difference between the amount of payments that actually were made and the amount of payments that CMS estimates should have been made in the absence of a determination of provider-based status. Existing § 413.65(j)(2) states that we would adjust future payments to approximate as closely as possible the amounts that would be paid, in the absence of a provider-based determination, if all other requirements for billing are met. In addition, existing § 413.65(j)(5) describes a procedure under which CMS would continue payments to a provider for services of a facility or organization that had been found not to be provider-based, at an adjusted rate calculated as described in existing paragraph (j)(2), for up to 6 months in order to permit the facility or organization adequate time to meet applicable enrollment and other billing requirements. While CMS is not legally obligated to continue payments in this matter, we believe it would be

appropriate to do so, on a time-limited basis, to allow for an orderly transition to either provider-based or freestanding status for the facility and to avoid disruption in the delivery of services to patients, particularly Medicare patients, who may be relying on the facility for their medical care.

We are proposing to adopt a policy concerning recoupment and continuation of payment that closely parallels the policy stated in existing regulations at § 413.65(j). Under proposed § 413.65(j)(1), if CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request an advance determination of provider-based status from CMS under proposed § 413.65(b)(3), and CMS determines that the facility or organization did not meet the requirements for provider-based status under proposed § 413.65(d) through (i), as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS would take several actions. First, we are proposing to issue notice to the provider, in accordance with proposed paragraph (j)(3), that payments for past cost reporting periods may be reviewed and recovered as described in proposed paragraph (j)(2)(ii), that future payments for services in or at the facility or organization will be adjusted as described in proposed paragraph (j)(4), and that continued payments to the provider for services of the facility or organization will be made only in accordance with proposed paragraph (j)(5). In addition, as detailed in proposed § 413.65(j)(1)(ii), CMS would, except for providers protected under section 404(a) or (c) of BIPA (implemented at § 413.65(b)(2) and (b)(5)) or the exception for good faith effort at existing § 413.65(i)(2) and (i)(3)), recover the difference between the amount of payments that actually was made to that provider for services at the facility or organization and an estimate of the payments that CMS would have made to that provider for services at the facility or organization in the absence of compliance with the requirements for provider-based status. We are proposing to make recovery for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889. Also, we are proposing to adjust future payments to approximate the amounts that would be paid for the same services furnished by a freestanding facility.

Recovery of past payments would be limited in certain circumstances. If a provider did not request a provider-

based determination for a facility by October 1, 2002, but is included in the grandfathering period under § 413.65(b)(2), we are proposing to recoup all payments subject to the reopening rules at §§ 405.1885 and 405.1889, but not for any period before the provider's cost reporting period beginning on or after July 1, 2003.

(2) Good Faith Effort

We are proposing to retain the existing exception for good faith effort (proposed redesignated § 413.65(j)(2)). Under this exception, we would not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001 (the effective date of the existing provider-based regulations for providers not grandfathered under § 413.65(b)(2)) if during all of that period—

- The requirements regarding licensure and public awareness at § 413.65(d)(1) and proposed redesignated (d)(4) were met;
- All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and
- All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described at proposed redesignated and revised § 413.65(h)(2).

Under proposed § 413.65(j)(5), CMS would continue payment to a provider for services of a facility or organization for a limited period of time, in order to allow the facility or organization or its practitioners to meet necessary enrollment and other requirements for billing on a freestanding basis. Specifically, the notice of denial of provider-based status sent to the provider would ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, as to whether the provider intends to seek an advance determination of provider-based status for the facility or organization, or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services as a freestanding facility. If the provider indicates that it will not be seeking an advance determination or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payments under proposed paragraph (j)(5) would end as of the 30th day after the date of notice.

If the provider indicates that it will be seeking an advance determination, or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization would continue, at the adjusted amount described in proposed paragraph (j)(4) for as long as is required for all billing requirements to be met (but not longer than 6 months). Continued payment would be allowed only if the provider or the facility or organization or its practitioners submits, as applicable, a complete request for an advance provider-based determination or a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization or its practitioners furnishes all other information needed by CMS to process the request for provider-based status or, as applicable, the enrollment application and verify that other billing requirements are met. If the necessary applications or information are not provided, CMS would terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

j. Temporary Treatment as Provider-Based and Correction of Errors

Under proposed revised § 413.65(k), we would specify the procedures for payment for the period between the time a request is submitted until a provider-based determination is made, and the steps we would take if we discover that a facility for which a provider previously received a provider-based determination no longer meets the requirements for provider-based status.

First, we are proposing that, if a provider submits a complete request for a provider-based determination for a facility that has not previously been found by CMS to have been inappropriately treated as provider-based under proposed revised § 413.65(j), the provider may bill and be paid for services at the facility as provider-based from the date of the application until the date that we determine that the facility or organization does not meet the provider-based rules under § 413.65. If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete request for a provider-based determination was submitted and the amount of payments that CMS estimates

should have been made in the absence of compliance with the provider-based requirements. We would consider a request "complete" only if it included all information we need to make an advance determination of provider-based status under § 413.65(b)(3).

Second, similar to what we specify in existing § 413.65(k), if we determine that a facility or organization that previously received a provider-based determination no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider reported to CMS as is required under § 413.65(c), treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

Third, if we determine that a facility or organization that had previously received a provider-based determination no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS, as required under § 413.65(c), we are proposing to take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in proposed paragraphs (j)(3), (j)(4), and (j)(5). In short, we would treat such cases in the same way as if the provider had never obtained an advance determination. However, with respect to recovery of past payments for providers included in the grandfathering provision at proposed revised § 413.65(b)(2), we would not recover payments for any period before the provider's first cost reporting period beginning on or after July 1, 2003.

Also, we are proposing that the exception for good faith effort concerning recovery of overpayments under proposed revised §§ 413.65(j)(2) described above would apply to any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001.

k. Technical Amendments

We are proposing to correct a typographical error in the heading of paragraph (m) of § 413.65 so that it reads "FQHCs and 'look alikes'".

In paragraph (n) of § 413.65, we are proposing to add a cross-reference to the requirements for provider-based status described in paragraph (b), for purposes

of specifying the effective date of provider-based status.

L. CMS Authority Over Reopening of Intermediary Determinations and Intermediary Hearing Decisions on Provider Reimbursement

Our existing regulations provide various means for the reopening and revision of an intermediary determination or an intermediary hearing decision on provider reimbursement by the fiscal intermediary or the intermediary hearing officer(s) responsible for the determination or the hearing decision, respectively. (In this discussion, we will use the term "intermediary" to refer to, as applicable, the intermediary responsible for an intermediary determination (see §§ 405.1801(a) and 405.1803) or the intermediary hearing officer or panel of intermediary hearing officers responsible for an intermediary hearing decision (see §§ 405.1817 and 405.1831.)) Section 405.1885(a) provides that an intermediary "may" reopen an intermediary determination or an intermediary hearing decision, on its own initiative or at the request of a provider, within 3 years of the date of the notice of the intermediary determination or intermediary hearing decision. However, while § 405.1885(a) provides the intermediary with some discretion about whether to reopen an intermediary determination or an intermediary hearing decision, we have always considered the intermediary's discretion to be limited by any directives that may be issued by CMS. Thus, although § 405.1885(a) provides that the intermediary "may" reopen, that provision neither states nor implies that the Secretary lacks authority to direct the intermediary to reopen or not reopen a specific matter. Furthermore, CMS has prescribed, in Medicare Provider Reimbursement Manual, Part I ("PRM"), section 2931.2, criteria that guide the intermediary's reopening actions under "405.1885(a) in the absence of a particular directive from CMS. Also, given that the intermediaries are CMS' contractors, we have always believed that, under basic principles of agency law, we have inherent authority to direct the actions of our own agents with respect to reopening matters under "405.1885(a), just as for any other aspect of program administration. See also 42 U.S.C. 1395h and 1395kk(a); and 42 CFR 421.1(c), 421.5(b), 421.100(f), 421.124(a), and 421.126(b).

Under § 405.1885(b), an intermediary determination or an intermediary hearing decision "shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, the

Centers for Medicare & Medicaid Services notifies the intermediary that such determination or decision is inconsistent with the applicable law, regulations, or general instructions issued by the Centers for Medicare & Medicaid Services." We have always considered the CMS notice, which is a precondition of mandatory intermediary reopening under § 405.1885(b), to be one in which we explicitly direct the intermediary to reopen. We have never considered a notice or other document from CMS that only states or implies that an intermediary determination or an intermediary hearing decision is inconsistent with law, regulations, CMS ruling, or CMS general instructions, sufficient to require intermediary reopening under § 405.1885(b). Moreover, our understanding has always been that the phrase "law, regulations, or general instructions" in § 405.1885(b) refers to the legal provisions in effect, as we understand such legal provisions, at the time the intermediary rendered the determination or hearing decision. Conversely, we have never considered changes in, or judicial explications of, "law, regulations, or general instructions," that occur after the intermediary rendered the determination or hearing decision, sufficient to require intermediary reopening under § 405.1885(b). Also, § 405.1885(b) refers to the Secretary's agreement with an intermediary; we believe such agreement requires the intermediary to apply the law, regulations, CMS rulings, and CMS general instructions in effect, as we understand such legal provisions, when the intermediary determination or hearing decision was rendered. Accordingly, we have not instructed intermediaries to reopen and recover reimbursement, or to reopen and award additional reimbursement, due to a subsequent change in law or policy, whether the subsequent change is made in response to judicial precedent or otherwise.

Section 405.1885(c) provides: "Jurisdiction for reopening a determination or decision rests exclusively with that administrative body that rendered the last determination or decision." We have always interpreted § 405.1885(c) to provide that authority to reopen an intermediary determination or an intermediary hearing decision is vested exclusively with the responsible intermediary, as distinct from the Provider Reimbursement Review Board (PRRB) and the Administrator of CMS (in the context of reviewing PRRB

decisions (see § 405.1875)) which may not reopen an intermediary determination or hearing decision and may not review an intermediary's denial of reopening. However, we have never considered the intermediary's authority to reopen an intermediary determination or hearing decision, which is exclusive under § 405.1885(c) only as to the PRRB and the Administrator of CMS (in the context of reviewing PRRB decisions), to limit CMS' authority to direct the actions of its own agents with respect to reopening matters. See *Your Home Visiting Nurse Services, Inc. v. Shalala*, 525 U.S. 449, 452–53 (1999). (Section 405.1885(c) divests the PRRB of “appellate jurisdiction to review the intermediary's refusal” to reopen, but does not limit the Secretary's authority to direct an intermediary's “original jurisdiction” in the reopening area). As discussed previously, the regulations do not constrain CMS' authority to direct the intermediary to reopen or not reopen a specific matter; instead, CMS has placed generally applicable limits on the intermediary's discretion through the reopening criteria prescribed in section 2931.2 of the PRM. In addition, we have always believed that, under basic principles of agency law, the intermediary's discretion over a particular reopening matter is no less circumscribed by any directives that may be issued by CMS than would be the case for any other aspect of program administration.

Two recent court decisions conflict with our longstanding interpretation of the forgoing provisions of the reopening regulations. In *Monmouth Medical Center v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001), the court found that a statement in a CMS ruling, changing CMS' interpretation of the statute in response to circuit court precedent, constituted a directive to the intermediary under § 405.1885(b) to reopen, notwithstanding an explicit directive in the CMS ruling that the change in interpretation was to be applied only prospectively. The court ordered the intermediary to reopen over the Secretary's objection. We disagree with the court's decision, which we believe does not comport with our settled interpretation (discussed above) of § 405.1885(b). Therefore, we are proposing to revise § 405.1885(b) to make clear that, in order to trigger the intermediary's obligation to reopen, the notice from CMS to the intermediary must explicitly direct the intermediary to reopen based on a finding that an intermediary determination or an intermediary hearing decision is

inconsistent with the law, regulations, CMS ruling, or CMS general instructions in effect, and as we understood those legal provisions, at the time the determination or decision was rendered. We are also proposing to clarify § 405.1885 to reflect our longstanding interpretation (discussed above) that a change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

The *Monmouth Medical Center* decision was followed in *Bartlett Memorial Medical Center v. Thompson*, 171 F. Supp. 2d 1215 (W.D. Okla. 2001). In a subsequent order in the *Bartlett Memorial Medical Center* case, the court concluded that a CMS ruling, which prohibited intermediary reopening on a particular reimbursement issue, improperly interfered with the intermediary's discretion under § 405.1885(c) over provider requests for reopening under § 405.1885(a). Accordingly, the court ordered the intermediary to act on the provider reopening requests without regard to the CMS ruling or any other involvement of the Secretary. We disagree with the court's decision, which we believe is contrary to our settled interpretation (discussed above) of § 405.1885(a) and (c). We believe the court's decision is also inconsistent with CMS' inherent authority to direct the activities of its own contractor-agents, the fiscal intermediaries, with respect to particular reopening matters, just as with any other aspect of program administration. Therefore, we are proposing, in a new paragraph (e) of § 405.1885 (the existing paragraph is proposed to be redesignated as paragraph (f)), to clarify that, notwithstanding an intermediary's discretion to reopen or not reopen under paragraphs (a) and (c) of § 405.1885, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section. To illustrate our proposal, revised § 405.1885(e) would clarify that CMS has full authority to direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision under § 405.1885(a) and (c) based on the reopening criteria of “new and material evidence” or “clear and obvious error.” See PRM § 2931.2.

VI. Proposed Changes to the Prospective Payment System for Capital-Related Costs

A. Background

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services “in accordance with a prospective payment system established by the Secretary.” Under the statute, the Secretary has broad authority in establishing and implementing the capital prospective payment system. We initially implemented the capital prospective payment system in the August 30, 1991 final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

Federal fiscal year (FY) 2001 was the last year of the 10-year transition period established to phase in the prospective payment system for hospital capital-related costs. Beginning in FY 2001, capital prospective payment system payments were based solely on the Federal rate for the vast majority of hospitals. The basic methodology for determining capital prospective payments based on the Federal rate is set forth in § 412.312. For the purpose of calculating payments for each discharge, the standard Federal rate is adjusted as follows:

$$(\text{Standard Federal Rate}) \times (\text{DRG Weight}) \times (\text{Geographic Adjustment Factor (GAF)}) \times (\text{Large Urban Add-on, if applicable}) \times (\text{COLA Adjustment for Hospitals Located in Alaska and Hawaii}) \times (1 + \text{DSH Adjustment Factor} + \text{IME Adjustment Factor})$$

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year that are specified in § 412.312(c) of existing regulations. (Refer to the August 1, 2001 final rule (66 FR 39910) for a summary of the statutory basis for the system, the development and evolution of the system, the methodology used to determine capital-related payments to hospitals both during and after the transition period, and the policy for providing special exceptions.)

B. New Hospitals

Under the prospective payment system for capital-related costs, at § 412.300(b), a new hospital is defined as a hospital that is newly participating in the Medicare program (under current or previous ownership) for less than 2 years (see 56 FR 43418, August 30,

1991). During the 10-year transition period, under § 412.324(b), a new hospital was exempt from capital prospective payment system for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Effective with its third cost reporting period, a new hospital was paid under the appropriate transition methodology (either hold-harmless or fully prospective) for the remainder of the transition period. (If the hold-harmless methodology was applicable, hold-harmless payments would be made for 8 years, even if they extend beyond the 10-year transition period, which ended beginning with cost reporting periods beginning during FY 2002.)

This payment provision was implemented to provide special protection to new hospitals during the transition period in response to concerns that prospective payments under a DRG system may not be adequate initially to cover the capital costs of newly built hospitals. These hospitals may not have sufficient occupancy in those initial 2 years and may have incurred significant capital startup costs, so that capital prospective payment system payments may not be sufficient. For instance, hospitals newly participating in the Medicare program may not initially have adequate Medicare utilization. Because capital prospective payment system payments are made on a per discharge basis, a hospital only receives payments for its capital-related costs upon discharge of its Medicare patients. In addition, these hospitals did not have an opportunity to reserve previous years' capital prospective payment system payments to finance capital projects.

While the regulations provided for payments based on a percentage of costs for new hospitals for the first 2 years during the 10-year transition period, no provision was made for new hospitals once the 10-year transition was completed. However, we believe that the rationale for the policy applies equally to new hospitals even after the completion of the 10-year transition period. Accordingly, we are proposing, under § 412.304(c)(2), to provide special payment to new hospitals for cost reporting periods beginning on or after October 1, 2002. That is, we would pay new hospitals, as defined under § 412.300(b), 85 percent of their reasonable costs for their first 2 years of operation. Effective with their third year of operation, a new hospital would be paid based on the Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital prospective payment system). We believe this proposal would provide for

more appropriate payments to new hospitals for their capital-related costs since initial capital expenditures may reasonably exceed the capital prospective payment system per discharge payment based on the Federal rate. The capital prospective payment Federal rate is based on industry-wide average capital costs rather than the experience of a new hospital. We believe this proposed policy would allow new hospitals to provide efficiency in the delivery of services and still make reasonable payments for their capital expenditures.

As was the case during the 10-year transition period, this proposed new hospital exemption would only be available to those hospitals that have not received reasonable cost-based payments under the Medicare program in the past, and would need special protection during their initial period of operation. This proposed exemption from the capital prospective payment system for the first 2 years of operation would not apply to a hospital that is "new" as an acute care hospital but that has operated in the past (under current or previous ownership) and has an historical Medicare asset base. Furthermore, a hospital that replaces its entire facility (regardless of a change of ownership) would not qualify for the new hospital exemption even though it may experience a significant change in its asset base. Thus, in accordance with § 412.300(b), a new hospital exemption would not apply in the following situations:

- A hospital that builds new or replacement facilities at the same or a new location, even if a change of ownership or a new leasing arrangement is involved;
- A hospital that closes and then reopens under the same or different ownership;
- A hospital that has been in operation for more than 2 years but has been participating in the Medicare program for less than 2 years; or
- A hospital that changes status from a prospective payment system-excluded hospital (paid under the TEFRA methodology) or another hospital prospective payment system (such as the inpatient rehabilitation facility prospective payment system) to a hospital that is subject to the capital prospective payment system for acute care hospitals.

C. Extraordinary Circumstances

When we implemented the capital prospective payment system in FY 1992, a number of commenters requested that we provide for a separate exceptions payment to account for extraordinary

circumstances beyond a hospital's control that would require the hospital to make unanticipated major capital expenditures (56 FR 43411, August 30, 1991). In response to the commenters' request, we provided in the regulations at § 412.348(f) that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of \$5 million due to extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a flood, a fire, or an earthquake. For more detailed information regarding this policy, refer to the August 30, 1991 **Federal Register** (56 FR 43411).

To clarify that this policy regarding additional payments for extraordinary circumstances also applies to periods beginning on or after October 1, 2001, we are proposing to revise § 412.312 by adding a new paragraph (e) to specify that payment is made for extraordinary circumstances as provided for in § 412.348(f) for cost reporting periods after the transition period, that is, on or after October 1, 2001.

D. Restoration of the 2.1 Percent Reduction to the Standard Federal Capital Prospective Payment System Payment Rate

Section 1886(g)(1)(A) of the Act, as amended by section 4402 of Public Law 105-33, requires the Secretary to reduce the unadjusted standard Federal capital prospective payment system payment rate (and the unadjusted hospital-specific rate) by 2.1 percent for discharges on or after October 1, 1997, and through September 30, 2002, in addition to applying the budget neutrality factor used to determine the Federal capital prospective payment system payment rate in effect on September 30, 1995. The budget neutrality factor effective for September 30, 1995, was 0.8432 (59 FR 45416). Therefore, application of the budget neutrality factor (as specified under section 1886(g)(1)(A) of the Act) was equivalent to a 15.68 percent reduction to the unadjusted standard Federal capital prospective payment system payment rate and the unadjusted hospital-specific rate in effect on September 30, 1997. The additional 2.1 percent reduction to the rates in effect on September 30, 1997 resulted in a total reduction of 17.78 percent. Accordingly, under the statute, the additional 2.1 percent reduction no longer applies to discharges occurring after September 30, 2002 (§ 412.308(b)(5)). Therefore, we are proposing to revise § 412.308(b) to add a new paragraph (b)(6) to restore the 2.1 percent reduction to the unadjusted

standard Federal capital prospective payment system payment rate (as provided under § 412.308(c)) for discharges occurring on or after October 1, 2002, to the level that it would have been without the reduction. (Since FY 2001 was the final year of the 10-year transition period, we no longer update the hospital-specific rate and, therefore, we also no longer restore the 2.1 percent reduction to that rate as provided under § 412.328(e)(1).)

As described in the August 29, 1997 final rule (62 FR 46012), we determined the reduction factor for FY 1998 by deducting both the FY 1995 budget neutrality factor (0.1568) and the 2.1 percent reduction (0.021) from 1 ($1 - 0.1568 - 0.021 = 0.8222$). We then applied the 0.8222 to the unadjusted standard Federal rate. Therefore, to determine the adjustment factor needed to restore the 2.1 percent reduction, we would divide the amount of the adjustment without the 2.1 percent reduction ($1 - 0.1568 = 0.8432$) by the amount of the adjustment with the 2.1 percent reduction (0.8222). Accordingly, we are proposing to restore the 2.1 percent reduction for discharges occurring on or after October 1, 2002, under proposed § 413.308(b)(6), by applying a factor of 1.02554 ($0.8432 / 0.8222$) to the unadjusted standard Federal capital prospective payment system payment rate under § 412.308(c), that was in effect on September 30, 2002.

E. Clarification of Special Exceptions Policy

Under the special exceptions provisions at § 412.348(g), an additional payment may be made through the 10th year beyond the end of the capital prospective payment system transition period for eligible hospitals that meet (1) a project need requirement as described at § 412.348(g)(2), which, in the case of certain urban hospitals, includes an excess capacity test described at § 412.348(g)(4); and (2) a project size requirement as described at § 412.348(g)(5). In accordance with § 412.348(g)(7), hospitals are eligible to receive special exceptions payments for the 10 years after the cost reporting year in which they complete their project, which can be no later than the hospital's cost reporting period beginning before October 1, 2001.

During the 10-year capital prospective payment system transition period, regular exceptions under §§ 412.348(b) through (e) paid the same as or more (between 70 percent and 90 percent of costs, depending on the type of hospital) than the special exceptions provision under § 412.348(g) (70 percent for all

eligible hospitals). Therefore, it was not until cost reporting periods beginning on or after October 1, 2001 (the end of the transition period) that eligible hospitals could actually begin receiving additional payments under the special exceptions provision. As we stated in the July 30, 1999 final rule (64 FR 41528), we believe that, since any substantive changes to this policy could have a significant impact, the appropriate forum for addressing the special exceptions policy is through the legislative process in Congress rather than the regulations process. Since hospitals are beginning to receive additional payments under this provision, we have received several questions regarding current policy at § 412.348(g). Therefore, while we are not proposing any changes to the special exceptions policy, we are providing the following clarifications to the existing regulations.

Under § 412.348(g)(1), to be eligible for special exception payments, a hospital must be either a sole community hospital (SCH), an urban hospital with at least 100 beds that has a disproportionate share (DSH) percentage of at least 20.2 percent or qualify for DSH payments under § 412.106(c)(2), or a hospital with a combined Medicare and Medicaid inpatient utilization of at least 70 percent. Because a hospital's SCH status, DSH patient percentage, and combined utilization may fluctuate from one cost reporting year to the next, the special exceptions eligibility criteria are applied for each cost reporting period throughout the 10-year special exceptions period. A hospital receives special exceptions payments only for those years in the 10-year period in which it meets the eligibility requirements in § 412.348(g)(1). Therefore, a hospital might be eligible for a special exception payment in one year, not be eligible the next year, and then subsequently qualify during the 10-year special exceptions period.

The project need criteria in § 412.348(g)(2) also state that a hospital must obtain any required approval from a State or local planning authority. However, in States where a certificate of need or approval is not required by the State or local planning authority, the hospital must provide the fiscal intermediary with appropriate documentation (such as project plans from the hospital's board of directors) that demonstrates that the requirements of § 412.348(g)(3) concerning the age of assets test and § 412.348(g)(4) concerning the excess capacity test for urban hospitals are met. We understand that a State planning authority and a

hospital may define a project differently. Accordingly, we would allow the hospital to use either the definition provided by the project within the certificate of need (in States where a certificate of need is required), or other appropriate documentation provided from the hospital's project plans (such as project plans as specified in the minutes of the meetings of the hospital's board of directors).

In determining a hospital's special exceptions payment amount, as described in § 412.348(g)(8), for each cost reporting period, the cumulative payments made to the hospital under the capital prospective payment system are compared to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the capital prospective payment system. This comparison is offset by any amount by which the hospital's current year Medicare inpatient operating and capital prospective payment system payments (excluding 75 percent of its operating DSH payments) exceed its Medicare inpatient operating and capital costs (or its Medicare inpatient margin). The minimum payment level is 70 percent for all hospitals, regardless of class, as set forth in § 412.348(g)(6), for the duration of the special exceptions provision.

In order to assist our fiscal intermediaries in determining the end of the 10-year period in which an eligible hospital will no longer be entitled to receive special exception payments, § 412.348(g)(9) requires that hospitals eligible for special exception payments submit documentation to the intermediary indicating the completion date of their project (the date the project was put in use for patient care) that meets the project need and project size requirements outlined in §§ 412.348(g)(2) through (g)(5). In order for an eligible hospital to receive special exception payments, this documentation had to be submitted in writing to the intermediary by the later of October 1, 2001, or within 3 months of the end of the hospital's last cost reporting period beginning before October 1, 2001, during which a qualifying project was completed.

VII. Proposed Changes for Hospitals and Hospital Units Excluded From the Acute Care Hospital Inpatient Prospective Payment System

A. Payments to Excluded Hospitals and Hospital Units (§§ 413.40(c), (d), and (f))

1. Payments to Existing Excluded Hospitals and Hospital Units

Section 1886(b)(3)(H) of the Act (as amended by section 4414 of Public Law 105–33) established caps on the target amounts for certain existing hospitals and hospital units excluded from the acute care hospital inpatient prospective payment system for cost reporting periods beginning on or after October 1, 1997 through September 30, 2002. For this period, the caps on the target amounts apply to the following three classes of excluded hospitals or units: psychiatric hospitals and units, rehabilitation hospitals and units, and long-term care hospitals.

In accordance with section 1886(b)(3)(H)(i) of the Act and effective for cost reporting periods beginning on or after October 1, 2002, payments to these classes of existing excluded hospitals or hospital units are no longer subject to caps on the target amounts. In accordance with existing §§ 413.40(c)(4)(ii) and (d)(1)(i) and (ii), these excluded hospitals and hospital units continue to be paid on a reasonable cost basis, and payments are based on their Medicare inpatient operating costs, not to exceed the ceiling. The ceiling would be computed using the hospital's or unit's target amount from the previous cost reporting period updated by the rate-of-increase specified in § 413.40(c)(3)(viii) of the regulations.

2. Updated Caps for New Excluded Hospitals and Units

Section 1886(b)(7) of the Act establishes a payment methodology for new psychiatric hospitals and units, new rehabilitation hospitals and units, and new long-term care hospitals. A discussion of how the payment limitation was calculated can be found in the August 29, 1997 final rule with comment period (62 FR 46019); the May 12, 1998 final rule (63 FR 26344); the July 31, 1998 final rule (63 FR 41000); and the July 30, 1999 final rule (64 FR 41529). Under the statutory methodology, a “new” hospital or unit is a hospital or unit that falls within one of the three classes of hospitals or units (psychiatric, rehabilitation or long-term care) that first receives payment as a hospital or unit excluded from the acute care hospital inpatient prospective payment system on or after October 1,

1997. The amount of payment for a “new” hospital or unit would be determined as follows:

- Under existing § 413.40(f)(2)(ii), for the first two 12-month cost reporting periods, the amount of payment is the lesser of: (1) the operating costs per case; or (2) 110 percent of the national median (as estimated by the Secretary) of the target amounts for the same class of hospital or unit for cost reporting periods ending during FY 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital or unit first receives payments under section 1886 of the Act, as adjusted for differences in area wage levels.

- Under existing § 413.40(c)(4)(v), for cost reporting periods following the hospital's or unit's first two 12-month cost reporting periods, the target amount is equal to the amount determined under section 1886(b)(7)(A)(i) of the Act for the third period, updated by the applicable hospital market basket increase percentage.

The proposed amounts included in the following table reflect the updated 110 percent of the national median target amounts proposed for each class of new excluded hospitals and hospital units for cost reporting periods beginning during FY 2003. These figures are updated to reflect the proposed projected market basket increase percentage of 3.4 percent. This projected percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient hospital services (as projected by the CMS Office of the Actuary based on its historical experience with the hospital inpatient prospective payment system). For a new provider, the labor-related share of the target amount is multiplied by the appropriate geographic area wage index, without regard to prospective payment system reclassifications, and added to the nonlabor-related share in order to determine the per case limit on payment under the statutory payment methodology for new providers.

| Class of excluded hospital or unit | FY 2003 proposed labor-related share | FY 2003 proposed nonlabor-related share |
|------------------------------------|--------------------------------------|---|
| Psychiatric | \$7,047 | \$2,801 |
| Long-Term Care | 17,269 | 6,866 |

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation is no longer applicable to new rehabilitation hospitals and units since they will be paid under the inpatient rehabilitation facility prospective payment system.

3. Establishment of a Prospective Payment System for Inpatient Rehabilitation Hospitals and Units

Section 1886(j) of the Act, as added by section 4421(a) of Public Law 105–33, provided the phase-in of a case-mix adjusted prospective payment system for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation hospital unit (referred to in the statute as rehabilitation facilities) for cost reporting periods beginning on or after October 1, 2000 and before October 1, 2002, with a fully implemented prospective payment system for cost reporting periods beginning on or after October 1, 2002. Section 1886(j) of the Act was amended by section 125 of Public Law 106–113 to require the Secretary to use a discharge as the payment unit under the prospective payment system for inpatient hospital services furnished by rehabilitation facilities and to establish classes of patient discharges by functional-related groups. Section 305 of Public Law 106–554 further amended section 1886(j) of the Act to allow rehabilitation facilities to elect to be paid the full Federal prospective payment rather than the transitional period payments specified in the Act.

On August 7, 2001, we issued a final rule in the **Federal Register** (66 FR 41316) establishing the prospective payment system for inpatient rehabilitation facilities, effective for cost reporting periods beginning on or after January 1, 2002. Under the inpatient rehabilitation prospective payment system, for cost reporting periods beginning on or after January 1, 2002, and before October 1, 2002, payment will consist of 33 $\frac{1}{3}$ percent of the facility-specific payment amount (based on the reasonable cost-based reimbursement methodology) and 66 $\frac{2}{3}$ percent of the adjusted Federal prospective payment. For cost reporting periods beginning on or after October 1, 2002, payment will be based entirely on the Federal prospective payment rate determined under the inpatient rehabilitation facility prospective payment system.

4. Implementation of a Prospective Payment System for Long-Term Care Hospitals

In accordance with the requirements of section 123 of Public Law 106–113, as modified by section 307(b) of Public Law 106–554, we are proposing (as published in the March 22, 2002 proposed rule (67 FR 13415)) the establishment of a per discharge, DRG-based prospective payment system for long-term care hospitals as described in

section 1886(d)(1)(B)(iv) of the Act for cost reporting periods beginning on or after October 1, 2002. As part of the implementation process, we are proposing a 5-year transition period from reasonable cost-based reimbursement to the long-term care hospital prospective payment system Federal rate. We are also proposing that a long-term care hospital may elect to be paid based on 100 percent of the Federal prospective rate. Under the March 22, 2002 proposed rule, a blend of the reasonable cost-based reimbursement percentage and the prospective payment Federal rate percentage would be used to determine a long-term care hospital's total payment under the prospective payment system during the transition period. We would expect long-term care hospitals to be paid under the full Federal prospective rate for cost reporting periods beginning on or after October 1, 2006.

B. Criteria for Exclusion of Satellite Facilities from the Hospital Inpatient Prospective Payment System

Existing regulations at 42 CFR 412.22(e) define a hospital-within-a-hospital as a hospital that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Section 412.22(h), relating to satellites of hospitals excluded from the acute care hospital inpatient prospective payment system, defines a satellite facility as a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Section 412.25(e), relating to satellites of excluded hospital units, defines a satellite facility as a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. Because of the similarities between the definitions of the two types of satellite facilities and the definition of a hospital-within-a-hospital, questions have been raised as to whether satellite facilities must meet the "hospital-within-a-hospital" criteria in § 412.22(e) regarding having a governing body, chief medical officer, medical staff, and chief executive officer that are separate from those of the hospital with which space is shared.

Although the separateness of satellite facilities of excluded hospitals and satellite facilities of excluded units of hospitals is not explicitly required under existing regulations, we believe

these two types of satellite facilities are similar enough to hospitals-within-hospitals to warrant application of more closely related criteria to all of them. Specifically, satellite facilities are like hospitals-within-hospitals in that the satellites are physically located in acute care hospitals that are paid for their inpatient services under the acute care hospital inpatient prospective payment system. Moreover, both satellite facilities and hospitals-within-hospitals provide inpatient hospital care that is paid for at higher rates than would apply if the facility were treated by Medicare as a part of the acute care hospital.

In view of these facts, it is important that we establish clear criteria for ensuring that these facilities are not merely units of the hospitals in which they are located, but are, in fact, organizationally and functionally separate from those hospitals. Therefore, we are proposing to revise § 412.22(h)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2002, a hospital having a satellite facility would qualify for exclusion from the acute care hospital inpatient prospective payment system only if that satellite facility is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located. We also are proposing to revise § 412.25(e)(2)(iii) to state that, effective for cost reporting periods beginning on or after October 1, 2002, a hospital unit having a satellite facility would qualify for exclusion from the acute care hospital inpatient prospective payment system only if it is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 provides for a nationwide Medicare Rural Hospital Flexibility Program (MRHF). (MRHF replaced the 7-State Essential Access Community Hospital/Rural Primary Care Hospital (EACH/RPCH) program.) Under section 1820 of the Act, as amended, certain rural providers may be designated as critical access hospitals

(CAHs) under the MRHF program if they meet qualifying criteria and the conditions for designation specified in the statute. Implementing regulations for section 1820 of the Act are located at 42 CFR Part 485, Subpart F.

2. Election of Optional Payment Method

Under existing regulations at 42 CFR 413.70(b), CAHs may elect to be paid for services to their outpatients under an optional method. Facilities making this election are paid an amount for each outpatient visit that is the sum of the reasonable costs of facility services, as determined under applicable regulations, and, for professional services otherwise payable to the physician or other practitioner, 115 percent of the amounts that otherwise would be paid for the services if the CAH had not elected payment under the optional method. To enable intermediaries to make these payments accurately and to avoid possible delays in or duplications of payment, we specify in § 413.70(b)(3) that each CAH electing payment under the optional method must inform the intermediary in writing of that election annually, at least 60 days before the start of the affected cost reporting period (65 FR 47100, August 1, 2000, and 66 FR 31272, June 13, 2001).

Since the publication of this regulation, some CAHs have expressed concern that requiring a 60-day advance notice of the election of the optional payment method limits their flexibility, and have suggested that a shorter advance notice period would be appropriate. We have contacted our fiscal intermediaries to obtain feedback on the feasibility of changing the period of advance notification, since the fiscal intermediaries would need to make appropriate bill processing changes to allow any shorter time for notification of election of the optional method. Some fiscal intermediaries stated that requiring less than 60 days' advance notice is impractical, while others believed that needed changes could be made with as little as 2 weeks' advance notice. Given the diversity of feedback on this issue and our desire to allow CAHs as much flexibility as possible, we are proposing to revise § 412.30(b)(3) to allow the required advance notice period to be determined by each individual fiscal intermediary for the CAHs it services, as long as the required advance notice is not less than 14 days or more than 60 days before the start of each affected cost reporting period.

3. Use of the Resident Assessment Instrument (RAI) by CAHs

Among the existing regulations implementing section 1820 of the Act are specific conditions that a hospital must meet to be designated as a CAH. To help protect the health and safety of Medicare patients who are being furnished post-hospital skilled nursing facility (SNF) level of care in a CAH, our regulations require CAHs to comply with some, but not all, of the Medicare SNF conditions of participation at 42 CFR part 483, subpart B. Specifically, the regulations at § 485.645(d) provide that in order for a CAH to use its beds to provide post-hospital SNF care, the CAH must be in substantial compliance with nine of the SNF requirements contained in part 483, subpart B. Included among the nine requirements are requirements for comprehensive assessments, comprehensive care plans, and discharge planning as specified in § 483.20(b), (k), and (l). (We note that the existing § 485.645(d)(6) incorrectly cites these regulation cross-references as “§ 483.20(b), (d), and (e).” When we revised § 483.20 on December 23, 1997 (63 FR 53307), we inadvertently did not make conforming cross-reference changes in § 485.645(d)(6). In this proposed rule, we are proposing to make these conforming cross-reference changes.) Section 483.20(b) provides that a facility must make a comprehensive assessment of a resident’s needs using the resident assessment instrument (RAI), specified by the State, on all its swing-bed patients.

We have received inquiries regarding the need for CAHs to use the RAI for patient assessment and care planning. The inquirers consider the RAI a lengthy and burdensome instrument and pointed out that CMS currently does not require CAHs to report data from the RAI for quality or payment purposes.

We required former RPCHs to use the RAI for the assessment of swing-bed patients to avoid the possibility of negative outcomes that might extend the length of stays in these hospitals, which provided limited services. In addition, we believed that the use of the RAI would help to ensure that patient needs are met when patients are in the facility for an extended period of time. Swing-bed hospitals were not required to use any patient assessment instrument because we believed that the hospital conditions of participation included requirements that were appropriate safeguards to protect the health and safety of Medicare patients. Currently, the regulations at § 483.20(f) require all

long-term care facilities to collect and submit assessment data from the RAI to the State for quality and payment purposes. There are no such collection and submission requirements for CAHs.

We have gathered information from the provider community, State surveyors, and staff involved in the development of quality indicators and prospective payment system rates for SNFs to determine the feasibility of continuing to require CAHs to comply with the requirement for use of the RAI for patient assessments. Based on the information received, we have determined that there are no specific patient benefits involved in requiring CAHs to use the RAI for patient assessment purposes.

In the interest of reducing burden, where possible, and based on our analysis of the current significance of the requirement for use of the RAI for patient assessments in CAHs, we believe it is appropriate to propose the elimination of the requirement for CAHs to complete an RAI without jeopardizing patient health and safety. A CAH would still be required to capture assessment data for its SNF patients but would have the flexibility to document the assessment data in the medical record in a manner appropriate for its facility. We believe there are sufficient safeguards in the CAH regulations to ensure the health and safety of each SNF patient in a CAH. The facility would still be required to develop a comprehensive care plan for each SNF patient that includes measurable objectives and a timetable to meet a patient’s medical, nursing, and psychosocial needs that are identified in an assessment. Also, a post-discharge plan of care would address post-hospital care needs of the patient. All of this information (assessment, plan of care, and discharge plans) must be maintained in the patient’s medical record.

We are proposing to revise § 485.645 to specify that CAHs are required to complete a comprehensive assessment, comprehensive care plan, and discharge planning in accordance with the requirements of § 483.20(b), (k), and (l), except that the CAH is not required to use the RAI specified by the State, and is not required to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b).

VIII. MedPAC Recommendations

We have reviewed the March 1, 2002 report submitted by MedPAC to Congress and have given it careful consideration in conjunction with the proposals set forth in this document.

MedPAC’s recommendations for payments for Medicare inpatient hospital services in its March 2002 report focused mainly on accounting for changes in input prices for the hospital market basket (Recommendation 2A) and on increases in the base rate for inpatient hospital services by applying the annual update factors (Recommendations 2B–1 and 2B–2).

In Recommendation 2A, MedPAC recommended that the Secretary should use wage and benefit proxies that most closely match the training and skill requirements of health care occupations in all input price indexes used for updating payments. MedPAC further indicated that, in determining index weights, measures specific to the health sector and to occupation categories in which health care plays a major role should be emphasized. Our proposal to rebase and revise the hospital market basket, including cost category weights and price proxies, that is used in determining the update factors for payments for inpatient hospital services is presented in section IV. of this proposed rule.

Recommendations 2B–1 and 2B–2 concerning the update factor for inpatient hospital operating costs and for hospitals and hospital distinct-part units excluded from the acute care hospital inpatient prospective payment system are discussed in Appendix C to this proposed rule.

IX. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are available in computer tape or cartridge format; however, some files are available on diskette as well as on the Internet at <http://www.hcfa.gov/stats/pufiles.htm>. Data files, and the cost for each, are listed below. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost to the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, Maryland 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. Expanded Modified MedPAR–Hospital (National)

The Medicare Provider Analysis and Review (MedPAR) file contains records

for 100 percent of Medicare beneficiaries using hospital inpatient services in the United States. (The file is a Federal fiscal year file, that is, discharges occurring October 1 through September 30 of the requested year.) The records are stripped of most data elements that would permit identification of beneficiaries. The hospital is identified by the 6-position Medicare billing number. The file is available to persons qualifying under the terms of the Notice of Proposed New Routine Uses for an Existing System of Records published in the **Federal Register** on December 24, 1984 (49 FR 49941), and amended by the July 2, 1985 notice (50 FR 27361). The national file consists of approximately 11,420,000 records. Under the requirements of these notices, an agreement for use of CMS Beneficiary Encrypted Files must be signed by the purchaser before release of these data. For all files requiring a signed agreement, please write or call to obtain a blank agreement form before placing an order. Two versions of this file are created each year. They support the following:

- Notice of Proposed Rulemaking (NPRM) published in the **Federal Register**. This file, scheduled to be available by the end of April, is derived from the MedPAR file with a cutoff of 3 months after the end of the fiscal year (December file).
- Final Rule published in the **Federal Register**. The FY 2001 MedPAR file used for the FY 2003 final rule will be cut off 6 months after the end of the fiscal year (March file) and is scheduled to be available by the end of April. *Media:* Tape/Cartridge. *File Cost:* \$3,655.00 per fiscal year. *Periods Available:* FY 1988 through FY 2001.

2. Expanded Modified MedPAR-Hospital (State)

The State MedPAR file contains records for 100 percent of Medicare beneficiaries using hospital inpatient services in a particular State. The records are stripped of most data elements that will permit identification of beneficiaries. The hospital is identified by the 6-position Medicare billing number. The file is available to persons qualifying under the terms of the Notice of Proposed New Routine Uses for an Existing System of Records published in the December 24, 1984 **Federal Register** notice, and amended by the July 2, 1985 notice. This file is a subset of the Expanded Modified MedPAR-Hospital (National) as described above. Under the requirements of these notices, an

agreement for use of CMS Beneficiary Encrypted Files must be signed by the purchaser before release of these data. Two versions of this file are created each year. They support the following:

- NPRM published in the **Federal Register**. This file, scheduled to be available by the end of April, is derived from the MedPAR file with a cutoff of 3 months after the end of the fiscal year (December file).
- Final Rule published in the **Federal Register**. The FY 2001 MedPAR file used for the FY 2003 final rule will be cut off 6 months after the end of the fiscal year (March file) and is scheduled to be available by the end of April. *Media:* Tape/Cartridge. *File Cost:* \$1,130.00 per State per year. *Periods Available:* FY 1988 through FY 2001.

3. CMS Wage Data

This file contains the hospital hours and salaries for FY 1999 used to create the proposed FY 2003 prospective payment system wage index. The file will be available by the beginning of January for the NPRM and the beginning of May for the final rule.

| Processing year | Wage data year | PPS fiscal year |
|-----------------|----------------|-----------------|
| 2002 | 1999 | 2003 |
| 2001 | 1998 | 2002 |
| 2000 | 1997 | 2001 |
| 1999 | 1996 | 2000 |
| 1998 | 1995 | 1999 |
| 1997 | 1994 | 1998 |
| 1996 | 1993 | 1997 |
| 1995 | 1992 | 1996 |
| 1994 | 1991 | 1995 |
| 1993 | 1990 | 1994 |
| 1992 | 1989 | 1993 |
| 1991 | 1988 | 1992 |

These files support the following:

- NPRM published in the **Federal Register**.
- Final Rule published in the **Federal Register**. *Media:* Diskette/most recent year on the Internet. *File Cost:* \$165.00 per year. *Periods Available:* FY 2003 PPS Update.

4. CMS Hospital Wages Indices (Formerly: Urban and Rural Wage Index Values Only)

This file contains a history of all wage indices since October 1, 1983. *Media:* Diskette/most recent year on the Internet. *File Cost:* \$165.00 per year. *Periods Available:* FY 2003 PPS Update.

5. PPS SSA/FIPS MSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social

Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a historical list of Metropolitan Statistical Area (MSA).

Media: Diskette/Internet. *File Cost:* \$165.00 per year. *Periods Available:* FY 2003 PPS Update.

6. Reclassified Hospitals New Wage Index (Formerly: Reclassified Hospitals by Provider Only)

This file contains a list of hospitals that were reclassified for the purpose of assigning a new wage index. Two versions of these files are created each year. They support the following:

- NPRM published in the **Federal Register**.
- Final Rule published in the **Federal Register**. *Media:* Diskette/Internet. *File Cost:* \$165.00 per year. *Periods Available:* FY 2003 PPS Update.

7. PPS-IV to PPS-XII Minimum Data Set

The Minimum Data Set contains cost, statistical, financial, and other information from Medicare hospital cost reports. The data set includes only the most current cost report (as submitted, final settled, or reopened) submitted for a Medicare participating hospital by the Medicare fiscal intermediary to CMS. This data set is updated at the end of each calendar quarter and is available on the last day of the following month. *Media:* Tape/Cartridge. *File Cost:* \$770.00 per year.

| | Periods beginning on or after | and before |
|----------------|-------------------------------|------------|
| PPS-IV | 10/01/86 | 10/01/87 |
| PPS-V | 10/01/87 | 10/01/88 |
| PPS-VI | 10/01/88 | 10/01/89 |
| PPS-VII | 10/01/89 | 10/01/90 |
| PPS-VIII | 10/01/90 | 10/01/91 |
| PPS-IX | 10/01/91 | 10/01/92 |
| PPS-X | 10/01/92 | 10/01/93 |
| PPS-XI | 10/01/93 | 10/01/94 |
| PPS-XII | 10/01/94 | 10/01/95 |

(Note: The PPS-XIII, PPS-XIV, PPS-XV, PPS-XVI, and PPS-XVII Minimum Data Sets are part of the PPS-XIII, PPS-XIV, PPS-XV, PPS-XVI, and PPS-XVII Hospital Data Set Files (refer to item 9 below).)

8. PPS-IX to PPS-XII Capital Data Set

The Capital Data Set contains selected data for capital-related costs, interest expense and related information and complete balance sheet data from the Medicare hospital cost report. The data set includes only the most current cost report (as submitted, final settled or

reopened) submitted for a Medicare certified hospital by the Medicare fiscal intermediary to CMS. This data set is updated at the end of each calendar quarter and is available on the last day of the following month.

Media: Tape/Cartridge.
File Cost: \$770.00 per year.

| | Periods beginning on or after | and before |
|---------------|-------------------------------|------------|
| PPS-IX | 10/01/91 | 10/01/92 |
| PPS-X | 10/01/92 | 10/01/93 |
| PPS-XI | 10/01/93 | 10/01/94 |
| PPS-XII | 10/01/94 | 10/01/95 |

(Note: The PPS-XIII, PPS-XIV, PPS-XV, PPS-XVI, and PPS-XVII Capital Data Sets are part of the PPS-XIII, PPS-XIV, PPS-XV, PPS-XVI, and PPS-XVII Hospital Data Set Files (refer to item 9 below).)

9. PPS-XIII to PPS-XVII Hospital Data Set

The file contains cost, statistical, financial, and other data from the Medicare Hospital Cost Report. The data set includes only the most current cost report (as submitted, final settled, or reopened) submitted for a Medicare-certified hospital by the Medicare fiscal intermediary to CMS. The data set are updated at the end of each calendar quarter and is available on the last day of the following month.

Media: Diskette/Internet.
File Cost: \$2,500.00.

| | Periods beginning on or after | and before |
|----------------|-------------------------------|------------|
| PPS-XIII | 10/01/95 | 10/01/96 |
| PPS-XIV | 10/01/96 | 10/01/97 |
| PPS-XV | 10/01/97 | 10/01/98 |
| PPS-XVI | 10/01/98 | 10/01/99 |
| PPS-XVII | 10/01/99 | 10/01/00 |

10. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's system to compute DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Diskette/Internet.
File Cost: \$265.00.
Periods Available: FY 2003 PPS Update.

11. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- NPRM published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Diskette/most recent year on Internet.
Price: \$165.00 per year/per file.
Periods Available: FY 1985 through FY 2001.

12. DRG Relative Weights (Formerly Table 5 DRG)

This file contains a listing of DRGs, DRG narrative description, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. The hard copy image has been copied to diskette. There are two versions of this file as published in the **Federal Register**:

- NPRM.
- Final rule.

Media: Diskette/Internet.
File Cost: \$165.00.
Periods Available: FY 2003 PPS Update.

13. PPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, Minimum Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. This file is available for release 1 month after the proposed and final rules are published in the **Federal Register**.

Media: Diskette/Internet.
File Cost: \$165.00.
Periods Available: FY 2003 PPS Update.

14. AOR/BOR Tables

This file contains data used to develop the DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by DRG for length of stay and standardized charges. The BOR tables are "Before Outliers Removed" and the AOR is "After Outliers

Removed." (Outliers refers to statistical outliers, not payment outliers.) Two versions of this file are created each year. They support the following:

- NPRM published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Diskette/Internet.
File Cost: \$165.00.
Periods Available: FY 2003 PPS Update.

15. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the prospective payment system. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, disproportionate share, and the Metropolitan Statistical Area (MSA). The file supports the following:

- NPRM published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet.
File cost: No charge.
Periods Available: FY 2003 PPS Update.

For further information concerning these data tapes, contact the CMS Public Use Files Hotline at (410) 786-3691.

Commenters interested in obtaining or discussing any other data used in constructing this rule should contact Stephen Phillips at (410) 786-4548.

B. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

However, the majority of the collection requirements contained in this proposed rule are currently approved.

Section IX.B.1. below lists the OMB approval numbers and the current

expiration dates for the collection requirements, referenced by 42 CFR Part, in this proposed rule that are currently approved. In addition, as

summarized below, section IX.B.2. of this proposed rule outlines the proposed collection requirements referenced in this proposed rule for which we are

seeking public comment, as required under the PRA of 1995.

1. Currently Approved Requirements

| Regulation references in 42 CFR | OMB approval No. | Current expiration date |
|---------------------------------|------------------|-------------------------|
| Part 412 | 0938-0691 | September 30, 2002. |
| | 0938-0050 | May 31, 2004. |
| | 0938-0573 | September 30, 2002. |
| Part 413 | 0938-0050 | May 31, 2004. |
| | 0938-0667 | October 31, 2002. |
| | 0938-0477 | June 30, 2002. |
| Part 489 | 0938-0667 | October 31, 2002. |

2. Proposed Requirements for Public Comment

Section 412.230 Criteria for an Individual Hospital Seeking Redesignation to Another Rural Area or an Urban Area.

Appropriate Wage Data

As specified in this section, a new hospital must accumulate and provide at least 1 year of wage data to CMS for the purposes of applying for reclassification. While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

Section 413.65 Requirements for a Determination That a Facility or an Organization Had Provider-Based Status Responsibility for Obtaining Provider-Based Determinations

As summarized in this section, a potential main provider seeking an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. In addition, the provider seeking such an advance determination would be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

We believe the burden associated with these requirements is estimated to average 1.5 hours per provider, for approximately 3,000 providers per year, for an annual burden of 4,500 annual burden hours. This estimate is based on fact the providers currently maintain the necessary data and that minimal effort

would be required to locate and review the appropriate data.

Clinical Services

The clinical services of the facility or organization seeking provider-based status and the main provider would be required to maintain a unified retrieval system (or cross reference) of the main provider for all patient medical records for those patients treated in the facility or organization.

While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b) (2) and (b)(3).

Section 482.12 Conditions of Participation: Governing Body Standard: Emergency Services

If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital would be required to assure that the medical staff have written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

Section 489.24 Special Responsibilities of Medicare Hospitals in Emergency Cases

Application to Inpatients—Admitted Emergency Patients

If a hospital admits an individual with an unstable emergency medical condition for stabilizing treatment, as an inpatient, and stabilizes that individual's emergency medical condition, the period of stability would be required to be documented by relevant clinical data in the individual's medical record, before the hospital has satisfied its special responsibilities

under this section with respect to that individual.

While this collection requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: John Burke, Attn: CMS-1203-P, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Eydt, CMS Desk Officer Attn: CMS-1203-P.

C. Public Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments concerning the provisions of this proposed rule that we receive by the date and time specified in the "DATES" section of this preamble and respond to those comments in the preamble to that rule. We emphasize that section 1886(e)(5) of the Act requires the final rule for FY 2003 to be published by August 1, 2002, and we will consider only those comments that deal specifically with the matters discussed in this proposed rule.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, 42 CFR chapter IV is proposed to be amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:
1. The authority citation for Part 405, Subpart R continues to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

2. Section 405.1885 is amended by revising paragraph (b), redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e), to read as follows:

§ 405.1885 Reopening a determination or decision.

* * * * *

(b)(1) An intermediary determination or an intermediary hearing decision shall be reopened and revised by the intermediary if, within the aforementioned 3-year period, CMS—

(i) Provides notice to the intermediary that the intermediary determination or the intermediary hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or CMS general instructions in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the intermediary; and

(ii) Explicitly directs the intermediary to reopen and revise the intermediary determination or the intermediary hearing decision.

(2) A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening an intermediary determination or an intermediary hearing decision under this section.

* * * * *

(e) Notwithstanding an intermediary's discretion to reopen or not reopen an intermediary determination or an intermediary hearing decision under paragraphs (a) and (c) of this section, CMS may direct an intermediary to reopen, or not to reopen, an intermediary determination or an intermediary hearing decision in accordance with paragraphs (a) and (c) of this section.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

B. Part 412 is amended as follows:
1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 412.4 [Amended]

2. In § 412.4 (f)(1), the reference “paragraph (b) or (c)” is removed and “paragraph (b)(1) or (c)” is added in its place.

3. Section 412.22 is amended by—

- a. Revising the introductory text of paragraph (h)(2).
- b. Republishing the introductory text of paragraph (h)(2)(iii).
- c. Redesignating paragraphs (h)(2)(iii)(A) through (F) as paragraphs (h)(2)(iii)(B) through (G), respectively.
- d. Adding new paragraph (h)(2)(iii)(A).

§ 412.22 Excluded hospitals and hospital units: General rules.

* * * * *

(h) *Satellite facilities.* * * *

(2) Except as provided in paragraph (h)(3) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

* * * * *

(iii) The satellite facility meets all of the following requirements:

- (A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care

through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

4. Section 412.25 is amended by—
a. Revising the introductory text of paragraph (e)(2).

b. Republishing the introductory text of paragraph (e)(2)(iii).

c. Redesignating paragraphs (e)(2)(iii)(A) through (F) as paragraphs (e)(2)(iii)(B) through (G), respectively.

d. Adding new paragraph (e)(2)(iii)(A).

§ 412.25 Excluded hospitals units: Common requirements.

* * * * *

(e) *Satellite facilities.* * * *

(2) Except as provided in paragraph (e)(3) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

* * * * *

(iii) The satellite facility meets all of the following requirements:

- (A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the authority or control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the authority or control of the medical staff or chief medical officer of the hospital in which it is located.

* * * * *

§ 412.63 [Amended]

5. Section 412.63 is amended by—
a. In paragraph (x)(2)(i)(A), removing the phrase “tabulating the hospital's data” and adding in its place “tabulating its data”.

b. Removing paragraphs (x)(3) and (x)(4).

c. Redesignating paragraph (x)(5) as paragraph (x)(3).

6. Section 412.80 is amended by revising paragraph (a)(2) to read as follows:

§ 412.80 Outlier cases: General provisions.

(a) *Basic rule.* * * *

(2) *Discharges occurring on or after October 1, 1997 and before October 1, 2001.* For discharges occurring on or after October 1, 1997 and before October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments, to a

hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, as described in § 412.84(h), exceed the DRG payment for the case, payments for indirect costs of graduate medical education (§ 412.105), and payments for serving disproportionate share of low-income patients (§ 412.106), plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

7. Section 412.92 is amended by revising paragraph (c)(2), to read as follows:

§ 412.92 Special treatment: Sole community hospitals.

(c) *Terminology.*

(2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, if a hospital seeking sole community hospital designation can demonstrate that no more than 3 percent of the services it provides overlap with the services provided by a nearby hospital that would otherwise be considered a like hospital under this definition, CMS will not consider the nearby hospital to be a like hospital.

- 8. Section 412.105 is amended by—
A. Republishing the introductory text of paragraph (a).
B. Revising paragraph (a)(1).
C. Revising paragraph (b).
D. Revising paragraph (f)(1)(vi).
E. Making the following cross-reference changes in paragraph (f)(1):

- i. In paragraph (f)(1)(vii), the reference “§ 413.86(g)(12)” is removed and “§ 413.86(g)(13)” is added in its place.
ii. In paragraph (f)(1)(viii), the reference “§ 413.86(g)(7)” is removed and “§ 413.86(g)(8)” is added in its place.
iii. In paragraph (f)(1)(ix), the reference “§§ 413.86(g)(8)(i) and (g)(8)(ii) of this subchapter” is removed and “§ 413.86(g)(9)(i) and (g)(9)(ii) of this subchapter” is added in its place; the reference “§§ 413.86(g)(8)(i) and (g)(8)(iii)(B) of this subchapter” is removed and “§ 413.86(g)(9)(i) and (g)(9)(iii)(A) of this subchapter” is added in its place; and the reference “§§ 413.86(g)(8)(i) and (g)(8)(iii)(A) of this subchapter” is removed and “§ 413.86(g)(9)(i) and (g)(9)(iii)(A) of this subchapter” is added in its place.
iv. In paragraph (f)(1)(x), the reference “§ 413.86(g)(12)” is removed and “§ 413.86(g)(13)” is added in its place;

and the reference “§ 413.86(g)(11)” is removed and “§ 413.86(g)(12)” is added in its place.

v. In paragraph (f)(1)(xi), the reference “§ 413.86(g)(9)” is removed and “§ 413.86(g)(10)” is added in its place.

vi. In paragraph (f)(1)(xii), the reference “§ 413.86(g)(10)” is removed and “§ 413.86(g)(11)” is added in its place.

The revisions read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent residents (except as limited under paragraph (f) of this section) to the number of beds (as determined under paragraph (b) of this section).

(i) Except for the special circumstances for affiliated groups and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

(ii) The exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.

(iii) The exception for closed hospitals and closed programs described in paragraph (f)(1)(ix) of this section applies only in the first cost reporting period in which the receiving hospital trains the displaced full-time equivalent residents.

(iv) In the cost reporting period following the last year the receiving hospital's full-time equivalent cap is adjusted for the displaced resident(s), the resident-to-bed ratio cap in paragraph (a)(1) of this section is calculated as if the displaced full-time equivalent residents had not trained at the receiving hospital in the prior year.

(b) *Determination of number of beds.* (1) For purposes of this section, subject

to the provisions of paragraph (b)(2) of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period, not including beds or bassinets in the healthy newborn nursery, custodial care beds, or beds in excluded distinct part hospital units, and dividing that number by the number of days in the cost reporting period.

(2) Effective for discharges occurring on or after October 1, 2002, a hospital's number of beds is equal to the lower of the number of beds as determined under paragraph (b)(1) of this section, or the average daily census (as determined in accordance with § 412.322(a)(2) of this chapter) divided by 35 percent.

(f) *Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.*

(vi) Hospitals that are part of the same affiliated group (as defined in § 413.86(b) of this subchapter) may elect to apply the limit at paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in § 413.86(g)(7) of this chapter.

9. Section 412.108 is amended by revising paragraph (b) to read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

(b) *Classification procedures.* (1) The fiscal intermediary determines whether a hospital meets the criteria specified in paragraph (a) of this section.

(2) A hospital must submit a written request along with qualifying documentation to its fiscal intermediary to be considered for MDH status based on the criterion under paragraph (a)(1)(iii)(C) of this section.

(3) The fiscal intermediary will make its determination and notify the hospital within 90 days from the date that it receives the hospital's request and all of the required documentation.

(4) A determination of MDH status made by the fiscal intermediary is effective 30 days after the date the fiscal intermediary provides written notification to the hospital. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

(5) The fiscal intermediary will evaluate on an ongoing basis, whether or not a hospital continues to qualify for MDH status. This evaluation includes an ongoing review to ensure that the hospital continues to meet all of the

criteria specified in paragraph (a) of this section.

(6) If the fiscal intermediary determines that a hospital no longer qualifies for MDH status, the change in status will become effective 30 days after the date the fiscal intermediary provides written notification to the hospital.

(7) A hospital may reapply for MDH status following its disqualification only after it has completed another cost reporting period that has been audited and settled. The hospital must reapply for MDH status in writing to its fiscal intermediary and submit the required documentation.

(8) If a hospital disagrees with an intermediary's determination regarding the hospital's initial or ongoing MDH status, the hospital may notify its fiscal intermediary and submit other documentable evidence to support its claim that it meets the MDH qualifying criteria.

(9) The fiscal intermediary's initial and ongoing determination is subject to review under subpart R of Part 405 of this chapter. The time required by the fiscal intermediary to review the request is considered good cause for granting an extension of the time limit for the hospital to apply for that review.

* * * * *

10. Section 412.113 is amended by revising paragraphs (c)(2)(ii) and (c)(2)(iii) to read as follows:

§ 412.113 Other payments.

* * * * *

(c) *Anesthesia services furnished by hospital employed nonphysician anesthetists or obtained under arrangements.* * * *

(2) * * *

(ii) To maintain its eligibility for reasonable cost payment under paragraph (c)(2)(i) of this section in calendar years after 1989, a qualified hospital or CAH must demonstrate prior to January 1 of each respective year that for the prior year its volume of surgical procedures requiring anesthesia service did not exceed 500 procedures; or, effective October 1, 2002, did not exceed 800 procedures.

(iii) A hospital or CAH that did not qualify for reasonable cost payment for nonphysician anesthetist services furnished in calendar year 1989 can qualify in subsequent years if it meets the criteria in paragraphs (c)(2)(i)(A), (B), and (D) of this section, and demonstrates to its intermediary prior to the start of the calendar year that it met these criteria. The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987 and the year

immediately preceding its election of reasonable cost payment, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 500 procedures, or, effective October 1, 2002, did not exceed 800 procedures.

* * * * *

11. Section 412.230 is amended by adding a new paragraph (e)(2)(iii) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(e) *Use of urban or other rural area's wage index.* * * *

(2) *Appropriate wage data.* * * *

(iii) For purposes of this paragraph (e)(2), if a new owner does not accept assignment of the existing hospital's provider agreement in accordance with § 489.18 of this chapter, the hospital will be treated as a new provider with a new provider number. In this case, the wage data associated with the previous owner of the hospital cannot be used in calculating the new hospital's 3-year average hourly wage. Once a new hospital has accumulated at least 1 year of wage data, it is eligible to apply for reclassification on the basis of those data.

* * * * *

12. Section 412.273 is amended by—

A. Revising the section heading.

B. Revising paragraph (b)(2).

C. Redesignating paragraph (d) as paragraph (e).

D. Add a new paragraph (d).

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

* * * * *

(b) *Request for termination of approved 3-year wage index reclassifications.* * * *

(2) *Reapplication within the approved 3-year period.* (i) If a hospital elects to withdraw its wage index application after the MGCRB has issued its decision, it may 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.

(ii) A hospital may apply for reclassification for purposes of the wage index to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or

termination of another 3-year reclassification, regardless of whether the withdrawal or termination request is made within 3 years from the date of the withdrawal or termination.

(iii) In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1.

* * * * *

(d) *Process for canceling a previous withdrawal or termination.* A hospital may cancel a previous withdrawal or termination by submitting written notice of its intent to the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

* * * * *

13. Section 412.304 is amended by revising paragraph (c) to read as follows:

§ 412.304 Implementation of the capital prospective payment system.

* * * * *

(c) *Cost reporting periods beginning on or after October 1, 2001.*

(1) *General.* Except as provided in paragraph (c)(2) of this section, for cost reporting periods beginning on or after October 1, 2001, the capital payment amount is based solely on the Federal rate determined under § 412.308(a) and (b) and updated under § 412.308(c).

(2) *Payment to new hospitals.* For cost reporting periods beginning on or after October 1, 2002—

(i) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost report ending at least 2 years after the hospital accepts its first patient.

(ii) For the third year and subsequent years, the hospital is paid based on the Federal rate as described under § 412.312.

* * * * *

14. Section 412.308 is amending by adding a new paragraph (b)(6) to read as follows:

§ 412.308 Determining and updating the Federal rate.

* * * * *

(b) *Standard Federal rate.* * * *

(6) For discharges occurring on or after October 1, 2002, the 2.1 percent reduction provided for under paragraph (b)(5) of this section is eliminated from the unadjusted standard Federal rate in effect on September 30, 2002, used to

determine the Federal rate each year under paragraph (c) of this section.

15. Section 412.312 is amended by adding a new paragraph (e) to read as follows:

§ 412.312 Payment based on the Federal rate.

(e) Payment for extraordinary circumstances. Payment for extraordinary circumstances is made as provided for in § 412.348(f) for cost reporting periods beginning on or after October 1, 2001.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

C. Part 413 is amended as follows: 1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

- 2. Section 413.65 is amended by— A. Revising paragraph (a)(1)(ii)(G) and adding a new paragraph (a)(1)(ii)(J). B. Revising the definition of “Department of a provider”, “Provider-based entity”, and “Remote location of a hospital” under paragraph (a)(2). C. Revising paragraphs (b)(2), (b)(3), and (d). D. Removing paragraph (j). E. Redesignating paragraphs (h) and (i) as paragraphs (i) and (j), respectively. F. Redesignating paragraph (f) as paragraph (h). G. Redesignating paragraph (e) as paragraph (f). H. Adding a new paragraph (e). I. Revising redesignated paragraph (f). J. Revising the introductory text of paragraph (g), and paragraphs (g)(1), (g)(2), and (g)(7). K. Revising redesignated paragraphs (h), (i), and (j). L. Revising paragraph (k). M. Revising the heading of paragraph (m). N. Revising paragraph (n).

§ 413.65 Requirements for a determination that a facility or an organization had provider-based status.

- (a) Scope and definitions. (1) Scope. (ii) This section does not apply to the following facilities:

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services.

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(2) Definitions. Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term “department of a provider” does not include an RHC or, except as specified in paragraph (m) of this section, an FQHC.

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-

based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term “remote location of a hospital” does not include a satellite facility as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter.

(b) Responsibility for obtaining provider-based determinations. (2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (g), (h), and (i), of this section will not apply to that hospital or CAH until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks an advance determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and

hospital-based entities described in paragraph (g) of this section. The provider seeking such an advance determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS upon request.

(ii) If the facility is not located on the main campus of the potential main provider, the provider seeking an advance determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated as a joint venture or under a management contract, the requirements of paragraph (f) or paragraph (h) of this section, as applicable. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

* * * * *

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and

other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the provider.

(ii) The main provider and the facility or organization seeking status as a department of the provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by

compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location.* The facility or organization is located within a 35-mile radius of the main campus of the hospital or CAH that is the potential main provider, except when the requirements in paragraph (e)(3)(i), (e)(3)(ii), or (e)(3)(iii) of this section are met:

(i) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(e)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(ii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or

(C) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(ii)(A) or paragraph (e)(3)(ii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(ii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(ii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(iv) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(v) An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criteria in paragraphs (e)(3)(i) through (e)(3)(iii) of this section.

(f) *Provider-based status for joint ventures.* A facility or organization that is not located on the campus of the potential main provider cannot be

considered provider-based if the facility or organization is owned by two or more providers engaged in a joint venture. For example, where a hospital has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the hospital or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of § 489.20(l), (m), (q), and (r) and § 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of part 414 of this chapter.

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(7) When a Medicare beneficiary is treated in a hospital outpatient department of hospital-based entity (other than an RHC) that is not located on the main provider's campus, and the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, the hospital must provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability).

(i) The notice must be one that the beneficiary can read and understand.

(ii) If the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.